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To: Members of the State Board of Health

From: Melanie Mattson, STI/HIV/Viral Hepatitis Branch Chief, Disease Control and Environmental Epidemiology Division (DCEED)

Through: Rachel Herlihy, MD, MPH, DCEED Director RH

Date: December 30, 2016

Subject: **Request for Rulemaking Hearing**
Proposed amendments to 6 CCR 1009-10, Colorado HIV and AIDS Prevention Grant Program, with a request for the rulemaking hearing to occur in March of 2017

In preparation for a Public Rulemaking Hearing, please find copies of the following documents: Proposed Amendments to 6 CCR 1009-10, Statement of Basis and Purpose and Specific Statutory Authority, Stakeholder Comment, and Regulatory Analysis.

The *Colorado HIV and AIDS Prevention Grant Program* rules were created to address local community needs in areas of medically accurate human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS) prevention and education through a competitive grant process. The rule includes procedures and timelines by which an entity may apply for program grants, the required content of these grants, criteria for selection and the qualifications of an adequate proposal

Recent legislation (Senate Bill 16-146) updated and modernized the statutes related to sexually transmitted infections to bring them in line with current medical knowledge and practice, as well as to reduce stigma that may be associated with HIV. To align our rules with statute, the Department is proposing the update to the statutory references in 6 CCR 1009-10. Additionally, the Department proposes the deletion the grant application timeline that limits the solicitation of grant applications to twice per fiscal year.

Details regarding this amendment are summarized in the Statement of Basis and Purpose and Statutory authority.

The Department has reached out to a wide variety of stakeholders to solicit input regarding the proposed amendments to 6 CCR 1009-10. These proposed amendments align our rules with statute, continue to bring clarity to the rules, minimize potential confusion among end-users of the rules and enable effective administration of the grant program. As always, the Department will continue to solicit and incorporate stakeholder feedback.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
6 CCR 1009-10
Colorado HIV and AIDS Prevention Grant Program

Basis and Purpose.

The *Colorado HIV and AIDS Prevention Grant Program* rules were created to address local community needs in areas of medically accurate human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS) prevention and education through a competitive grant process. The rule includes procedures and timelines by which an entity may apply for program grants, the required content of these grants, criteria for selection and the qualifications of an adequate proposal.

The following changes to the rule are being proposed:

- 1) Senate Bill 16-146 (SB146), known as the Sexually Transmitted Infection (STI) Modernization bill, was passed in this last legislative session. This bill combined Parts 4 and 14 in Article 4 of Title 25 (the public health laws on STI and HIV) to make protections and policies apply equally to all STIs, including HIV and relevant forms of viral hepatitis. The Department proposes an update to the statutory references in 6 CCR 1009-10 as the statutes governing the Colorado HIV and AIDS Prevention Grant Program have changed.
- 2) The Department proposes the deletion of the timelines for grant applications. This timeline limits the solicitation of grant applications to twice per fiscal year and inhibits the Department's ability to rapidly respond to emerging issues, such as an outbreak of acute HIV infection due to injection drug use or utilizing new technology to prevent HIV and AIDS. Lifting this restriction will allow the Department, in consultation with the Advisory Committee, to respond to these types of issues more efficiently and effectively.

While the Department needs a flexible grant process so we can efficiently distribute funds to meet emerging needs, the Department want grant applicants to be informed of the overall timeline so, drawing upon language utilized by other Department grant programs, the proposed rule adds language to let applicants know their application will be reviewed within 120 days and that a funding recommendation would be made to the board within 180 days. We anticipate that this is the maximum length needed and that most applications would beprocessed within 60-90 days.

Specific Statutory Authority.

These rules are promulgated pursuant to the following statutes:

C.R.S. 25-4-1401 et. Seq. *HIV Treatment & Prevention Resources*

SB146 amended the *HIV Infection and Acquired Immune Deficiency Syndrome* statutes in 2016, resulting in the relocation of sections 25-4-1411, C.R.S through 25-4-1415, C.R.S., to sections 25-4-1401, C.R.S. through 25-4-1405, C.R.S. Due to an oversight, the act did not repeal the previous version of Part 14 as it existed prior to July 1, 2016 when these amendments became effective. Because of this oversight, the previous version of Part 14 as it existed in 2015 that was not relocated by the act is printed below. The proposed rules are not affected. The rules comport with the requirements delineated in Part 4 and Part 14 of Article 4, Title 25, C.R.S.

SUPPLEMENTAL QUESTIONS

Is this rulemaking due to a change in state statute?

Yes, in part, SB16-146; rules are ___ authorized required.
 No

Is this rulemaking due to a federal statutory or regulatory change?

Yes
 No

Does this rule incorporate materials by reference?

Yes
 No

Does this rule create or modify fines or fees?

Yes
 No

REGULATORY ANALYSIS
for Amendments to
6 CCR 1009-10
Colorado HIV and AIDS Prevention Grant Program

- 1. A description of the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.**

Classes of persons affected by the proposed rule changes include 1) persons living with HIV/AIDS, 2) persons at risk for acquiring HIV, 3) local health departments, and 4) community based organizations.

Persons living with or at risk for acquiring HIV will garner the most benefit from the proposed rule changes. Updating the statutory citations aligns the rule with statute and reduces confusion for readers of the rule. The benefit of allowing the Department to solicit applications more than twice a year is that it increases the Department's ability to issue funding to assist partner agencies to respond to emerging or emergency issues, such as an outbreak of acute HIV infection in an at risk population.

- 2. To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.**

This change will better align rule and statute and provide the Department more flexibility in funding programs that impact persons living with, or at risk for acquiring HIV infection.

- 3. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.**

The proposed rule revision will not affect costs to the Department, any affiliated agencies or state revenue. Staff time is needed to develop and oversee a Request for Application (RFA) process; however, the Department wants to allow for multiple RFAs in a given fiscal year, when the Department determines that it is necessary to address emerging issues and emergencies, or to enable partners to utilize every opportunity to prevent HIV and AIDS.

- 4. A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.**

The benefit of these changes includes the Department's ability to solicit grant applications more than twice per fiscal year, if needed. Lifting the restriction will allow the Department, in consultation with the Advisory Committee, to respond to emerging issues by providing funding for our partner agencies' HIV prevention related activities, or to respond to an emergency situation such as an outbreak of acute HIV in an at risk population.

Inaction would result in a delay in the Department's ability to rapidly respond to emerging issues, such as a HIV related outbreak, or to redirect previously unspent funds to critical HIV prevention projects. These types of delays could result in more persons acquiring HIV or other sexually transmitted infections (STIs).

5. **A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.**

No alternative methods are available to achieve the purposes of the authorizing statutes.

6. **Alternative Rules or Alternatives to Rulemaking Considered and Why Rejected.**

No alternative methods for achieving the purpose of the proposed rules were considered because there are no other available mechanism to administer the Colorado HIV and AIDS Prevention Grant Program. The Department proposes repealing the restriction regarding the limit of two solicitations for grant applications per fiscal year.

7. **To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.**

Not applicable.

STAKEHOLDER COMMENTS
for Amendments to
6 CCR 1009-10
Colorado HIV and AIDS Prevention Grant Program

Early Stakeholder Engagement:

The following individuals and/or entities were invited to provide input and included in the development of these proposed rules:

AIDS Service Organizations, Community Based Organizations, "Mod-Squad" Participants (activists), The Alliance for HIV Care the Prevention (CDPHE/Gov appointed advisory group to the Branch), Colorado Organizations Responding to AIDS - CORA (Lobbying group), State and Local Health Department Staff, Ryan White Part A Planning Council Members, Members of the Positive Women's Network (PWN), and other individuals interested in STI/HIV/VH related issues and rules.

Targeted outreach was conducted at several points through a series of 3 facilitated meetings to gather feedback specific to proposed integration of 6 CCR 1009-9 into the communicable disease rule 6 CCR 1009-1 as well as to proposed amendments to 6 CCR 1009-10.

Stakeholder Group Notification

The stakeholder group was provided notice of the rulemaking hearing and provided a copy of the proposed rules or the internet location where the rules may be viewed. Notice was provided prior to the date the notice of rulemaking was published in the Colorado Register (typically, the 10th of the month following the Request for Rulemaking).

Not applicable. This is a Request for Rulemaking Packet. Notification will occur if the Board of Health sets this matter for rulemaking.

Yes.

Summarize Major Factual and Policy Issues Encountered and the Stakeholder Feedback Received. If there is a lack of consensus regarding the proposed rule, please also identify the Department's efforts to address stakeholder feedback or why the Department was unable to accommodate the request.

The Department held meetings with stakeholders to discuss concerns and answer questions. There were no major concerns expressed by stakeholders about the Department's proposed amendments to this rule.

Please identify health equity and environmental justice (HEEJ) impacts. Does this proposal impact Coloradoans equally or equitably? Does this proposal provide an opportunity to advance HEEJ? Are there other factors that influenced these rules?

This proposal is in response to Senate Bill 146, known as STI Modernization that was passed in this last legislative session. This bill combined Parts 4 and 14 in Article 4 of Title 25 (the public health laws on STI and HIV) to make protections and policies apply equally to all sexually transmitted infections, including HIV and relevant forms of viral hepatitis, thus, bringing them in line with current medical knowledge and practice, as well as to reduce stigma that may be associated with HIV. This is a critical component in the advancement of HEEJ in our STI and HIV related programming.

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**Disease Control and Environmental Epidemiology Division****COLORADO HIV AND AIDS PREVENTION GRANT PROGRAM****6 CCR 1009-10**

Adopted by the Board of Health on _____, 2017. Effective _____, 2017.

1 **1.1 Definitions**

2 *****

3 B. "Advisory Committee" means the seven member committee set forth in Section ~~25-4-1414~~ **25-4-**
4 **1404**(1) (a), C.R.S. that is responsible for overseeing the Colorado Human Immunodeficiency
5 Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS) Prevention Program that shall
6 fund medically accurate and evidence based HIV and AIDS prevention and education programs
7 through a competitive grant process pursuant to Section ~~25-4-1413~~ **25-4-1403**, C.R.S.

8 *****

9 D. "Colorado HIV and AIDS Prevention Grant Program" (CHAPP) means the grant program created
10 to address local community needs in the areas of medically accurate HIV and AIDS prevention
11 and education through a competitive grant process established pursuant to Section ~~25-4-1413~~
12 **25-4-1403**(1), C.R.S. administered by the Disease Control and Environmental Epidemiology
13 Division at the Colorado Department of Public Health and Environment.

14 **1.3 Procedures for Grant Application**

15 B. Timelines for Grant Application

16 Grant applications may be solicited ~~up to two times each fiscal year,~~ on dates determined by the Division
17 and in consultation with the Advisory Committee. APPLICATIONS WILL BE REVIEWED WITHIN 120
18 DAYS OF SUBMISSION AND REFERRAL OF RECOMMENDED APPLICATIONS TO THE BOARD OF
19 HEALTH WILL BE WITHIN 180 DAYS OF SUBMISSION.

20 *****

21 **1.5 Criteria for Selecting Entities**

22 A. The Division shall solicit competitive applications. The Advisory Committee shall review
23 applications received pursuant to Section ~~25-4-1413~~ **25-4-1403** and Section ~~25-4-1414~~ **25-4-1404**
24 C.R.S. and submit to the Board and the Executive Director of the Department recommended
25 recipients, recommended grant amounts, and the duration of each recommended grant. In
26 making recommendations for grants, the Advisory Committee shall follow the purpose of the
27 program as outlined in section ~~25-4-1413~~ **25-4-1403**.

28 *****

29 F. The Board shall have final authority to approve the grants administered under Section ~~25-4-1414~~
30 **25-4-1404** and Section ~~25-4-1413~~ **25-4-1403** C.R.S.

31 *****

32 **1.6 Awarding of Program Grants**

33 *****

34 B. Any actual or prospective applicant who is aggrieved in connection with the solicitation or award
35 of a contract pursuant to Section ~~25-4-1413~~ **25-4-1403** may protest to the Executive Director of
36 the department or his/her designee.

37 *****

38 4. At the discretion of the Board, a protest may result in changes in the final selection of
39 entities receiving awards, the amount and duration of awards, and the termination of
40 contracts or other agreements that were awarded pursuant to Section ~~25-4-1413~~ **25-4-**
41 **1403.**

42 *****