COLORADO

Department of Public Health & Environment

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To: Members of the State Board of Health

From: Amy Warner, Viral Hepatitis Program Manager, Disease Control and Environmental Epidemiology Division AW

Through: Rachel Herlihy, Disease Control and Environmental Epidemiology Division Director RH

Date: July 15, 2015

Subject: **Request for Rulemaking Hearing**
Request for a rulemaking hearing to occur in September 2015 for a proposed new rule, 6 CCR 1009-11 Hepatitis C Education and Screening

Hepatitis C is a liver disease that results from infection with the hepatitis C virus. Hepatitis C presents as either an acute short-term infection or can progress to a chronic infection that can result in long-term health problems and even death. Hepatitis C is transmitted when the blood of an infected person enters the body of someone that is not infected. Major routes of transmission of the hepatitis C virus include sharing needles, syringes or other equipment to inject drugs; needle stick injuries in health care settings; being born to a mother who has hepatitis C; sharing personal care items that may have come in contact with another person's blood (i.e. razors or toothbrushes); and having sexual contact with a person infected with hepatitis C (1).

The Centers for Disease Control and Prevention (CDC) recommend that adults born between 1945 through 1965 receive one-time testing for hepatitis C without prior ascertainment of hepatitis C risk (2). In Colorado in 2013, there were a total of 23 acute hepatitis C cases identified, and 3,253 chronic hepatitis C cases identified. The majority of chronic hepatitis C cases were in the 50-59 years of age range (34.4%, n=1,118) and 40-49 years of age range (18.8%, n=610), which supports the CDC recommendations to test this cohort. In 2013, the majority of chronic hepatitis C cases were among White non-Hispanic populations (23.0%, n=749) and Hispanic populations (7.7%, n=250); with intravenous drug use being the most frequently reported risk factor (6.5%, n=210) (3).

In 2014, the Colorado legislature passed SB 14-173, now §25-4-2005, C.R.S. SB14-173, which promotes testing for hepatitis C virus (HCV). The legislation encourages health care providers to offer a test to individuals born between 1945 and 1965. If a health care provider offers a screening test, the legislation requires, "the health care provider shall make the offer of a hepatitis C screening to the patient in a linguistically and culturally appropriate manner, as determined by rules promulgated by the department."

To implement the legislative mandate regarding offering hepatitis C screening in a linguistically and culturally appropriate manner, the department recommends the Board of Health adopt the National Culturally and Linguistically Appropriate Services (CLAS) Standards. These are uniform standards widely known to the public health and health care community.

The purpose of the National CLAS Standards is to "provide a blueprint for health and health care organizations to implement culturally and linguistically appropriate services that will advance health equity, improve quality, and help eliminate health care disparities."(4)

There are "15 Standards that provide individuals and organizations with a blueprint for successfully implementing and maintaining culturally and linguistically appropriate services. Culturally and linguistically appropriate health care and services, broadly defined as care and services that are respectful of and responsive to the cultural and linguistic needs of all individuals, are increasingly seen as essential to reducing disparities and improving health care safety and quality. All 15 Standards are necessary to advance health equity, improve quality, and help eliminate health care disparities. As important as each individual Standard is, the exclusion of any Standard diminishes health professionals' and organizations' ability to meet an individual's health and health care needs in a culturally and linguistically appropriate manner. Thus, it is recommended that each of the 15 Standards be implemented by health and health care organizations."(4) Organizations such as the American Nurses Association, American Academy of Family Physicians, and the American Academy of Pediatrics all support cultural proficiency and providing cross cultural and linguistically appropriate care.

Culturally and linguistically appropriate services are included in and referenced by many local and national legislative, regulatory, and accreditation mandates. The use of the National CLAS Standards is supported by the Department of Justice (5); the Institute of Medicine (6); the Patient Protection and Affordable Care Act—to assist individuals in accessing and taking advantage of the exchanges in a culturally and linguistically appropriate manner; under Title VI of the Civil Rights Act of 1964, as implemented by Executive Order 13166—organizations receiving federal funds must take reasonable steps to provide meaningful access to their programs for individuals with limited English proficiency (7); The Joint Commission and the National Committee for Quality Assurance "have established accreditation standards that target the improvement of communication, cultural competency, patient-centered care, and the provision of language assistance services." (1)

Providing culturally and linguistically appropriate services in health and health care is necessary for the following reasons identified by the National Center for Cultural Competence (8):

1. To respond to current and projected demographic changes in the United States.
2. To eliminate long-standing disparities in the health status of people of diverse racial, ethnic and cultural backgrounds.
3. To improve the quality of services and primary care outcomes.
4. To meet legislative, regulatory and accreditation mandates.
5. To gain a competitive edge in the market place.
6. To decrease the likelihood of liability/malpractice claims.

We urge the Board of Health to consider this request for rulemaking to provide a set of standards by which hepatitis C testing services are delivered in Colorado.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
6 CCR 1009-11 Hepatitis C Education and Screening Program

Basis and Purpose.

§25-4-2005, C.R.S., states, "each primary health care provider or physician, physician assistant, or nurse practitioner who treats a patient in an inpatient or outpatient setting may offer a person born between the years of 1945 and 1965 a hepatitis C screening test or hepatitis C diagnostic test unless the health care provider providing such services reasonably believes that (a) The patient is being treated for a life-threatening emergency; (b) The patient has previously been offered or has been the subject of a hepatitis C screening; or (c) The patient lacks capacity to consent to a hepatitis C screening test… (3) the health care provider shall make the offer of a hepatitis c screening to the patient in a linguistically and culturally appropriate manner, as determined by rules promulgated by the department."

The proposal is to adopt the National Culturally and Linguistically Appropriate Services (CLAS) Standards, as recommended by the United States Department of Health and Human Services, Office of Minority Health, when offering hepatitis C screening. This ensures the offer occurs in a linguistically and culturally appropriate manner.

Specific Statutory Authority.
These rules are promulgated pursuant to the following statute: C.R.S. §25-4-2005.

SUPPLEMENTAL QUESTIONS

Is this rulemaking due to a change in state statute?

__X___ Yes, the bill number is SB 14-173; rules are __authorized _X_ required.
______ No

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

______ Yes
___X___ No

Does this rule incorporate materials by reference?

______ Yes
____X__ No

Does this rule create or modify fines or fees?

______ Yes
___X___ No

REGULATORY ANALYSIS
for Amendments to
6 CCR 1009-11 Hepatitis C Education and Screening 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.**

The classes of people affected by the proposed amendments to the rule are health care providers offering hepatitis C tests, and people born between 1945 and 1965 that get a hepatitis C test offered to them by a health care provider.

Health care providers understand the importance of clear and understandable communication with patients. Implementing the National CLAS Standards for offering a hepatitis C test to anyone born between 1945 and 1965 represents a cost investment for health care providers. If health care providers are operating under federal funding they are already required to use culturally and linguistically appropriate health services under Title VI of the Civil Rights Act of 1964, as implemented by Executive Order 13166. Resource allocation is the responsibility of the health care provider.

Following the proposed rule can represent a cost savings by decreasing the risk of liability. For example, clear communication "avoids cases of malpractice due to diagnostic and treatment errors. When communicating with culturally and linguistically diverse populations, the opportunity for miscommunication and misunderstanding increases, which subsequently increases the likelihood of errors. These errors, in turn, can cost millions of dollars in liability or malpractice claims. Culturally and linguistically appropriate services can reduce the possibility of such errors." According to the Health Resources and Services Administration (HRSA) health professionals that lack cultural and linguistic competency can be found liable under tort principles in several areas. For example, a health care provider is considered negligent if an individual is unable to follow guidelines because they conflict with his/her beliefs and the provider failed to identify and attempt to accommodate those beliefs. Therefore, culturally and linguistically appropriate communication is essential to minimize the likelihood of liability and malpractice claims. (4)

People born between 1945 and 1965 benefit from having a hepatitis C test offered in a culturally and linguistically appropriate manner. Risk factors for hepatitis C transmission include sensitive issues such as injection drug use and sexual behaviors, therefore having health care providers offer a test in a respectful manner is important. Limited English Proficient populations that are at high risk for hepatitis C benefit from the use of the National CLAS Standards as well by having a test offered in a culturally and linguistically appropriate manner. These individuals will be informed of the availability of language assistance services in their preferred language under the proposed rule.

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.**

Costs associated with the proposed rule will vary for health care providers based upon the extent a health care provider has already incorporated tools to promote culturally

and linguistically appropriate communication with patients. For example, some health care providers may allocate funds for the use of language services, hiring of bilingual staff, and contracted resources etc.

The implementation of the National CLAS Standards in offering a hepatitis C test can improve the quality of service and care. When health care providers take into account cultural beliefs and practices that can influence health outcomes, this can increase the quality care and services that people receive. "Culturally and linguistically appropriate services are increasingly recognized as effective in improving the quality of services, increasing patient safety (e.g., through preventing miscommunication, facilitating accurate assessment and diagnosis), enhancing effectiveness, and underscoring patient-centeredness."(4) Offering a hepatitis C test early and in a culturally and linguistically appropriate manner can lead to better patient outcomes with the benefit of cost savings of early detection and treatment and avoidance of long-term costly complications such as cirrhosis of the liver or liver cancer.

As stated above, providing culturally and linguistically appropriate services minimize the likelihood of liability and malpractice claims.

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 department incurs a minimal cost to develop this rule and will continue to provide on-going technical assistance to the health care and public health community. No additional resources were provided to the Department to implement SB 14-173. The Department absorbs the minimal cost associated with the proposed rule.

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

The rule is required by statute; inaction is not an option. The benefit of using a nationally accepted standard is alignment across a specific provider's funding streams and consistency across the wide variety of health care providers that may offer hepatitis C screening. Some health care providers have already implemented the National CLAS Standards. For those that have not, a health care provider may incur implementation costs; however, the National CLAS Standards afford providers flexibility in designing solutions that are feasible. Given that standards are required, the National CLAS Standards are not as burdensome as alternatives.

The benefits of implementing the amendments to the rule include:

- Patient benefits: If patients are offered a test in a culturally and linguistically appropriate manner they will know their status sooner in the course of the disease leading to better health outcomes. Knowing their status sooner can decrease the possibility of transmission, linkage to care and treatment sooner, the opportunity to limit hepatitis C associated disease progression (i.e. avoidance or reduction of alcohol use, and vaccination against hepatitis A and B), and begin treatment to reach a sustained virologic response or be cured, and inform those that are not infected of their status.(9)

- Health care service provider benefits:
  - By offering culturally and linguistically appropriate services, health care providers can gain a competitive edge in the market place by developing a positive reputation and by helping develop a loyal patient base. These factors help organizations avoid high turnover, low utilization rates, and unused capacity.(4)
  - Being able to track variables such as race, ethnicity, and language leads to quality metrics on a granular level which identifies needs to improve overall quality of service and promotes equity.(6)
  - Culturally and linguistically appropriate services can decrease the risk of liability and reduce the possibility of errors by avoiding cases of malpractice due to diagnostic and treatment errors. (4) Health care service providers can be found liable under tort principles in several areas. For example, "providers may be presumed negligent if an individual is unable to follow guidelines because they conflict with his/her beliefs and the provider neglected to identify and try to accommodate the beliefs. Additionally, if a provider proceeds with treatment or an intervention based on miscommunication due to poor quality language assistance, he/she and his/her organization may face increased civil liability exposure. Thus, culturally and linguistically appropriate communication is essential to minimize the likelihood of liability and malpractice claims."(4)

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

Though alternative standards could be used or Colorado could design its own standards, this course is not recommended. The National CLAS Standards are well known, well utilized, and provide flexibility for users.

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

These rules are required by SB14-173.

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.

The National CLAS Standards were developed by the Office of Minority Health because there was a lack of comprehensive standards or guidance for organizations and providers to follow regarding implementing culturally and linguistically appropriate services in health care settings. Other standards and practices have been developed but the National CLAS Standards support a more consistent and comprehensive approach to cultural and linguistic competence in health care. It is recommended that the National CLAS Standards be implemented because they are federally recognized as best practice, well known, well utilized, and provide flexibility for users. As previously mentioned, all 15 Standards must be included because "the exclusion of any Standard diminishes health professionals' and organizations' ability to meet an individual's health and health care needs in a culturally and linguistically appropriate manner." (4)

STAKEHOLDER COMMENTS
for Amendments to
6 CCR 1009-11 Hepatitis C Education and Screening Program

The following individuals and/or entities were included in the development of these proposed rules: (Please be specific. Identify your stakeholders with enough specificity the Board has context for the extent of the outreach.)

- Hepatitis C testing sites
- Health care providers
- Kaiser Permanente
- Colorado Association of Family Physicians
- American Academy of Pediatrics-Colorado Chapter
- Colorado Hospital Association
- Local health departments
- Federally Qualified Health Centers
- Health Equity Commission
- Advocates of Limited English Proficient populations (non-profit organizations)
- International Medical Interpreter Association
- Local language service providers

The following individuals and/or entities were notified that this rule-making was proposed for consideration by the Board of Health:

Same as above.

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 remains committed to fully engaging its stakeholders during this rulemaking process. The stakeholders that have responded to a memorandum sent out regarding the proposed changes are pleased to learn that the Department is "becoming more proactive in terms of cultures." Thus far, stakeholders are appreciative of the opportunity to provide feedback on the proposed regulation. A few stakeholders are also looking forward to a report back of how their feedback was used through this process.

An important issue that was raised by a local language service provider concerns the limited English proficient populations that are seen by providers that do not need to comply with Title VI (i.e. private practices). Since they are not federally obligated to implement these services, education about the benefits of providing CLAS in terms of cost and outcomes can encourage organizations to provide these services to limited English proficient clients. The Department's future efforts around CLAS are included in Healthy Colorado: Shaping a State of Health, Colorado's plan for improving public health and the environment from 2015-2019. This is a starting point and there are many considerations to keep in mind as measured progress is made in this area.

Another concern was that the National CLAS Standards could be too expensive or too time consuming for providers to implement and could inadvertently result in less testing for hepatitis C or harm Medicaid provider retention. The suggestion to substitute ‘culturally and linguistically appropriate services’ for each reference to CLAS was made to leave room for interpretation without being held to the official federal standards. However, the Department recognizes this regulation as a valuable step in promoting health equity and does not want to soften the health equity interest. The Department appreciates that this regulation is ambitious and is following legislative requirements that will result in reaching underserved populations that may be currently overlooked.

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?

- Health equity impact: all hepatitis C tests will be offered in a culturally and linguistically appropriate manner.
- The enhanced National CLAS Standards are intended to advance health equity, improve quality, and help eliminate health care disparities by establishing a blueprint for individuals as well as health and health care organizations to implement culturally and linguistically appropriate services.
- No environmental justice impacts were identified.

References

1. Centers for Disease Control and Prevention. Hepatitis C Information for the Public

2. Centers for Disease Control and Prevention. Recommendations for the Identification of Chronic Hepatitis C Virus Infection Among Persons Born During 1945–1965. *MMWR 61*(RR04), 1-18.

3. Colorado Department of Public Health and Environment. Hepatitis C in Colorado 2013 Surveillance Report

4. Office of Minority Health. U.S. Department of Health and Human Services. April 2013. National Standards for CLAS in Health and Health Care: A Blueprint for Advancing and Sustaining CLAS Policy and Practice

5. U.S. Department of Justice, Language Access Assessment and Planning Tool for Federally Conducted and Federally Assisted Programs, May 2011

6. The Institute of Medicine, Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement, August 2009

7. Exec. Order No. 13166, 65 Fed Reg. 50,121 (Aug. 11, 2000), http://www.lep.gov/13166/eolep.pdf.

8. Cohen, E., & Goode, T. D. (1999), revised by Goode, T. D., & Dunne, C. (2003). Policy Brief 1: Rationale for Cultural Competence in Primary Care. Washington, DC: National Center for Cultural Competence, Georgetown University Center for Child and Human Development.

9. Centers for Disease Control and Prevention. Testing for HCV Infection: An Update of Guidance for Clinicians and Laboratorians *Morbidity and Mortality Weekly Report*, May 10, 2013 / 62(18); 362-365.

10. United States Census Bureau. 2013 State and County QuickFacts

11. United States Census Bureau. 2013 American Community Survey: Selected Characteristics of the Native and Foreign Born Populations—Colorado

12. United States Census Bureau. 2013 American Community Survey: Limited English Speaking Households—Colorado

COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Disease Control and Environmental Epidemiology Division

HEPATITIS C EDUCATION AND SCREENING

6 CCR 1009-11

Adopted by the State Board of Health; September, 2015.

Primary health care providers, including physicians, physicians assistants and nurse practitioners who treat patients in an inpatient or outpatient setting, are encouraged to offer persons born between the years of 1945 and 1965 a Hepatitis C screening test or a Hepatitis C diagnostic test unless specific circumstances delineated in § 25-4-2005, C.R.S., are met.

When a hepatitis C screening test or diagnostic test is offered it shall be made in a linguistically and culturally appropriate manner in accordance with the following U.S. Department of Health and Human Services,-Culturally and Linguistically Appropriate Services (CLAS) standards:

1. Provide effective, equitable, understandable, and respectful quality care and services that are responsive to diverse cultural health beliefs and practices, preferred languages, health literacy, and other communication needs.

2. Advance and sustain organizational governance and leadership that promotes CLAS and health equity through policy, practices, and allocated resources.

3. Recruit, promote, and support a culturally and linguistically diverse governance, leadership, and workforce that are responsive to the population in the service area.

4. Educate and train governance, leadership, and workforce in culturally and linguistically appropriate policies and practices on an ongoing basis.

5. Offer language assistance to individuals who have limited English proficiency and/or other communication needs, at no cost to them, to facilitate timely access to all health care and services.

6. Inform all individuals of the availability of language assistance services clearly and in their preferred language, verbally and in writing.

7. Ensure the competence of individuals providing language assistance, recognizing that the use of untrained individuals and/or minors as interpreters should be avoided.

8. Provide easy-to-understand print and multimedia materials and signage in the languages commonly used by the populations in the service area.

9. Establish culturally and linguistically appropriate goals, policies, and management accountability, and infuse them throughout the organization's planning and operations.

10. Conduct ongoing assessments of the organization's CLAS-related activities and integrate CLAS-related measures into measurement and continuous quality improvement activities.

11. Collect and maintain accurate and reliable demographic data to monitor and evaluate the impact of CLAS on health equity and outcomes and to inform service delivery.

12. Conduct regular assessments of community health assets and needs and use the results to plan and implement services that respond to the cultural and linguistic diversity of populations in the service area.

13. Partner with the community to design, implement, and evaluate policies, practices, and services to ensure cultural and linguistic appropriateness.

14. Create conflict and grievance resolution processes that are culturally and linguistically appropriate to identify, prevent, and resolve conflicts or complaints.

15. Communicate the organization's progress in implementing and sustaining CLAS to all stakeholders, constituents, and the general public.