COLORADO
Department of Public Health & Environment

Dedicated to protecting and improving the health and environment of the people of Colorado

To: Members of the State Board of Health

From: Jeff Groff, Certification Program Manager, Laboratory Services Division

Through: Dana Erpelding, Laboratory Services Division Director DE

Date: November 1, 2017

Subject: **Request for Rulemaking Hearing**
Proposed Amendments to 5CCR 1005-2 State Board of Health Rules Pertaining to the Testing for Alcohol and Other Drugs with a request for a rulemaking hearing to be set for January 2018.

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Colorado statute directs the Colorado Department of Public Health and Environment ("Department") to: regulate the methods of testing a person's alcohol or drug level; certify the design and operation of devices for testing a person's blood, breath, saliva, or urine to determine such person's alcohol or drug level, and; certify the contents, sterility, chemical makeup, and amounts of chemicals contained in the kits used to obtain blood, urine, saliva, or breath specimens. Compliance with the rules is required for test results to be admissible in a criminal proceeding that concern driving under the influence (DUI), driving while ability impaired (DWAI) or with excessive alcoholic content; or illegal consumption of ethyl alcohol or marijuana by an underage person. In addition, to the extent necessary, the board promulgates collection and testing of samples associated with the bodies of all pilots in command, vessel operators in command, or drivers and pedestrians age fifteen or older who die within four hours after involvement in a crash involving a motor vehicle, vessel or aircraft. Rule 5 CCR 1005-2, Testing for Alcohol and Other Drugs, implements these portions of the statute.

The Department has reviewed 5 CCR 1005-2, Testing for Alcohol and Other Drugs, in compliance with Executive Order D 2012-002 and the State Administrative Procedure Act, 24-4-103.3, C.R.S. At this time, the Department is proposing the changes necessary to implement HB 14-1340. HB 14-1340 allows specific certifications requirements to be waived for laboratories that are accredited. The revisions streamline existing requirements, and reduce the regulatory burden placed on accredited forensic toxicology laboratories while maintaining the appropriate level of regulatory oversight. The Department has incorporated stakeholder feedback into the proposed language and will continue to engage stakeholders during the rulemaking process.

The Department requests that the Board review and approve the proposed changes to the existing rule. The proposed changes have been incorporated after stakeholder engagement, discussion and recommendations have been received and considered. The intent of the proposed revisions are to ensure the rule is aligned with current statutory requirements.

Though the Department has identified other changes to align with current statute, current regulatory practice, and national forensic toxicology practice, the Department is not proposing those revisions at this time. The Department anticipates that it will return to the board in the summer of 2018 with those recommendations after it has engaged stakeholders and collected the feedback necessary to propose these future revisions.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
5CCR 1005-2
State Board of Health Rules Pertaining to the Testing for Alcohol and Other Drugs

Basis and Purpose.

- Alignment of the requirements found in this rule to current statute(s).
- Implement HB 14-1340, which modified Section 42-4-1304, C.R.S., to allow specific laboratory certification requirements to be waived for laboratories that are accredited by the American Board of Forensic Toxicology (ABFT), the International Standards Organization (ISO) or a successor to either organization. Some Colorado Forensic Toxicology Laboratories voluntarily achieved ISO-17025 accreditation from an internationally recognized accrediting organization. Forensic Toxicology Laboratories that have voluntarily achieved ISO-17025 accreditation from an internationally recognized accrediting organization are meeting the highest professional standards established within the industry. The proposed rule aligns the accreditation and certification processes and eliminates the biennial onsite survey for accredited laboratories. The biennial onsite survey unnecessarily duplicates the accreditation processes. The rule, which authorizes the Department to perform an onsite survey in response to a complaint at any time, is unchanged.

Specific Statutory Authority.
These rules are promulgated pursuant to the following statutes:

Sections 42-4-1304, C.R.S.

Is this rulemaking due to a change in state statute?

___X___ Yes, the bill number is HB 14-1340. Rules are ___ authorized _X__ required.
_____ No

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

_____ Yes
___X__ No

Does this rulemaking incorporate materials by reference?

_____ Yes
___X__ No

If "Yes," the rule needs to provide the URL of where the material is available on the internet (CDPHE website recommended) or the Division needs to provide one print or electronic copy of the incorporated material to the State Publications Library. § 24-4-103(12.5)(c), C.R.S.

Does this rulemaking create or modify fines or fees?

_____ Yes
___X__ No

REGULATORY ANALYSIS
for Amendments to
5CCR 1005-2
State Board of Health Rules Pertaining to the Testing for Alcohol and Other Drugs

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 persons affected are:

- Accredited Forensic Toxicology Laboratories that have or are seeking certification.

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.

Quantitative Impact:
The proposed changes will have the following quantitative impact:

- The proposed changes to the rules have no impact on non-accredited forensic toxicology laboratories certified by the department. Accredited labs are relieved of the annual onsite inspection by the department.

Qualitative Impact:
The proposed changes will have the following qualitative impact:

- Alignment with current statutory requirements.
- The certification of forensic toxicology laboratories remains the same regardless of whether is accredited or not; however, to the extent a streamlined process encourages more entities to seek accreditation, this supports best practice.

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.

- There is a possibility of a nominal savings to state revenues due to the small number of certified forensic toxicology laboratories, the number of onsite visits and the number of accredited laboratories. However, those savings will be slightly offset by the costs of reviewing the accreditation materials.

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

Action cost and benefits of the proposed rule:

- Alignment of the rule with current statutory requirements.
- Clarification of existing language.
- Reduction in financial costs to the department.

Inaction cost and benefits of the proposed rule:

- Current rule may not be aligned with existing statutory requirements.
- Continuation of existing department practices and survey schedules.

5. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.
    - No other less costly or less intrusive methods have been identified.
    - Another option is for the department to only provide certification to forensic toxicology laboratories performing testing for DUI/DUID purposes that are ISO-17025 accredited by an internationally recognized accrediting organization. However, this option potentially will have a negative business and financial impact to those laboratories not currently ISO-17025 accredited.

6. Alternative Rules or Alternatives to Rulemaking Considered and Why Rejected.
    - The Department has identified the need for revisions to the current rules to align with current statutory requirements by clarifying the current language.

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.
    - Currently there are 9 forensic toxicology laboratories certified by the department to perform testing on samples for DUI/DUID purposes.
    - Of the 9 laboratories certified, 5 (CBI-3 labs, Denver PD, NMS) are currently accredited by an internationally recognized accrediting organization that include ABFT and/or ASCLD/LAB.

STAKEHOLDER COMMENTS
for Amendments to
5CCR 1005-2
State Board of Health Rules Pertaining to the Testing for Alcohol and Other Drugs

State law requires agencies to establish a representative group of participants when considering to adopt or modify new and existing rules. This is commonly referred to as a stakeholder group.

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

The forensic toxicology lab directors are identified as the primary stakeholders. These laboratories are directly impacted by the proposed rule revisions:

- Dan Anderson – CBI (3 locations)
- Sarah Urfer – Chematox
- Dr. Patricia Sulik, PhD – Rocky Mountain Instrumental Labs (RMIL)
- Dr. Gregory Dooley, PhD – CSU Analytical Toxicology Laboratory
- Greggory LeBerge, PhD – Denver Crime Laboratory
- Dr. Robert Bux, M.D. – El Paso County Coroner's Office
- Dr. Robert Middleberg, PhD – National Medical Services, Inc. (NMS)

While the change affects accredited laboratories seeking certification, the draft rule will also be posted on the Department's website to make the community aware of the Department's effort to implement HB 14-1340. The Department is also gathering stakeholder suggestions on other improvements that can be made to the rule for future rule-making.

Initial notification was sent to the stakeholders on September 25, 2017 and a copy of the proposed changes were provided. A follow-up email was sent on October 16, 2017 informing the stakeholders that an onsite meeting was being scheduled for November 1, 2017 at the Laboratory Services Division. In addition, the proposed changes were posted on the division's website. A reminder email of the onsite meeting was sent on October 31, 2017.

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).

__X__ 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.

- Of the 7 stakeholders, 2 have expressed concerns regarding the annual onsite inspection process being waived all together and have recommended that the current language remain which requires onsite inspections be conducted by the department during the alternate years.
- One of the stakeholders would like to see the department's onsite inspections be changed to every two-years for those labs not accredited.
- Two stakeholders expressed concern that the ISO-17025 accrediting organization known as ASCLD/LAB may not perform a review of the toxicology specialty every two years when performing the biennial onsite inspections. To address this concern, one stakeholder recommended that accredited labs perform and provide a cross-walk analysis of the current laboratory standards found in the rule to the accrediting organizations standards and provide this to the department in the alternating years where an onsite inspection is not performed. This is intended to ensure the department's standards are being implemented.
- One stakeholder made a recommendation that in addition to the alternating year cross-walk when requesting reciprocity, that only labs accredited by the American Board of Forensic Toxicology (ABFT) be eligible for reciprocity.
- One stakeholder made a recommendation that in the event the ISO-17025 accrediting body does not perform a review of the toxicology specialty during the biennial accreditation inspection, that the department would then perform an onsite inspection of the facility(s).

The department will continue to work with the stakeholders prior to the hearing in order to achieve a consensus that is consistent with statutory language and still ensures the highest level of analytical performance is verified and maintained.

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?

- N/A

**DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**

**Laboratory Services Division**

**TESTING FOR ALCOHOL AND OTHER DRUGS**

**5 CCR 1005-2**

**ADOPTED BY THE BOARD OF HEALTH _____, 20____.**

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**Part 5: Certification Requirements for Forensic Toxicology Laboratories**

5.1 Laboratory Analysis of Blood, Urine and Post Mortem Specimens

5.1.1 Laboratories must be certified by the Department to provide analysis. Participation in the Forensic Toxicology Laboratory certification program is based upon either; successful on-site annual inspection for non-accredited labs, or, ongoing accreditation status for accredited labs, and, successful participation in the designated proficiency testing and ongoing compliance with the applicable requirements in this rule.

5.1.2 Laboratories seeking certification that are accredited by an internationally recognized accreditation organization may forgo the annual onsite inspection as long as accreditation remains active. ~~the American Board of Forensic Toxicology (ABFT) may be granted reciprocity on a biennial basis as long as accreditation remains active. Laboratories certified by the department will be inspected on the alternating accreditation years.~~

5.1.3 Accredited laboratories that are granted reciprocity must provide the Department a copy of the accrediting organizations inspection report in addition to any accepted plan of correction submitted to the accrediting organization by the laboratory.

5.1.~~4~~3 Laboratories certified by the Department who send samples to a reference laboratory for testing, must send those samples to either another Department certified lab, or a forensic toxicology laboratory accredited by an internationally recognized accrediting organization. ~~ABFT~~.

5.2 Initial Application

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5.3.3 Certified laboratories referring specimens to ~~ABFT~~ another accredited laboratory ~~laboratories~~ must include documentation with the application (Appendix B) that the reference laboratory is ~~ABFT~~ accredited~~.~~ by an internationally recognized accrediting organization.

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5.3.5 To maintain certification, laboratories shall meet all applicable requirements found in Parts 5-8, and Appendix C. Non-accredited laboratories must ~~and~~ participate in an annual on-site inspection~~.~~

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