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.

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.

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 regulatory 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.

As discussed during the request for rulemaking presentation, the Department anticipated further revisions to the rulemaking packet based upon stakeholder feedback. The Statement of Basis and Purpose, Regulatory Analysis and proposed rule have been revised. Though revisions occur throughout these pages, the substantive changes have been highlighted in yellow to assist with your review. The applicable portion of the legislation has also been included.

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.

- 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 accreditation from an internationally recognized accrediting organization whose standards meet the ISO-17025 requirements but the statute specifically states at the accreditation must be conferred by the ABFT or ISO so accreditation by other accrediting organizations, such as Ansi-ASQ National Accreditation Board (ANAB), does not qualify for waiver of the Department's certification requirements.
- Forensic Toxicology Laboratories that have voluntarily achieved accreditation from an internationally recognized accrediting organization are evaluated through onsite and paper review processes that are comparable to the onsite visit that occurs as part of the certification process. Entities that are accredited 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 if the biennial inspection by the authorized accreditation entity includes the specialty of toxicology. The biennial onsite survey unnecessarily duplicates the accreditation processes.

- Importantly, the portion of 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 _X__ authorized ___ 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. Currently there are 9 forensic toxicology laboratories certified by the department to perform testing on samples for DUI/DWAI purposes. Of the 9 Department certified laboratories, 4 (CBI-3, NMS-1) are currently accredited by the American Board of Forensic Toxicologists (ABFT).
   - 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.
   - For accredited labs, the Department will review and rely on the accreditation evaluation and documentation rather than perform an annual onsite inspection. For non-accredited labs, the Department will continue the current practice of performing an annual onsite inspection. The remainder of the certification process is unchanged.
   - 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 associated with reviewing accreditation documentation rather than performing an onsite evaluation. Given the small number of certified forensic toxicology laboratories, the number of onsite visits and the number of accredited laboratories that will be submitting accreditation document, any savings would be minimal.

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 authorizations to streamline the accreditation and certification process avoids duplicate efforts.

   Inaction cost and benefits of the proposed rule:
   - Duplication of accreditation and certification efforts.
   - 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. The statute requires rulemaking.

6. Alternative Rules or Alternatives to Rulemaking Considered and Why Rejected.
   - The changes are minimal and are needed to align with statute. Though the proposed rule could have afforded more benefit to accredited entities, this would occur to the detriment of the other certified laboratories. Similarly, the proposed rule could have afforded less benefit to accredited entities, however, this would occur to the detriment of the accredited laboratories and fails to honor the intent and direction in HB 14-1340. While stakeholders sought to align the certification and accreditation processes, none positioned for a market advantage.

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/DWAI purposes.
   - Of the 9 Department certified laboratories, 4 (CBI-3, NMS-1) are currently accredited by the American Board of Forensic Toxicologists (ABFT). As a point of clarification, none of the laboratories are accredited by the International Standards Organization (ISO) or a successor to either organization as referenced in HB 14-1340 because ISO only sets the standards, but does not accredit. Accrediting organizations such as Ansi-ASQ National Accreditation Board (ANAB) will evaluate labs to those standards and then will provide accreditation if those standards are met.

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. Robert Lantz, PhD – Rocky Mountain Instrumental Labs (RMIL)
- Dr. Gregory Dooley, PhD – CSU Analytical Toxicology Laboratory
- Dr. 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.

Timeline:
September 25, 2017 - Initial notification was sent to stakeholders along with a copy of the proposed changes. Stakeholders were encouraged to submit written feedback.

October 16, 2017 – A second notification was sent to stakeholders along with an invitation to an onsite meeting scheduled on November 1, 2017 at the Laboratory Services Division to discuss stakeholder feedback. The proposed changes were posted on the division's website and stakeholders were encouraged to provide written feedback if they were unable to participate in the onsite meeting.

October 31, 2017 – Stakeholders were sent an email reminder to participate in the onsite meeting.

November 1, 2017 – An onsite stakeholder meeting was held at the Laboratory Services Division. The following comments were received either in person or in writing.

- 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).

November 28, 2017 – Notification was sent to the stakeholders containing revisions to the proposed language based upon initial feedback. A second onsite stakeholder meeting was scheduled and additional feedback was solicited by the Department.

December 7, 2017 – A second onsite stakeholder meeting was held at the Laboratory Services Division where comments received were reviewed and additional edits were made to the proposed language.

December 12, 2017 – Additional edits to the proposed language based upon addition stakeholder feedback and comments offered by the Attorney General's office were incorporated and provided to the stakeholders.

December 15, 2017 – Department's deadline to receive any additional comments prior to submission of the final proposed changes to the Board of Health for the scheduled January 2018 hearing.

The proposed language strives to achieve an equitable balance for accredited and non-accredited toxicology laboratories and reflects feedback provided by impacted stakeholders. The department believes the proposed language is consistent with the revised statute while ensuring the highest level of analytical performance continues to be verified and maintained.

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.

__X__ 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 proposed language strikes a balance that streamlines certification and accreditation in a manner that ensures this work is performed well. In addition, the proposed language does not place additional burdens on accredited entities such that the benefits are accreditation are lost because one set of requirements is merely exchanged for another.

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

SECTION 3. In Colorado Revised Statutes, 42-4-1304, amend (4)(a) as follows:

42-4-1304. Samples of blood or other bodily substance - duties of department of public health and environment. (4) The state board of health shall establish and promulgate such administrative regulations and procedures as are necessary to ensure that collection and testing of samples is accomplished to the fullest extent. Such regulations and procedures shall include but not be limited to the following:

(a) The certification of laboratories to ensure that the collection and testing of samples is performed in a competent manner, WHICH MAY INCLUDE WAIVING SPECIFIC CERTIFICATION REQUIREMENTS FOR LABORATORIES THAT ARE ACCREDITED BY THE AMERICAN BOARD OF FORENSIC TOXICOLOGY, THE INTERNATIONAL STANDARDS ORGANIZATION, OR A SUCCESSOR TO EITHER ORGANIZATION; and

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____.

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 the American Board of Forensic Toxicology (ABFT), the International Standards Organization (ISO), or a successor to the either organization may elect to forgo the annual onsite inspection as long as accreditation remains active, and, the biennial inspection performed by the accrediting organization includes review of the specialty of toxicology. ~~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 requesting certification from the Department must provide the Department a copy of the accrediting organizations final biennial inspection report within 30 days of receipt for the specialty of toxicology in addition to any accepted plan of correction submitted to the accrediting organization by the laboratory.

5.1.4 The Department will perform an onsite inspection of an accredited laboratory in the event that the specialty of toxicology is not reviewed by the accrediting organization during the biennial inspection.

5.1.5~~63~~ 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 the American Board of Forensic Toxicology (ABFT), the International Standards Organization (ISO), or a successor to the either 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~~.~~ the American Board of Forensic Toxicology

(ABFT), the International Standards Organization (ISO), or a successor to the either 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 or accredited laboratories identified in 5.1.4 must ~~and~~ participate in an annual on-site inspection.~~.~~

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