Regulatory Analysis

Notice of Intended Action to be published: 641—Chapter 12
"Approval of Confirmatory Laboratories for Private Sector Drug-Free Workplace Testing"

Iowa Code section(s) or chapter(s) authorizing rulemaking: 730.5(7)"f"
State or federal law(s) implemented by the rulemaking: Iowa Code section 730.5(7)"f"

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

November 6, 2024 2 to 3 p.m.	Microsoft Teams Meeting ID: 238 807 808 374 Passcode: sCAuM5

Public Comment

Any interested person may submit written or oral comments concerning this Regulatory Analysis, which must be received by the Department of Health and Human Services no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

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Purpose and Summary

The purpose of this rulemaking is to allow the Department to approve confirmatory laboratories so that non-Substance Abuse and Mental Health Services Administration (SAMHSA)-certified laboratories are conducting confirmatory drug testing in accordance with state and federal regulations.

Analysis of Impact

1. Persons affected by the proposed rulemaking:

- Classes of persons that will bear the costs of the proposed rulemaking:

Laboratories applying with the Department will bear the costs.

- Classes of persons that will benefit from the proposed rulemaking:

Laboratories that are not approved by the SAMHSA will benefit.

2. Impact of the proposed rulemaking, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred:

- Quantitative description of impact:

There are five laboratories that are approved by the Department. Each must submit a $300 renewal fee each year to maintain the certification.

- Qualitative description of impact:

This rulemaking allows laboratories that are not certified by SAMHSA to conduct confirmatory drug testing in Iowa in conformance with state and federal laws.

3. Costs to the State:

- Implementation and enforcement costs borne by the agency or any other agency:

There are administrative costs to approve the certification applications each year.

- Anticipated effect on state revenues:

None.

4. Comparison of the costs and benefits of the proposed rulemaking to the costs and benefits of inaction:

Not having the chapter would reduce the number of laboratories that can perform confirmatory drug testing for employers in Iowa.

5. Determination whether less costly methods or less intrusive methods exist for achieving the purpose of the proposed rulemaking:

None.

6. Alternative methods considered by the agency:

- Description of any alternative methods that were seriously considered by the agency:

None.

- Reasons why alternative methods were rejected in favor of the proposed rulemaking:

Not applicable.

Small Business Impact

If the rulemaking will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rulemaking on small business:

- Establish less stringent compliance or reporting requirements in the rulemaking for small business.
- Establish less stringent schedules or deadlines in the rulemaking for compliance or reporting requirements for small business.
- Consolidate or simplify the rulemaking's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rulemaking for small business.
- Exempt small business from any or all requirements of the rulemaking.

If legal and feasible, how does the rulemaking use a method discussed above to reduce the substantial impact on small business?

This rulemaking has no impact on small business.

Text of Proposed Rulemaking

ITEM 1. Rescind 641—Chapter 12 and adopt the following **new** chapter in lieu thereof:

CHAPTER 12
APPROVAL OF CONFIRMATORY LABORATORIES FOR
PRIVATE SECTOR DRUG-FREE WORKPLACE TESTING

641—12.1(730) Definitions. For the purpose of these rules, the following definitions apply:

"Alcohol or drug testing" means analysis of a sample for the purpose of detecting the presence or absence of alcohol or other drugs, or their metabolites, in the sample tested.

"CLIA" means the Clinical Laboratory Improvement Amendments of 1988.

"CMS" means the Centers for Medicare and Medicaid Services.

"GC/MS" means gas chromatography/mass spectrometry.

"Laboratory" means a facility inside or outside the state of Iowa approved to conduct confirmatory testing of samples for the detection of alcohol or other drugs, or their metabolites.

"Sample," for the purpose of these rules, means the substances determined by the department to be samples from the human body capable of accurately and reliably revealing the presence of alcohol or other drugs, or their metabolites, including hair, urine, saliva, breath, and blood.

"SHL" means the state hygienic laboratory.

"Specimen" means a part taken from a sample to determine the character of the whole sample.

641—12.2(730) Powers and duties. The department is responsible for the following actions:

12.2(1) Processing applications from laboratories requesting approval to conduct confirmatory testing pursuant to Iowa Code section 730.5(7)*"f."*

12.2(2) Developing an application package.

a. The department will make an application package available to all laboratories requesting approval to conduct confirmatory testing for alcohol or other drugs, or their metabolites.

b. The package will contain application procedures, a standardized application form and a self-inspection questionnaire.

c. The self-inspection questionnaire will assist the department in assessing the quality of a laboratory's performance as a confirmatory testing laboratory. This questionnaire will comprise the major but not the sole objective criteria used during the initial on-site inspection conducted by the SHL.

d. The package will be available from the department upon request.

12.2(3) Reviewing each application submitted and determining the adequacy for approval.

12.2(4) Designating the SHL to conduct an on-site inspection of each approved confirmatory laboratory at least once every two years. Inspection may be waived by the director if the laboratory has been inspected and accredited for forensic drug testing by the College of American Pathologists, or if the laboratory has been inspected and certified, licensed, or approved to conduct confirmatory testing by another state whose requirements are at least equal to Iowa's.

12.2(5) Maintaining and providing upon request an updated list of all approved confirmatory laboratories.

12.2(6) Providing written notice of approval and assigning an expiration date.

641—12.3(730) Application procedures and requirements. Laboratories desiring to conduct confirmatory testing for Iowa's employers shall apply to the department for approval. Each laboratory requesting Iowa approval to conduct confirmatory testing shall provide the following to the department:

12.3(1) A completed laboratory survey checklist on a form provided by the department.

12.3(2) A completed self-inspection questionnaire provided by the department.

12.3(3) Proof of enrollment in a recognized proficiency testing program. Recognized programs include those approved by CMS.

12.3(4) Acceptable performance over a 12-month period in all appropriate areas of proficiency testing for alcohol or other drugs, or their metabolites, shall be documented and maintained on an ongoing basis. Acceptable performance is as follows:

a. Initial approval shall require at least 80 percent accuracy in the last two graded proficiency test cycles with no false positive results.

b. Renewal shall require at least 80 percent accuracy each year on graded proficiency surveys with no false positive results.

641—12.4(730) Requirements of laboratory personnel involved in confirmatory testing for alcohol or other drugs, or their metabolites.

12.4(1) The laboratory director shall be a pathologist or doctoral level individual who qualifies as a clinical laboratory director under CLIA regulations.

12.4(2) Supervisors of analysts shall possess at least a bachelor of science degree in chemistry, medical technology, or comparable education and two years of analytical alcohol or drug testing

experience. Supervisors must also have training in the theory and practice of laboratory procedures and an understanding of quality control concepts. Annual verification of the supervisor's skills must be documented by the laboratory director.

12.4(3) Analysts shall possess the necessary training and skills for assigned tasks. These individuals shall possess at least two years of college education in the physical or biological sciences. At a minimum, analysts shall be graduates of a medical laboratory technician program that is recognized by the department or have at least two years of college with a minimum of nine semester hours in chemistry.

12.4(4) Laboratory directors, supervisors and analysts involved in alcohol or drug testing shall annually complete at least one in-service continuing education program related to alcohol or drug testing. Continuing education programs include formal training programs where continuing education units are awarded, informal in-house training programs, and relevant correspondence courses. Dates, titles and subject matter for each completed course shall be documented and the information shall be available for review.

12.4(5) The following information about each of the laboratory staff involved in alcohol or drug testing shall be retained for two years from date of termination and shall be available for review:

a. Résumé of training and experience.
b. Certificate or license.
c. Job description.

641—12.5(730) Quality assurance program and procedure manual requirements. All approved confirmatory laboratories shall have a written quality assurance program and a procedure manual that encompasses all aspects of the alcohol or drug testing process.

12.5(1) Approved laboratories shall have written procedures for performing alcohol or drug testing that shall include the following:

a. Sample acquisition.
b. Chain of custody.
c. Sample and report security.
d. Test performance.
e. Reporting of results.
f. Confidentiality.

12.5(2) The quality assurance program and procedure manuals shall be available for review during any on-site inspection.

12.5(3) Approved laboratories shall review their performance in each of the above areas every 12 months.

12.5(4) Approved laboratories are responsible for developing the criteria necessary to establish and maintain an effective quality assurance program for confirmatory testing of alcohol or other drugs, or their metabolites.

641—12.6(730) Analytical quality control. The number and position of control specimens tested within a batch and the number of calibrators used for each batch of specimens shall be consistent with generally accepted laboratory practice for the methodology used to conduct confirmatory testing.

12.6(1) Positive and negative controls shall be used in testing each batch of specimens.

12.6(2) Procedures shall be implemented and documented to ensure that carryover from a positive specimen does not contaminate other subsequent specimens in that batch.

12.6(3) Approved laboratories shall develop criteria for the detection and rejection of adulterated samples.

641—12.7(730) Sample security and confidentiality of test results. Samples and reports must never be left unattended or unsecured.

12.7(1) Complete chain of custody documentation shall be maintained for each sample from the time of collection from the employee or prospective employee to the time the sample is discarded. Each time the sample is handled or transferred, the individual receiving the sample, the time and date of transfer, and the recipient or destination of the sample shall be documented.

12.7(2) If the first portion of the sample yielded a confirmed positive test result, the laboratory shall store the second portion of that sample until receipt of a confirmed negative test result or for a period of at least 45 calendar days following the completion of the initial confirmatory testing. Urine and blood samples shall be retained in secure storage at freezing temperatures.

12.7(3) All samples for which a negative test result was reported shall be disposed of within five working days after issuance of the negative test result report.

641—12.8(730) Confirmatory testing.

12.8(1) Reports for alcohol shall be confirmed by gas chromatography, or a test that is recognized by the department as an equivalent test before being reported as positive (or negative).

12.8(2) Reports for drugs or their metabolites, other than alcohol, shall not be issued in the absence of confirmation by GC/MS or a scientifically equivalent test approved by the department.

12.8(3) Complete chain of custody procedures shall be used for referred samples.

641—12.9(730) Documentation of the confirmatory testing process. The following documents shall be retained for at least two years and, if requested, made available for inspection.

12.9(1) Chain of custody documentation shall be maintained for each sample tested with the identification of the sample, the person(s) handling and testing the sample, the storage of the sample, and the eventual disposal of the sample.

12.9(2) Documents regarding the following: analytical information for each batch assayed, instrument identification, calibration records, identification of reagent lot numbers and expiration dates, quality control results, and any other pertinent information.

12.9(3) Copies of proficiency testing results for ongoing monitoring and evaluation of laboratory performance. Approved confirmatory laboratories inspected by the SHL shall submit copies of proficiency testing results to the SHL or shall ensure that proficiency testing programs submit copies of proficiency testing results directly to the SHL on their behalf.

12.9(4) Current procedure manuals must be maintained for all procedures.

12.9(5) An annual review of manuals shall be performed and documented. Alterations and additions to procedures shall be incorporated into manuals and approved by the laboratory director before implementation.

641—12.10(730) Reporting of confirmed positive test results to the medical review officer.

12.10(1) Each report shall identify the alcohol or other drugs, or their metabolites, being tested with the results of positive/negative or detected/nondetected clearly recorded.

12.10(2) Approved confirmatory laboratories shall have available a written summary of the established sensitivity levels used for the confirmatory tests conducted for alcohol or other drugs, or their metabolites. However, this information need not be issued with each report.

12.10(3) Approved confirmatory laboratories shall have written procedures for making both written and telephone reports to the medical review officer.

12.10(4) All test results must be reviewed and signed by the laboratory director, or a qualified designee, before being reported to the medical review officer.

641—12.11(730) Reporting requirements to department. Pursuant to Iowa Code section 730.5(16), approved confirmatory laboratories shall file a report with the department by March 1 of each year. The report shall include the number of positive and negative drug or alcohol test results for the previous calendar year for the following if available to the laboratory:

1. Employees who work in non-safety-sensitive positions,
2. Employees who work in safety-sensitive positions,

3. Employees during and after completion of drug or alcohol rehabilitation,
4. Employees as a consequence of reasonable suspicion drug or alcohol testing,
5. Prospective employees,
6. As a consequence of federal law or regulation, or by law enforcement,
7. As a consequence of accident investigation in the workplace,
8. The types of drugs which were found in the positive drug tests,
9. All significant available demographic factors relating to the positive test pool, and
10. Total number of positive and negative drug or alcohol test results for the previous calendar year for all employees and prospective employees who were tested.

641—12.12(730) Approval, renewal, and inspection fees. At the time of initial application and each year thereafter, laboratories shall remit to the department a fee in an amount sufficient to reimburse the department for expenses incurred in administering the confirmatory laboratory approval program. All fees shall be made payable to the department and are as follows:

12.12(1) *Approval.* An administration fee of $600 is required for new applications, including applicants seeking approval through reciprocity.

12.12(2) *Renewal.* An administration fee of $300 is required to renew laboratory approval.

12.12(3) *Inspections by the SHL.* Reimbursement for actual on-site inspection and related expenses shall be assessed to each laboratory after the completion of each inspection. Expenses related to the on-site inspection shall be reimbursed to the SHL. These expenses shall reflect the actual cost incurred for personnel time and travel expenses consistent with state of Iowa travel reimbursement policies and procedures. These expenses shall also include the time necessary for SHL inspection staff to:

a. Review the application and related laboratory materials in preparation for the on-site inspection,
b. Generate the written laboratory report regarding inspection findings,
c. Conduct postinspection follow-up activities, if any, and
d. Review proficiency test results on an ongoing basis.

641—12.13(730) Renewal. Laboratories wishing to continue confirmatory testing for alcohol or other drugs, or their metabolites, in Iowa must renew their certification annually. The request for renewal shall include the following:

1. Name and address of laboratory.
2. Renewal fee.
3. Information that reflects any changes that occurred during the current approval period.
4. Copy of supporting documents if the laboratory is accredited for forensic drug testing by the College of American Pathologists, or if it is certified, licensed, or approved through reciprocity.

641—12.14(730) Reciprocity.

12.14(1) Confirmatory laboratories certified, licensed, or approved by another state to conduct testing for alcohol or other drugs, or their metabolites, may request Iowa approval through reciprocity by:

a. Completing and submitting the department's application package, and
b. Including a copy of their current certificate, license, or approval document from the state whose requirements are at least equal to Iowa's.

12.14(2) Laboratories approved through reciprocity that lose their certification, license or approval from another state shall notify the department within five working days.

641—12.15(730) Changes during approval periods. The following changes that occur during an approval period shall be submitted to the department within five working days from the date the change took place:

1. Change in laboratory director.

2. Change of address.
3. Change in supervisor.
4. Change in confirmation procedures.
5. Change in proficiency testing program.
6. Addition or subtraction of alcohol or other drugs, or their metabolites, being tested.
7. Change of ownership.
8. Loss of accreditation for forensic drug testing by the College of American Pathologists.

641—12.16(730) Enforcement. Upon a determination of noncompliance by the director that these rules have been violated, the director may immediately move to suspend, modify, or revoke any approval issued under these rules.

641—12.17(730) Denial, suspension, modification or revocation of approval. Any one of the following can result in denial, suspension, modification or revocation of approval. Failure of the confirmatory laboratory to:

1. Remain in compliance with the requirements of these rules.
2. Provide required documentation, including documentation of laboratory personnel and proficiency test results.
3. Maintain confidentiality.
4. Meet proficiency testing criteria.
5. Provide correct information.
6. Satisfactorily complete the two most recent and relevant graded proficiency test reports from a recognized proficiency testing program (for initial approval).
7. Correctly represent facts on a self-inspection questionnaire or other application documents.
8. Pass an on-site inspection conducted by the College of American Pathologists for forensic drug testing, or by another state whose requirements are at least equal to Iowa's, or by the SHL.

641—12.18(730) Restoration of approval. A confirmatory laboratory whose approval has been suspended, modified, or revoked may be reinstated within 90 days following the receipt of the following:

1. Documentation of actions that correct the reasons for suspension, modification, or revocation.
2. Documentation of a successful on-site inspection, if necessary, conducted by the College of American Pathologists for forensic drug testing, or by another state whose requirements are at least equal to Iowa's, or by the SHL.

641—12.19(730) Appeals process.

12.19(1) *Denial, suspension, modification, or revocation.* The department will send written notice of denial, suspension, modification, or revocation by certified mail, return receipt requested, pursuant to 441—Chapter 16. The adverse action will become effective 30 days after receipt of the notice unless the applicant, within 90 days, gives written notice to the department requesting a hearing. In that event, the notice will be deemed to be suspended.

12.19(2) *Contested cases.* The procedures for contested cases as set out in Iowa Code chapter 17A and the rules adopted by the department in 441—Chapter 7 will be followed in all cases where proper notice has been made to the department of the intent to formally contest any denial, suspension, modification, or revocation of approval.

641—12.20(730) Complaints.

12.20(1) The department will accept complaints of alleged problems relating to confirmatory laboratory procedures. The information shall state in as specific a manner as possible the basis for the complaint. The complaint shall be presented to the department in writing, in person or by telephone.

12.20(2) Within 20 working days of the receipt of the complaint, the department will communicate with the laboratory director for initial evaluation of the specific matters alleged in the complaint. The complainant will be informed of the results of the action taken by the department.

These rules are intended to implement Iowa Code section 730.5.