Dear Senators VANORDEN, Zuiderveld, Wintrow, and
Representatives VANDER WOUDE, Erickson, Chew:

The Legislative Services Office, Research and Legislation, has received the enclosed rules of the Department of Health and Welfare:

IDAPA 16.02.06 - Quality Assurance for Clinical Laboratories (ZBR Chapter Rewrite) - Proposed Rule (Docket No. 16-0206-2301).

Pursuant to Section 67-454, Idaho Code, a meeting on the enclosed rules may be called by the cochairmen or by two (2) or more members of the subcommittee giving oral or written notice to Research and Legislation no later than fourteen (14) days after receipt of the rules' analysis from Legislative Services. The final date to call a meeting on the enclosed rules is no later than 09/28/2023. If a meeting is called, the subcommittee must hold the meeting within forty-two (42) days of receipt of the rules' analysis from Legislative Services. The final date to hold a meeting on the enclosed rules is 10/26/2023.

The germane joint subcommittee may request a statement of economic impact with respect to a proposed rule by notifying Research and Legislation. There is no time limit on requesting this statement, and it may be requested whether or not a meeting on the proposed rule is called or after a meeting has been held.

To notify Research and Legislation, call 334-4854, or send a written request to the address on the memorandum attached below.

Terri Kondeff
Director

Legislative Services Office
Idaho State Legislature

Serving Idaho's Citizen Legislature

MEMORANDUM

TO: Rules Review Subcommittee of the Senate Health & Welfare Committee and the House Health & Welfare Committee

FROM: Principal Legislative Drafting Attorney - Elizabeth Bowen

DATE: August 4, 2023

SUBJECT: Department of Health and Welfare

IDAPA 16.02.06 - Quality Assurance for Clinical Laboratories (ZBR Chapter Rewrite) - Proposed Rule (Docket No. 16-0206-2301)

Summary and Stated Reasons for the Rule

This proposed rule rewrites rules relating to quality assurance for clinical laboratories in order to simply the language pursuant to Executive Order 2020-01.

Negotiated Rulemaking / Fiscal Impact

Negotiated rulemaking was conducted. There is no anticipated negative fiscal impact on the state general fund.

Statutory Authority

This rulemaking appears to be authorized pursuant to Section 56-1003, Idaho Code.

cc: Department of Health and Welfare
Frank Powell and Trinette Middlebrook

***** PLEASE NOTE *****

Per the Idaho Constitution, all administrative rules may be reviewed by the Legislature during the next legislative session. The Legislature has 3 options with this rulemaking docket: **1)** Approve the docket in its entirety; **2)** Reject the docket in its entirety; or **3)** Reject the docket in part.

IDAPA 16 – DEPARTMENT OF HEALTH AND WELFARE

16.02.06 – QUALITY ASSURANCE FOR CLINICAL LABORATORIES

DOCKET NO. 16-0206-2301 (ZBR CHAPTER REWRITE)

NOTICE OF RULEMAKING – PROPOSED RULE

AUTHORITY: In compliance with Section 67-5221(1), Idaho Code, notice is hereby given that this agency has initiated proposed rulemaking procedures. The action is authorized pursuant to Section 56-1003, Idaho Code.

PUBLIC HEARING SCHEDULE: Public hearing(s) concerning this rulemaking will be scheduled if requested in writing by twenty-five (25) persons, a political subdivision, or an agency, not later than August 16, 2023.

The hearing site(s) will be accessible to persons with disabilities. Requests for accommodation must be made not later than five (5) days prior to the hearing, to the agency address below.

DESCRIPTIVE SUMMARY: The following is a nontechnical explanation of the substance and purpose of the proposed rulemaking:

Under Executive Order 2020-01: Zero-Based Regulation, the Division of Public Health, Bureau of Laboratories, is striving to prevent the accumulation of costly, ineffective, and outdated regulations and reduce regulatory burden to achieve a more efficient operation of government. The rule changes are intended to perform a comprehensive review of this chapter by collaborating with the public to streamline or simplify this rule language. This IDAPA chapter title is changing to Quality Assurance for Clinical Laboratories.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased: There are no fees associated with this chapter of rule.

FISCAL IMPACT: The following is a specific description, if applicable, of any negative fiscal impact on the State General Fund greater than ten thousand dollars ($10,000) during the fiscal year as a result of this rulemaking:

This rulemaking is not anticipated to have any fiscal impact on the State General Fund, or any other known funds.

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(1), Idaho Code, negotiated rulemaking was conducted. The Notice of Intent to Promulgate Rules - Negotiated Rulemaking was published in the March 1st, 2023 and April 5th, 2023, Idaho Administrative Bulletins, Vol. 23-3, pages 18 - 19 and Vol 23-4, pages 27 - 28.

INCORPORATION BY REFERENCE: Pursuant to Section 67-5229(2)(a), Idaho Code, the following is a brief synopsis of why the materials cited are being incorporated by reference into this rule: There are no incorporations by reference in this chapter of rules.

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Christopher Ball at 208-334-0568 or Micheal Dillon at 208-334-0545.

Anyone may submit written comments regarding this proposed rulemaking. All written comments must be directed to the undersigned and must be delivered on or before August 23, 2023.

DATED this 6th day of July, 2023.

Trinette Middlebrook and Frank Powell
DHW – Administrative Rules Unit
450 W. State Street – 10th Floor
P.O. Box 83720
Boise, ID 83720-0036
phone: (208) 334-5500
fax: (208) 334-6558
e-mail: dhwrules@dhw.idaho.gov

THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 16-0206-2301
(ZBR Chapter Rewrite)

16.02.06 – QUALITY ASSURANCE FOR ~~IDAHO~~ CLINICAL LABORATORIES

000. LEGAL AUTHORITY.
~~Under~~ Section 56-1003, Idaho Code, ~~the Idaho Legislature has delegated to~~ authorizes the Board of Health and Welfare ~~the authority~~ to set standards for Idaho laboratories ~~in the state of Idaho~~. ~~(3-17-22)~~( )

~~**001. TITLE AND SCOPE.**~~

~~**01. Title**. These rules are titled IDAPA 16.02.06, "Quality Assurance for Idaho Clinical Laboratories." (3-17-22)~~

~~**02. Scope**. These rules protect the public and individual health by requiring that all Idaho clinical laboratories develop satisfactory quality assurance programs that meet minimal standards approved by the Board. (3-17-22)~~

002~~1~~. -- 009. (RESERVED)

010. DEFINITIONS.
~~For the purposes of these rules, the following terms apply:~~ ~~(3-17-22)~~

01. Board. The Idaho Board of Health and Welfare. ( )

02. Department. The Idaho Department of Health and Welfare, or its designee. ~~(3-17-22)~~( )

~~**03. Director**. The Director of the Idaho Department of Health and Welfare, or their designee. (3-17-22)~~

0~~4~~3. ~~Laboratory or~~ Clinical Laboratory. A facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examinations of material derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease, or the impairment or assessment of human health. ~~(3-17-22)~~( )

0~~5~~4. Laboratory Director. The person under whose supervision the laboratory is operating. ( )

~~**06. Pathologist**. A physician who is:~~ ~~(3-17-22)~~

~~**a.** Licensed by the Idaho State Board of Medicine in accordance with IDAPA 24.33.01, "Rules of the Board of Medicine for the Licensure to Practice Medicine and Surgery and Osteopathic Medicine and Surgery in Idaho"; and (3-17-22)~~

~~**b.** Board certified by the American Board of Anatomic and Clinical Pathology. (3-17-22)~~

05. Nonwaived Test. A moderate or high complexity test system, assay, or examination that does not meet the criteria for a waiver as specified under Title 42 USC, Section 263a (3). ( )

0~~7~~6. Proficiency Testing. Evaluation of a laboratory's ability to perform laboratory procedures within acceptable limits of accuracy through analysis of unknown specimens distributed at periodic intervals. ( )

0~~8~~7. Quality Control. ~~A day-to-day a~~Analysis of reference materials to ensure reproducibility and accuracy of laboratory results~~,~~ and ~~also includes~~ an acceptable system to assure proper functioning of instruments,

equipment, and reagents. (3-17-22)( )

0~~9~~8. **Reviewer**. ~~An employee or other designated representative of t~~The Department's ~~Idaho Bureau of Laboratories,~~ representative who is knowledgeable and experienced in clinical laboratory methods and procedures. (3-17-22)( )

09. Waived Test. A low complexity test system, assay, or examination that meets the criteria for waiver specified under Title 42 USC, Section 263a (3). ( )

011. -- 099. (RESERVED)

100. REGISTRATION REQUIREMENTS ~~FOR CLINICAL LABORATORIES~~.

01. Registration Timeframes. ( )

a. ~~Every person responsible for the operation of a~~ A clinical laboratory ~~that performs tests on material derived from the human body~~ must register ~~such facility~~ with the Department ~~within thirty (30) days after first~~ prior to accepting specimens for testing. (3-17-22)( )

b. ~~Existing~~ Registered clinical laboratories must submit a completed ~~laboratory~~ registration form every two (2) years and indicate any changes in laboratory operations. (3-17-22)( )

02. Registration Form. Each clinical laboratory must ~~submit its registration information on~~ use the Department-approved form. ~~These f~~Forms are available upon request from the Department. Each ~~completed registration~~ form must include the following ~~information~~: (3-17-22)( )

a. Name and location of the clinical laboratory; (3-17-22)( )

b. Name of the laboratory director; ( )

c. ~~Types of laboratory t~~Tests performed in the laboratory; and (3-17-22)( )

d. Any ~~O~~other information requested by the Department ~~that it deems necessary~~ to evaluate ~~the~~ clinical laboratory performance ~~of the laboratory~~. (3-17-22)( )

101. -- 109. (RESERVED)

110. EXCLUSIONS.

01. Other Certifying Agencies. Clinical ~~L~~Laboratories will be excluded from compliance with these rules (except Sections 100, 130, and 200) upon submission of evidence of certification from one (1) of the following ~~agencies~~: (3-17-22)( )

a. Centers for Medicare and Medicaid Services (CMS), Clinical Laboratory Improvement Amendment (CLIA) certification program ~~http://www.cms.gov/CLIA/01_Overview.asp;~~ (3-17-22)( )

~~**b.** College of American Pathologists;~~ (3-17-22)

~~e~~**b.** Agencies approved by CMS as accreditation organizations. To review the current list of CMS-approved accreditation organizations go to, https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/AOList.pdf; ( )

~~**d.** Laboratories located in hospitals approved by the Joint Commission http://www.jointcommission.org/; and~~ (3-17-22)

~~e~~**c.** Other certification programs approved by the Department. ( )

02. Facilities and Laboratories. The following laboratories and facilities are also excluded from compliance with ~~this chapter~~ these rules: ~~(3-17-22)~~( )

a. Teaching, research, forensic, and pre-employment drug screening ~~L~~laboratories ~~operated for teaching or research purposes only, provided~~ if test~~s~~ results are not used for diagnosis or treatment; ~~(3-17-22)~~( )

b. Prosthetic dental laboratories; and ( )

c. Facilities performing skin testing solely for detection of allergies and sensitivities. ( )

111. -- 119. (RESERVED)

120. DEPARTMENT INSPECTIONS ~~OF CLINICAL LABORATORIES~~.
A ~~qualified representative of the~~ Department representative is authorized to inspect ~~the premises and operations of all approved laboratories for the purpose of determining~~ any registered clinical laboratory to determine the adequacy of the ~~quality control program and~~ supervision ~~of each laboratory~~, staffing, and quality control program. ~~(3-17-22)~~( )

121. -- 129. (RESERVED)

130. GENERAL REQUIREMENTS ~~FOR CLINICAL LABORATORIES~~.

01. Clinical Laboratory Facilities. Each clinical laboratory must have adequate space, equipment, and supplies to perform the services offered, with accuracy, precision, and safety. ~~(3-17-22)~~( )

02. Records. ( )

a. Clinical ~~L~~laboratory records must identify the person responsible for performing the procedure. ~~(3-17-22)~~( )

b. ~~Each laboratory~~ Clinical Laboratories must maintain ~~a suitable~~ testing record~~s of each test result~~ for ~~a period of~~ at least two (2) years. Test ~~R~~reports ~~of tests~~ must be ~~filed in a manner that permits ready identification and accessibility~~ readily accessible upon request. ~~(3-17-22)~~( )

c. Clinical ~~L~~laboratory records and reports must identify specimens referred to other certified laboratories and must identify the reference laboratory ~~testing such referred specimens~~ by name and address. ~~(3-17-22)~~( )

03. Test Orders and Results. ( )

a. Practitioners legally authorized to diagnose, treat, and prescribe are authorized to order both waived and nonwaived tests and receive results. ( )

b. Laboratory directors are authorized to order the waived tests listed on their approved registration form and receive test results. ( )

131. -- 149. (RESERVED)

150. PERSONNEL REQUIREMENTS ~~FOR CLINICAL LABORATORIES~~.
The laboratory director must ensure that ~~the~~ clinical laboratory staff ~~of the laboratory:~~ have appropriate education, experience, and training to maintain records, perform tests, and report results. The clinical laboratory must employ enough staff to provide timely and accurate test results. Staff must receive in-service training appropriate to the type and complexity of testing. Staff must not perform testing outside of their scope of training. ~~(3-17-22)~~( )

~~**01. Appropriate Education, Experience, and Training**. Have appropriate education, experience, and training to perform and report laboratory tests promptly and proficiently;~~ ~~(3-17-22)~~

~~**02. Sufficient in Number for the Scope and Complexity**. Are sufficient in number for the scope and~~

~~complexity of the services provided;~~ ~~(3-17-22)~~

~~**03. In-service Training**. Receive in-service training appropriate to the type and complexity of the laboratory services offered; and~~ ~~(3-17-22)~~

~~**04. Procedures and Tests that are Outside the Scope of Training**. Do not perform procedures and tests that are outside the scope of training of the laboratory personnel.~~ ~~(3-17-22)~~

151. -- 199. (RESERVED)

200. PROFICIENCY TESTING ~~OF CLINICAL LABORATORIES~~.

01. Scope. ~~All~~ Clinical laboratories must ~~subscribe to, and~~ satisfactorily participate in~~, a~~ proficiency testing program~~s that has been~~ approved by the Department. ~~(3-17-22)~~( )

02. Results to the ~~Bureau of Laboratories~~ Department. The clinical laboratory ~~director must furnish the Laboratory Improvement Section with copies of all proficiency testing results within thirty (30) days of receipt or make provisions for a duplicate of the results to be sent by the testing service directly~~ must ensure that all proficiency testing results are available to the Department. ~~(3-17-22)~~( )

201. -- 209. (RESERVED)

210. QUALITY CONTROL PROGRAM REQUIREMENTS ~~FOR CLINICAL LABORATORIES~~.

01. Establishment of Quality Control Program. ~~To ensure reliability of day-to-day results, each laboratory~~ Clinical laboratories must establish a quality control program ~~compatible with regional and statewide practices~~. ~~(3-17-22)~~( )

02. Program Scope. An acceptable quality control program must include ~~the following~~ written documentation of: ~~(3-17-22)~~( )

a. A~~n effective~~ preventive maintenance program that ensures proper functioning of all instruments and equipment; ~~(3-17-22)~~( )

b. ~~Routine~~ Proper testing of quality control materials along with patient specimens; ~~(3-17-22)~~( )

c. Quality control checks on reagents and media utilized in the performance of tests; ( )

d. ~~Maintenance of q~~Quality control records that ~~will enable determination of~~ demonstrate the reliability of all procedures performed. ~~(3-17-22)~~( )

211. -- 219. (RESERVED)

220. DEPARTMENT APPROVAL ~~OF CLINICAL LABORATORIES~~.
The Department will approve clinical laboratories for performance of tests on material from the human body if the laboratory meets the ~~minimum~~ standards specified in these ~~regulations~~ rules. ~~(3-17-22)~~( )

221. -- 229. (RESERVED)

230. DEPARTMENT REVOCATION OF APPROVAL.
The Department may revoke approval, either in total or in part, for any one (1) of the following reasons: ~~(3-17-22)~~( )

01. Failure to Participate in Proficiency Testing. The ~~approved~~ clinical laboratory fails to participate in a proficiency testing program ~~as outlined in Section 200 of these rules~~. ~~(3-17-22)~~( )

02. Failure to Participate in Quality Control. The ~~approved~~ clinical laboratory fails to implement a

quality control program ~~as outlined in Section 210 of these rules~~. ~~(3-17-22)~~( )

03. Failure to Obtain Satisfactory Results. The Department, through the quality review process, determines that the ~~approved~~ clinical laboratory has failed to obtain satisfactory results on two (2) consecutive or on two (2) out of three (3) consecutive sets of proficiency test program specimens in one (1) or more testing categories. ~~(3-17-22)~~( )

04. Failure to Submit Documentation. Failure to submit documentation of corrective action ~~as indicated in Subsection 240.02 of these rules~~ required by the Department. ~~(3-17-22)~~( )

231. -- 239. (RESERVED)

240. REVOCATION PROCEDURE.

01. Unacceptable Results. Clinical ~~L~~laboratories that fail to obtain passing results on two (2) consecutive proficiency testing events, or two (2) out of three (3) events, will be required to submit documentation of corrective action within fifteen (15) working days after receipt of the notification of the failures. Evaluation of proficiency testing results may overlap from one year to the next. ~~(3-17-22)~~( )

02. Corrective Action. Upon receipt of documentation of corrective action, a reviewer will determine the adequacy of the action taken. If~~, in the opinion of~~ the reviewer~~,~~ determines the corrective action is not adequate, the clinical laboratory ~~will be required to~~ must submit to an on-site inspection that may include on-site testing of unknown samples. ~~(3-17-22)~~( )

03. On-Site Inspection. If the results of the on-site inspection indicate that the clinical laboratory~~'s~~ performance is unacceptable in one (1) or more testing categories, the approval to perform the test(s) in question will be revoked. ~~(3-17-22)~~( )

04. Satisfactory Performance. The clinical laboratory will continue to be approved for performance of all test procedures for which it has demonstrated satisfactory performance. ~~(3-17-22)~~( )

05. Other Deficiencies. Failure to comply with other provisions of these rules may invoke revocation procedures. ( )

241. -- 249. (RESERVED)

250. RENEWAL OF APPROVAL OF DISAPPROVED TEST(S) ~~OR TESTS~~.

01. Renewal Granted. ( )

a. A clinical laboratory that has lost approval to perform certain tests ~~for reasons outlined in Section 240 of these rules~~ may gain reapproval ~~by documenting corrective action taken, and~~ by requesting the Department review the unacceptable performance and the corrective action taken. ~~(3-17-22)~~( )

b. Within ten (10) days after completion of this review, the reviewer will submit their report to the ~~Chief of the Bureau of Laboratories~~ Department. ~~(3-17-22)~~( )

c. Upon determination that corrections leading to satisfactory and acceptable performance have been made, the ~~Chief of the Bureau of Laboratories~~ Department may reinstate approval. ~~(3-17-22)~~( )

02. Renewal Denied. If the ~~Chief of the Bureau of Laboratories~~ Department does not grant reapproval of the clinical laboratory, they will provide ~~the laboratory supervisor with~~ written notice of actions to be taken to correct deficiencies. The clinical laboratory ~~supervisor~~ may request a new review at any time after thirty (30) days from the date of last review. The clinical laboratory ~~supervisor~~ may also file a written appeal ~~in accordance with~~ under IDAPA 16.05.03, "Contested Case Proceedings and Declaratory Rulings~~,~~.~~"~~ ~~Section 400.~~ ~~(3-17-22)~~( )

251. -- 269. (RESERVED)

270. ~~LIST OF APPROVED~~REGISTERED LABORATORIES.
The Department will maintain a list of registered clinical laboratories ~~approved in accordance with this chapter. This list must include the name and address of each approved laboratory, and the name of the person directing the laboratory~~. ~~(3-17-22)~~( )

271. -- 299. (RESERVED)

300. ~~PENALTY FOR~~ FAILURE TO REGISTER OR OPERATION OF AN ~~NON-APPROVED~~ UNREGISTERED CLINICAL LABORATORY.
Failure to register a clinical laboratory, operation of an ~~non-approved~~ unregistered clinical laboratory, or performance of unapproved testing constitutes a violation of these rules. Any violation of these rules constitutes a misdemeanor under Section 56-1008, Idaho Code. ~~(3-17-22)~~( )

301. -- 999. (RESERVED)