
LEGAL STATUS

This site displays a prototype of a “Web 2.0” version of the daily Federal Register. It is not an official legal edition of the Federal Register, and does not replace the official print version or the official electronic version on GPO’s govinfo.gov.

The documents posted on this site are XML renditions of published Federal Register documents. Each document posted on the site includes a link to the corresponding official PDF file on govinfo.gov. This prototype edition of the daily Federal Register on FederalRegister.gov will remain an unofficial informational resource until the Administrative Committee of the Federal Register (ACFR) issues a regulation granting it official legal status. For complete information about, and access to, our official publications and services, go to [About the Federal Register](#) on NARA’s archives.gov.

The OFR/GPO partnership is committed to presenting accurate and reliable regulatory information on FederalRegister.gov with the objective of establishing the XML-based Federal Register as an ACFR-sanctioned publication in the future. While every effort has been made to ensure that the material on FederalRegister.gov is accurately displayed, consistent with the official SGML-based PDF version on govinfo.gov, those relying on it for legal research should verify their results against an official edition of the Federal Register. Until the ACFR grants it official status, the XML rendition of the daily Federal Register on FederalRegister.gov does not provide legal notice to the public or judicial notice to the courts.

LEGAL STATUS

Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1988 Exemption of Laboratories Licensed by the State of Washington

A Notice by the [Centers for Medicare & Medicaid Services](#) on 04/01/2024

PUBLISHED CONTENT - DOCUMENT DETAILS

Agencies: Department of Health and Human Services

Centers for Medicare & Medicaid Services

Agency/Docket Number: CMS-3441-N

Document Citation: 89 FR 22406

Document Number: 2024-06802

Document Type: Notice

Pages: 22406-22408 (3 pages)

Publication Date: 04/01/2024

DOCUMENT HEADINGS

Department of Health and Human Services
Centers for Medicare & Medicaid Services
[CMS-3441-N]

AGENCY:

Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION:

Notice.

SUMMARY:

This notice announces that laboratories located in and licensed by the State of Washington that possess a valid license under the Medical Test Site law, chapter 70.42 of the Revised Code of Washington, are exempt from the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) for a period of 4 years.

DATES:

The exemption granted by this notice is effective from April 1, 2024 to April 1, 2028.

FOR FURTHER INFORMATION CONTACT:

Mary Hasan, (410) 786-6480.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

Section 353 of the Public Health Service Act (PHSA), as amended by the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100-578), which was enacted on October 31, 1988, generally provides that no laboratory may perform tests on human specimens for the diagnosis, prevention or treatment of any disease or impairment of, or assessment of the health of, human beings unless it has a certificate to perform that category of tests issued by the Secretary of the Department of Health and Human

Services (HHS). Under section 1861(s)(17)(A) of the Social Security Act (the Act), the Medicare program will only pay for laboratory services if the laboratory has an appropriate CLIA certificate for the testing they conduct. Under section 1902(a)(9)(C) of the Act, State Medicaid plans will generally only pay for laboratory services furnished by CLIA-certified laboratories. Thus, although subject to specified exemptions and exceptions, laboratories generally must have a current and valid CLIA certificate to test human specimens for the purposes noted above to be eligible for payment for those tests by the Medicare or Medicaid programs. Regulations implementing section 353 of the PHSA are contained in 42 CFR part 493 (<https://www.ecfr.gov/current/title-42/part-493>).

Section 353(p)(2) of the PHSA provides for the exemption of laboratories from CLIA requirements in States that enact legal requirements that are equal to or more stringent than CLIA's statutory and regulatory requirements. Section 353(p)(2) of the PHSA is implemented in subpart E of our regulations at 42 CFR part 493 (<https://www.ecfr.gov/current/title-42/part-493>). Sections 493.551(a) and 493.553 provide that CMS may exempt from CLIA requirements, for a period not to exceed 6 years, all State-licensed or State-approved laboratories in a State if the State licensure program meets the specified conditions. Section 493.559(a) provides that CMS will publish a notice in the **Federal Register** when CMS grants an exemption to an approved State licensure program. Section 493.559(b) provides that the notice will include the following:

- The name of the State licensure program.
- A description of how the laboratory requirements of the State are equal to or more stringent than those of part 493.
- The basis for granting the exemption.
- The term of approval, not to exceed 6 years.

A. State of Washington's Application for CLIA Exemption of Its Laboratories

The State of Washington has applied for exemption of its laboratories from CLIA program requirements. The State of Washington submitted all the applicable information and attestations required by §§ 493.551(a), 493.553, and (□ printed page 22407) 493.557(b) for State licensure programs seeking exemption of their licensed laboratories from CLIA program requirements. Examples of documents and information submitted include: a comparison of its laboratory licensure requirements with the comparable CLIA condition-level requirements (that is, a crosswalk); and a description of the following: its inspection

process; its proficiency testing (PT) monitoring process; its data management and analysis system; its investigative and response procedures for complaints received against laboratories; and its policy regarding announced and unannounced inspections.

B. CMS Analysis of Washington's Application and Supporting Documentation

To determine whether CMS should grant a CLIA exemption to laboratories licensed by a State, CMS reviews the application and additional documentation that the State submits to us and conducts a detailed and in-depth comparison of the State licensure program and CLIA's statutory and regulatory requirements to determine whether the State licensure program meets the requirements in part 493.

In summary, the State generally must demonstrate that:

- It has State laws in effect that provide for a State licensure program that has requirements that are equal to, or more stringent than, CLIA condition-level requirements for laboratories.
- It has implemented a State licensure program with requirements that are equal to, or more stringent than, the CLIA condition-level requirements such that a laboratory licensed by the State program would meet the CLIA condition-level requirements if it were inspected against those requirements.
- The requirements under that State licensure program meet or exceed the requirements of §§ 493.553, 493.555, and 493.557(b) and is suitable for approval by CMS under § 493.553(b)(3). For example, among other things, the program would need to:

++ Demonstrate that it has enforcement authority and administrative structures and resources adequate to enforce its laboratory requirements.

++ Permit CMS or CMS agents to inspect laboratories within the State.

++ Require laboratories within the State to submit to inspections by CMS or CMS agents as a condition of licensure.

++ Agree to pay any costs associated with our activities to validate its State licensure program as specified in § 493.557(b)(4) as well as the State's pro rata share of the general overhead to develop and implement CLIA as specified in § 493.649(a).

++ Take appropriate enforcement action against laboratories found by CMS or CMS agents to be out of compliance with requirements equivalent to CLIA requirements, as specified in § 493.557(b).

As specified in our regulations at §§ 493.555 and 493.557(b), our review of a State licensure program includes (but is not necessarily limited to) an evaluation of the following:

- Whether the State's requirements for laboratories are equal to, or more stringent than, the CLIA condition-level requirements.
- The State's inspection process requirements to determine the following:

++ The comparability of the full inspection and complaint inspection procedures to those of CMS, including, but not limited to, inspection frequency and the ability to investigate and respond to complaints against its laboratories.

++ The State's enforcement procedures for laboratories found to be out of compliance with its requirements.

- The ability of the State to provide CMS with electronic data and reports with the adverse or corrective actions resulting from PT results that constitute unsuccessful participation in CMS-approved PT programs and with other data CMS determines to be necessary for validation review and assessment of the State's inspection process requirements.
- The State's agreement with CMS that requires the State to do the following:

++ Notify CMS within 30 days of the action taken against any CLIA-exempt laboratory that has had its licensure or approval suspended, withdrawn, revoked, or limited; been in any way sanctioned; or had any adverse action taken against it.

++ Notify CMS within 10 days of any deficiency identified in a CLIA-exempt laboratory in cases when the deficiency poses an immediate jeopardy to the laboratory's patients or a hazard to the general public.

++ Notify each laboratory licensed by the State under its approved State licensure program within 10 days of a withdrawal of our approval of the State's licensure program, and the resulting loss of the laboratory's exemption from CLIA based on its licensure under that

program.

++ Provide CMS with written notification of any changes in the State's licensure (or approval) and inspection requirements.

++ Disclose to CMS or CMS' agent any laboratory's PT results in accordance with the State's confidentiality requirements.

++ Take appropriate enforcement action against laboratories that CMS or CMS agents find to be out of compliance with CLIA condition-level requirements and report these enforcement actions to CMS.

++ Notify CMS within 30 days of all newly licensed laboratories, including the specialty and subspecialty areas of testing, and notify CMS of any changes in the specialties and subspecialties for which any licensed laboratory in the State performs testing.

++ Provide CMS with inspection schedules, as requested, for validation purposes.

In keeping with the process described above, CMS evaluated the application and supporting materials that were submitted by Washington State to verify that the laboratories licensed through its program will meet or exceed the requirements of the following subparts of part 493:

- Subpart H, Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing;
- Subpart J, Facility Administration for Nonwaived Testing;
- Subpart K, Quality Systems for Nonwaived Testing,
- Subpart M, Personnel for Nonwaived Testing;
- Subpart Q, Inspection; and
- Subpart R, Enforcement Procedures.

CMS found that Washington State's laboratory licensure program requirements mapped to all the CLIA condition-level requirements. The State licensure program's inspection process and PT monitoring processes were adequate. Other materials that were submitted demonstrated compliance with the other above-referenced requirements of subpart E of part 493. As a result, CMS concluded that the submitted documents

supported exempting laboratories licensed under that program from the CLIA program requirements. Furthermore, a review of our validation inspections conducted by the CMS office in Seattle, Washington, supported this conclusion.

The Federal validation inspections of CLIA-exempt laboratories, as specified in § 493.563, were conducted on a representative sample basis, as well as in response to any substantial allegations of noncompliance (complaint inspections). The outcome of those validation inspections has been and will continue to be our principal tool for verifying that the laboratories located in, and licensed by, the State are in compliance with CLIA requirements. (□ printed page 22408)

The CMS office in Seattle, Washington, has conducted validation inspections of a representative sample of the laboratories inspected by the Washington State Office of Laboratory Quality Assurance (LQA). The validation inspections were primarily of the concurrent type; that is, our surveyors accompanied Washington State's inspectors, each inspecting against his or her agency's respective regulations. Analysis of the validation data revealed no significant differences between the State and Federal findings. The validation surveys verified that the State of Washington inspection process covers all CLIA conditions applicable to each laboratory being inspected and also verified that the State laboratory licensure requirements meet or exceed CLIA condition-level requirements. The validation surveys found the State inspectors highly skilled and qualified. The LQA inspected laboratories in a timely fashion; that is, all laboratories were inspected within the required 24-month cycle. All parameters monitored by the CMS office in Seattle, Washington, to date, indicate that the State of Washington is meeting all requirements for approval of CLIA exemption. This Federal monitoring will continue as an on-going process.

C. Conclusion

Based on review of the documents submitted by the Washington State licensure program under the requirements of subpart E of part 493, as well as the outcome of the validation inspections conducted by the CMS office in Seattle, Washington, CMS finds that the State of Washington's licensure program meets the requirements of § 493.553(a), and that, as a result, CMS may exempt all State-licensed laboratories from CLIA program requirements.

Approval of the CLIA exemption for laboratories located within and licensed by the State of Washington laboratory licensure program is subject to removal if CMS determines that the outcome of a comparability review or a validation review inspection is not acceptable,

as described under §§ 493.573 and 493.575, or if the State of Washington fails to pay the required fee every 2 years as required under § 493.649.

D. Laboratory Data

The approval of this exemption for laboratories located within and licensed by the State of Washington is conditioned on the State of Washington's continued compliance with the assertions made in its application, including the provision of information to us in accordance with our regulations at § 493.557(b)(8) about changes to a laboratory's specialties or subspecialties based on the State's survey, and changes to a laboratory's certification status.

E. Required Administrative Actions

CLIA is a user-fee funded program. The registration fee paid by laboratories is intended to cover the cost of the development and administration of the program. However, when a State's application for exemption is approved, CMS does not charge a fee to laboratories in the State. The State's share of the costs associated with CLIA must be collected from the State, as specified in § 493.649.

The State of Washington must pay for the following:

- Costs of Federal inspections of laboratories in the State to verify that standards are being enforced in an appropriate manner.
- Costs incurred for investigations of complaints against State of Washington laboratories if the complaint is substantiated.
- The State's pro rata share of general overhead to administer the laboratory certification program under section 353 of the PHS Act.

To estimate the State of Washington's proportionate share of the general overhead costs to develop and implement CLIA, CMS determined the ratio of laboratories in the State to the total number of laboratories nationally. Approximately 1.9 percent of the registered laboratories are in the State of Washington. CMS determined that a corresponding percentage of the applicable CMS, CDC, FDA, and their respective contractor costs should be borne by the State of Washington.

The State of Washington has agreed to pay the State's pro rata share of the anticipated overhead costs and costs of actual validation (including complaint investigation surveys) as specified in § 493.655(b). A final reconciliation for all laboratories and all expenses will be made. CMS will reimburse the State for any overpayment or bill it for any balance.

II. Approval

In light of the foregoing, CMS grants approval of the State of Washington's laboratory licensure program under subpart E. All laboratories located in and licensed by the State of Washington under the Medical Test Site law, chapter 70.42 of the Revised Code of Washington, are CLIA-exempt for all specialties and subspecialties until April 1, 2028.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Trenesha Fultz-Mimms, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register** .

Trenesha Fultz-Mimms,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2024-06802 (/d/2024-06802) Filed 3-29-24; 8:45 am]

BILLING CODE 4120-01-P

PUBLISHED DOCUMENT: 2024-06802 (89 FR 22406)