September 14, 2026

Submitted via Regulations.gov (Federal eRulemaking Portal)

The Honorable Mehmet Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-3485-NC
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Docket No. CMS-3485-NC; Request for Information; Clinical Laboratory Improvement Amendments of 1988 (CLIA) Regulations, 91 Fed. Reg. 43586 (July 16, 2026)[1]

Dear Administrator Oz:

Introduction and Position

The Washington State Department of Health (DOH) supports this request for information and appreciates the decision by the Centers for Medicare & Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC) to gather evidence before proposing changes to the CLIA regulations. Several of the topics the agencies raise address gaps in the current framework, and we offer comments on all four sections below.

Washington is one of only two states whose licensed laboratories are exempt from CLIA because CMS has determined the state program to be equal to or more stringent than the CLIA condition-level requirements.[2] DOH is commenting as the regulating agency for laboratories licensed under Washington's Medical Test Site Law (MTS) law, chapter 70.42 RCW. Washington state must comply with requirements in 42 CFR Part 493 to keep the CLIA exemption, so whatever emerges from this RFI generates large-scale rulemaking obligations for DOH.

That perspective produces one procedural request that runs through this letter: the agencies should solicit and separately analyze the effects of any proposal on approved state laboratory programs, and should consult Washington and New York before publishing proposed regulation text.

[1] Request for Information; Clinical Laboratory Improvement Amendments of 1988 (CLIA) Regulations, 91 Fed. Reg. 43586 (July 16, 2026) [hereinafter RFI]. Federal Register :: Request for Information; Clinical Laboratory Improvement Amendments of 1988 (CLIA) Regulations

[2] 42 C.F.R. § 493.551(a)(1) (CMS may exempt State-licensed laboratories where the State licensure program requirements are "equal to, or more stringent than, the CLIA condition-level requirements"). https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-E

Washington's Interest and the Exempt-State Posture

Washington's MTS program licenses clinical laboratories under chapter 70.42 RCW[3] and chapter 246-338 WAC.[4] CMS approved the current exemption for Washington-licensed laboratories for the period April 1, 2024 through April 1, 2028, after determining that Washington's requirements mapped to all CLIA condition-level requirements.[5] The program licenses or issues certificates of waiver to approximately 8,000 test sites, conducts biennial on-site surveys of approximately 400 non-waived sites, monitors proficiency testing performance, and performs validation inspections of a sample of accredited laboratories.

Three structural consequences follow and are not visible anywhere in the RFI.

First, the exemption is a mapping obligation that renews on a fixed cycle. Washington's current exemption is for four years, after which we must reapply.[6] When CLIA condition-level requirements change, Washington must amend chapter 246-338 WAC to match or exceed them, and must be able to demonstrate that match at the next reapplication. Washington rulemaking has procedural minimums under the state Administrative Procedure Act that cannot be compressed below a few months even on the expedited track. A federal package of any size, adopted with a conventional effective date, can leave a window in which Washington's rules do not yet reflect the new federal standard through no fault of the program.

Second, the direction of a change matters as much as its content. Because the exemption standard is equal to or more stringent, a relaxation of a federal requirement does not oblige Washington to relax the corresponding state rule. But, it does create a choice with consequences: if Washington retains a stricter standard that CLIA has dropped, Washington laboratories operate under a requirement their competitors in 48 states no longer face. Additive changes present a compliance obligation; deregulatory changes present a policy decision. Both take time, and the agencies' implementation timelines should account for both policy decisions.

Third, under 42 CFR 493.575, CMS may initiate an exemption review where validation inspection findings show a rate of disparity of 20 percent or more, or where findings indicate widespread or systematic problems suggesting the state's requirements are no longer equivalent taken as a whole. A rapid or broad CLIA expansion that Washington cannot match on the federal timeline creates equivalency exposure. Loss of exemption would obligate the full number of licensees to obtain direct federal certification, in addition to their state licensure obligations and oversight, which may be considered duplicative or administratively burdensome.

We ask the federal agencies to build these facts into any proposed rule. Concretely: publish implementation timelines of not less than 12 to 18 months for condition-level changes, so

[3]Ch. 70.42 RCW (Medical Test Sites). https://app.leg.wa.gov/rcw/default.aspx?cite=70.42

[4]Ch. 246-338 WAC (Medical Test Site Rules). https://app.leg.wa.gov/wac/default.aspx?cite=246-338

[5]Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1988 Exemption of Laboratories Licensed by the State of Washington, 89 Fed. Reg. 22406 (Apr. 1, 2024) https://www.federalregister.gov/documents/2024/04/01/2024-06802/medicare-medicaid-and-clia-programs-clinical-laboratory-improvement-amendments-of-1988-exemption-of

[6]42 C.F.R. § 493.557(b)(14); see also 42 C.F.R. § 493.553(c). https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-E

exempt states can complete conforming rulemaking; sequence federal effective dates against the exempt-state reapplication cycle; and publish updated survey and interpretive guidance concurrently with any final rule because exempt-state surveyors must survey against the new standard from the effective date.

Comments that Cross Sections:

The RFI contains no Tribal consultation statement and poses no question about Tribal or Indian Health Service laboratories, some of which operate within state licensure frameworks and some of which do not. We recommend that the agencies conduct Tribal consultation before proposing rules that would apply to Tribal laboratory operations. In addition, any personnel qualification standard the agencies consider should be assessed against laboratory workforce availability. Medical laboratory scientist and technician vacancies constrain small and rural laboratories now. A qualification standard that cannot be staffed does not raise quality; it removes a test from a community.

The RFI asks nothing about test report comprehensibility, patient access to results, or language access. As postanalytic interpretation becomes more algorithmically mediated, report interpretability for limited-English-proficiency patients and their providers becomes more relevant, not less.

The RFI also contains no distributional analysis or equity framing. This means that if no commenter raises subgroup validation of AI tools and differential capacity of small and rural laboratories, those considerations will not be in the record for the CMS and CDC to draw on when they draft the rules.

Impact Across Section A and B:

Across Section A and Section B there are questions as to whether the definition of a "laboratory" should be expanded to include additional facilities or currently unregulated activities: A. Breath Testing; B.2. Specimen Preparation Activities and Personnel; and B.7. Data-Only Facilities. Washington's rules already anticipate part of this problem: WAC 246-338-080(8) requires that a site receiving referred specimens hold a valid medical test site license or meet equivalent requirements as determined by CMS.[7] However, if the laboratory definition at 42 C.F.R. § 493.2 is amended so that breath testing, specimen preparation-only, or data-only facilities require certification, Washington must license them. These entities and activities are currently outside the MTS program entirely and DOH has no estimate of how many entities would be added to MTS regulation. DOH would need to identify them, build application and survey pathways, develop surveyor competency in software and data-interpretation review, and set fees.

We therefore recommend that the federal agencies publish, with any proposed rule, an estimate of how many currently unregulated entities each definitional expansion would newly capture,

[7] WAC 246-338-080(8). https://app.leg.wa.gov/wac/default.aspx?cite=246-338-080

and that scope not be expanded through definitional amendment without a distinct impact analysis. An amendment of a few words to a definition can add an unknown number of licensees to two state programs, and the RFI offers no way to estimate how many.

Impact across Section B and C:

Reviewing AI-assisted interpretation, cloud analytics, software validation, and cybersecurity controls requires skills that a traditional laboratory survey workforce does not typically hold. Cybersecurity in particular is not a laboratory science competency. If CLIA adds cybersecurity conditions, Washington must either build that capability inside the MTS program, contract for it, or coordinate it. The RFI asks laboratories which job position is responsible for cybersecurity but asks nothing about who is competent to survey it.

Section A. Breath Testing

DOH supports resolving the CLIA status of clinical breath testing in this rulemaking. If breath testing is brought under CLIA, breath-based tests deployed in clinics, schools, or field settings would require licensure and personnel qualification. If it stays outside CLIA, a growing diagnostic modality operates with no quality framework. CLIA does not consider breath samples to be valid samples requiring CLIA oversight. However, the CFR lacks a definition excluding breath samples.

Similarly, DOH does not provide a definition of "sample" under WAC 246-338-010. We do, however, provide a definition of test: *(43) "Test" means any examination or procedure conducted on a sample taken from the human body.* A simple policy interpretation could be issued stating that we will consider breath samples to fall under that category which requires an MTS license and compliance with the requirements of Chapter 246-338 WAC.

Not all breath testing should be considered the same. We recommend a tiered approach to which types of breath testing would require CLIA certification, like waived vs. moderate vs. high complexity testing systems. Breath testing is non-invasive, requires no phlebotomy, and is comparatively easy to deploy outside conventional clinical settings, which makes it promising for populations with poor access to venipuncture-based testing, for patients for whom blood draw is a barrier, and for pediatric use. Bringing breath testing inside CLIA supplies a quality floor, but a single uniform certification requirement would also erect a licensure barrier in exactly the low-resource settings where the modality has the most to offer. Categorizing breath tests by complexity, as CLIA already does for other methodologies, would give both results.

Section B. Laboratory Processes and Procedures

Each subsection within this section will likely result in obligatory rulemaking for DOH; increased training needs for staff to understand new rules and changes to how inspections are conducted; and increased numbers of complaints to be investigated. However, the possible changes would also likely result in improvements for patient care. The heavier burden will fall

on laboratories, some of which may not be able to meet additional regulatory requirements and decide to give up their MTS license.

Subsection 1. Pathology Specimen Block Retention

Washington's Table 070-1 sets a two-year retention period for histopathology and oral pathology specimen blocks,[8] matching the federal standard.[9] Extending that period would impose physical storage, climate control, and retrieval costs. Larger systems can absorb them; small pathology practices and critical access hospitals may not. If the federal agencies pursue an extension, we ask that the proposal quantify the storage burden by practice size.

Subsection 2. Specimen Preparation Activities and Personnel

This section will create new personnel standards. DOH supports this potential change because more stringent oversight of pre-analytic steps will result in mostly positive outcomes in patient care. Preparation steps are critical for specimen acceptability and will hopefully reduce the number of rejected samples due to improper specimen collection and processing.

Responses to RFI Questions in Section B, Subsection 2:

1. *What activities does the laboratory consider to be part of specimen preparation?*

   Centrifuging, aliquoting, loading, tissue processing, slide staining, culture plate inoculation, microtomy ("cutting"), routine and special staining, embedding, and cover slipping.

2. *What is the education and experience of the personnel who perform specimen preparation activities for your laboratory?*

   No specific educational qualifications or requirements. Laboratory trained staff. The laboratory director must ensure that there are documented trainings according to the laboratory's policies and procedures.

3. *What types of training does the laboratory provide for the personnel who perform specimen preparation activities?*

   Lab dependent as far as training requirements. The laboratory must have policies and procedures regarding the training.

4. *How does the laboratory ensure that personnel who perform specimen preparation activities remain competent?*

   Lab dependent as far as competency requirements. The laboratory must have policies and procedures regarding the assessment of competency of specimen preparation activities and staff.

[8] WAC 246-338-070, Table 070-1. https://app.leg.wa.gov/wac/default.aspx?cite=246-338-070

[9] 42 C.F.R. § 493.1105 https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-J/section-493.1105

Subsection 4. Establishment and Verification of Performance Specifications

Tightening performance specification requirements at 42 C.F.R. § 493.1253 for tests that are not FDA-cleared, including the next-generation sequencing applications the agencies name, could make some laboratory developed tests uneconomical to maintain.[10] In oncology in particular, minimal residual disease monitoring, somatic variant panels, and HLA matching, the affected tests often have no commercial FDA-cleared equivalent . Loss of a laboratory-developed test does not shift care to another setting; it removes the test. We ask the federal agencies to weigh that consequence explicitly.

Subsection 5. Calibration Verification

Calibration verification can be difficult with cartridge-based testing as changing to a new lot of cartridges is, in essence, a complete change of reagents. Then according to 493.1255(B)(3)(i) every lot of reagents that are changed would require a calibration verification procedure to be performed unless a study is done to show there is not a change of reportable range and no impact on quality control (QC) values.

Monitoring this in a large-scale hospital setting that may have 100+ cartridge-based readers/analyzers can be burdensome for a procedure that likely will not result in any impactful change or quality process.

Manufacturer-calibrated devices do not allow any calibration or user-based changes. They are usually standardized across devices and have limited issues or changes in reportable ranges.

Subsection 6. Postanalytic Interpretation and Use of Artificial Intelligence (AI)

If CLIA imposes software validation requirements written for high complexity molecular testing, laboratories and their counsel may apply them defensively to any software touching results, including middleware, laboratory information system rules engines, and autoverification logic that has operated for decades. The predictable response is to disable useful automation rather than validate it, which reduces both efficiency and consistency.
The federal agencies pose five questions framed around technical performance: image resolution, image quality, monitor and computer capability. None asks whether an artificial intelligence tool performs equivalently across racial, ethnic, sex, age, or disease-prevalence subgroups, or whether the datasets used to validate a tool represent the populations tested.

Diagnostic algorithms trained or validated on non-representative data can produce error rates that differ by subgroup[11], and in histopathology the clinical consequence of a subgroup-specific error is a missed or wrong cancer determination or a wrong drug-metabolism call. Verification framed only in terms of resolution and monitor performance will not detect it, because nothing in that framing requires anyone to measure it. This is the single strongest equity contribution DOH can

[10] 42 C.F.R. § 493.1253 https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-K/section-493.1253

[11] *See* Valbuena VSM, Merchant RM, Hough CL. *Racial and Ethnic Bias in Pulse Oximetry and Clinical Outcomes*. JAMA Intern Med. 2022;182(7):699–700. doi:10.1001/jamainternmed.2022.1903

make to this docket, and it is a gap in the record rather than a disagreement with a proposal. DOH recommends that any requirement to verify software or artificial intelligence performance requires validation across the demographic and clinical subgroups on which the tool will be used, with the representativeness of validation datasets documented and available for survey.

In addition, Washington regulations do not include AI or software validation provisions, so these potential changes would require building a new regulatory framework, rather than simply existing language.

Subsection 7. Data-only facilities

Data-only facilities should not require a CLIA certificate. The impact on testing or activities completed by these data-only facilities is not substantial enough that it would outweigh the burden on underfunded, understaffed, state CLIA and CLIA exempt state agencies.

The quantity of these facilities has not been enumerated, and more information should be obtained to address the impact on the teams who manage the licensing and inspecting of these locations.

Subsection 8. Remote Direct Observation Competency Assessment

DOH supports permitting remote assessment for the direct observation component of competency assessment, consistent with the November 2024 CLIAC recommendation the agencies cite.[12] Advancing technology such as video conferencing allows for remote direct observation for competency assessments, and Washington geography results in remote communities on the coastal region and throughout Eastern Washington. These areas, along with Tribal communities, face travel costs and scheduling barriers to in-person direct observation, and those barriers fall hardest on the small sites whose closure would leave the longest travel distances behind. Allowing remote direct observation will help support critical access laboratories and laboratories that serve rural communities to ensure they are able to have meaningful competency assessments. We ask that any provision includes documentation standards sufficient to preserve the integrity of the assessment.

Section C. Emergency Preparedness, Biosafety and Biosecurity, and Cybersecurity

This section will most likely require rulemaking and increased oversight by DOH inspectors.

In addition, approximately 7,500 of the roughly 8,000 licensed sites are not subject to biennial non-waived surveys, which indicates a large population of waived and small-volume sites, including rural physician office laboratories, tribal clinic labs, and local health jurisdiction sites. These sites operate with minimal compliance infrastructure, so new conditions in emergency preparedness, biosafety, and especially cybersecurity fall hardest on these sites. These are also the sites serving the most geographically isolated populations, meaning new requirements may force service reductions or closures, rather than improving compliance. A small rural laboratory reducing testing options in lieu of having to meet a new condition is a loss borne by the

[12] RFI, supra note 1, at 43588

community and the nearest alternative may be hours away. Any new requirement should be assessed for scalability by site size and complexity, and DOH should press the agencies to build tiering into whatever they propose rather than applying uniform conditions.

DOH agrees that emergency preparedness for laboratories is a genuine gap. The agencies note that the 2016 emergency preparedness final rule did not include CLIA-certified independent laboratories in its scope. In addition, a 2025 Office of Inspector General report recommended CMS consider requiring independent laboratories participating in Medicare to develop emergency preparedness plans to protect access to diagnostic testing during a public health emergency.[13] We support closing that gap. Washington's operational experience is directly responsive to the federal agencies' question about lessons learned from recent emergencies: pandemic surge testing, the 2021 heat dome, repeated wildfire smoke and power interruption events, and the specimen transport and reagent supply chain challenges of 2020 through 2022. DOH would welcome the opportunity to supply that experience in more detail. We ask that any federal framework align with existing state and local emergency management structures rather than establish a parallel one.

Cybersecurity belongs in this rulemaking. Health sector ransomware has taken laboratory information systems offline, and a laboratory that cannot report results is functionally closed regardless of its analytic capability. The public health interest here is continuity of diagnostic operations. We support the agencies' attention to it, with two conditions.

The first is tiering. Roughly 7,500 of Washington's approximately 8,000 licensed sites are not subject to biennial non-waived survey, which reflects a large population of waived and small-volume sites: rural physician office laboratories, Tribal clinic laboratories, and local health jurisdiction sites. New conditions in emergency preparedness, biosafety, and especially cybersecurity fall hardest on sites with no dedicated compliance, information technology, or emergency management staff. Applied uniformly, such conditions produce service reduction at the small and rural margin rather than improved compliance, and where a small rural laboratory stops offering a test rather than meet a new condition, the nearest alternative may be hours away. We ask that all new conditions in this section be tiered by site size, complexity, and test volume, with an explicit pathway for small and rural sites.

The second is guidance to states on how to regulate. Washington regulations contain no emergency preparedness, biosecurity, or cybersecurity provisions beyond general safety and hazardous waste language, so these potential changes would require building a new regulatory framework, rather than simply amending existing language.

Section D. Specialty Testing Areas

DOH supports the agencies' review of the CLIA specialty and subspecialty categories. As one example of a category the current federal structure does not reflect, Washington maintains a

[13] RFI, supra note 1, at 43588–89

radiobioassay and radioimmunoassay specialty tied to its radiation control statute and implementing rules.[14]

In microbiology, DOH supports adding blood culture contamination rate monitoring to the laboratory quality management system, consistent with the November 2023 CLIAC recommendation the federal agencies cite.[15] Contaminated cultures drive unnecessary antimicrobial therapy, and monitoring them advances state antimicrobial resistance objectives at modest cost. We recommend requiring monitoring and corrective action rather than a fixed numeric threshold, which would function differently across patient populations and collection settings.

Recommendations

1. Solicit and separately analyze the effects of any proposal on approved state laboratory programs, and consult Washington and New York before publishing proposed regulation text.
2. Publish, with any proposed rule, an estimate of how many currently unregulated entities each definitional expansion would newly capture.
3. Require validation across demographic and clinical subgroups, with documented dataset representativeness, in any requirement to verify software or artificial intelligence performance.
4. Tier all new emergency preparedness, biosafety, biosecurity, and cybersecurity conditions by site size, complexity, and test volume, with an explicit small and rural site pathway.
5. Pair any cybersecurity requirement with technical assistance and with survey guidance issued before the effective date.
6. Provide implementation timelines of not less than 12 to 18 months for condition-level changes, and sequence federal effective dates against the exempt-state reapplication cycle.
7. Publish updated survey and interpretive guidance concurrently with any final rule.
8. Resolve the CLIA status of breath testing through a complexity-tiered approach rather than a binary determination.
9. Add blood culture contamination rate monitoring to quality management, framed as monitoring and corrective action rather than a fixed threshold.
10. Conduct Tribal consultation before proposing rules affecting Tribal laboratory operations.
11. Use notice-and-comment rulemaking, rather than subregulatory guidance, for any change that alters a condition-level requirement or the scope of who must be certified.[16]

[14] See ch. 70.98 RCW (Nuclear Energy and Radiation) https://app.leg.wa.gov/rcw/default.aspx?cite=70.98

[15] RFI, supra note 1, at 43590

[16] RFI, supra note 1, at 43586.

H. Conclusion

DOH appreciates the agencies' willingness to build a record before drafting. We are prepared to supply operational data, survey experience, and implementation timelines from Washington's Medical Test Site program at any point in this process, and we would welcome direct engagement with CMS and CDC on the exempt-state questions this letter raises. Please contact Michael Ellsworth, DOH's Federal and Regulatory Affairs Director, at michael.ellsworth@doh.wa.gov with any questions.

Sincerely,

Shawna Fox
Assistant Secretary
Health Systems Quality Assurance
Washington State Department of Health