Maryland
DEPARTMENT OF HEALTH

Wes Moore, Governor · Aruna Miller, Lt. Governor · Meena Seshamani, M.D., Ph.D., Secretary

DATE: December 3, 2025

TO: All Licensed Medical Laboratory Providers

FROM: Paul Celli, Director of Laboratory Services
Office of Health Care Quality

RE: Revision of COMAR 10.10.01 - 10.10.08, 10.10.12

As you may know, the Maryland Department of Health's (MDH) Office of Health Care Quality (OHCQ) proposed regulatory revisions to COMAR 10.10.01 to 10.10.08 and 10.10.12 Medical Laboratories which were originally published in the May 30, 2025 Maryland Register. In response to stakeholders concerns, the comment period was re-opened and the second notice was published in the September 5, 2025 Maryland Register with comment period ending October 6, 2025. The regulations were adopted as proposed in the December 1, 2025 Maryland Register and have a delayed effective date of March 1, 2026, in order for licensed Maryland labs to have time to update their policies and procedures.

These revised regulations will protect public and individual health by requiring medical laboratories to employ qualified personnel, operate under reliable procedures, have in place effective quality control and quality assurance programs, and maintain qualified supervision. Further, the updated regulations will: (1) reflect current Maryland law; (2) delete obsolete terminology; (3) align with regulations from the Department of Health and Human Services, Clinical Laboratory Improvement Amendments (CLIA), where appropriate; (4) reflect current quality and safety standards of medical laboratories; and (5) address concerns brought forth by the industry.

To assist with understanding the revisions, OHCQ has provided a hypothetical test called "Alpha" on page 3 of this document, comparing "Alpha's" process under the old regs and the process under the revised regs. The proposed COMAR regulations streamline the procedure for small physician offices to use a CLIA-waived test. These revisions mean that the LAC is no longer needed for special approval, and the CLIA waived quality control requirements are now determined by the manufacturer. To reiterate, if a test is CLIA waived, it is now automatically an excepted test in Maryland. This applies for all CLIA waived tests. Maryland will continue to require all labs to notify OHCQ when adding tests to their license, so that OHCQ can confirm the CLIA test complexity (waived versus non-waived).

MDH is committed to modernizing the Letter of Exception process for CLIA waived tests but it is important to understand that MDH must work within existing authority, as both Letters of Exception (Health-General Article, §17-205) and the Laboratory Advisory Committee (LAC) (Health General Article, §17-217) are included in State statute. Therefore a statutory change would be required in order to remove them entirely from COMAR.

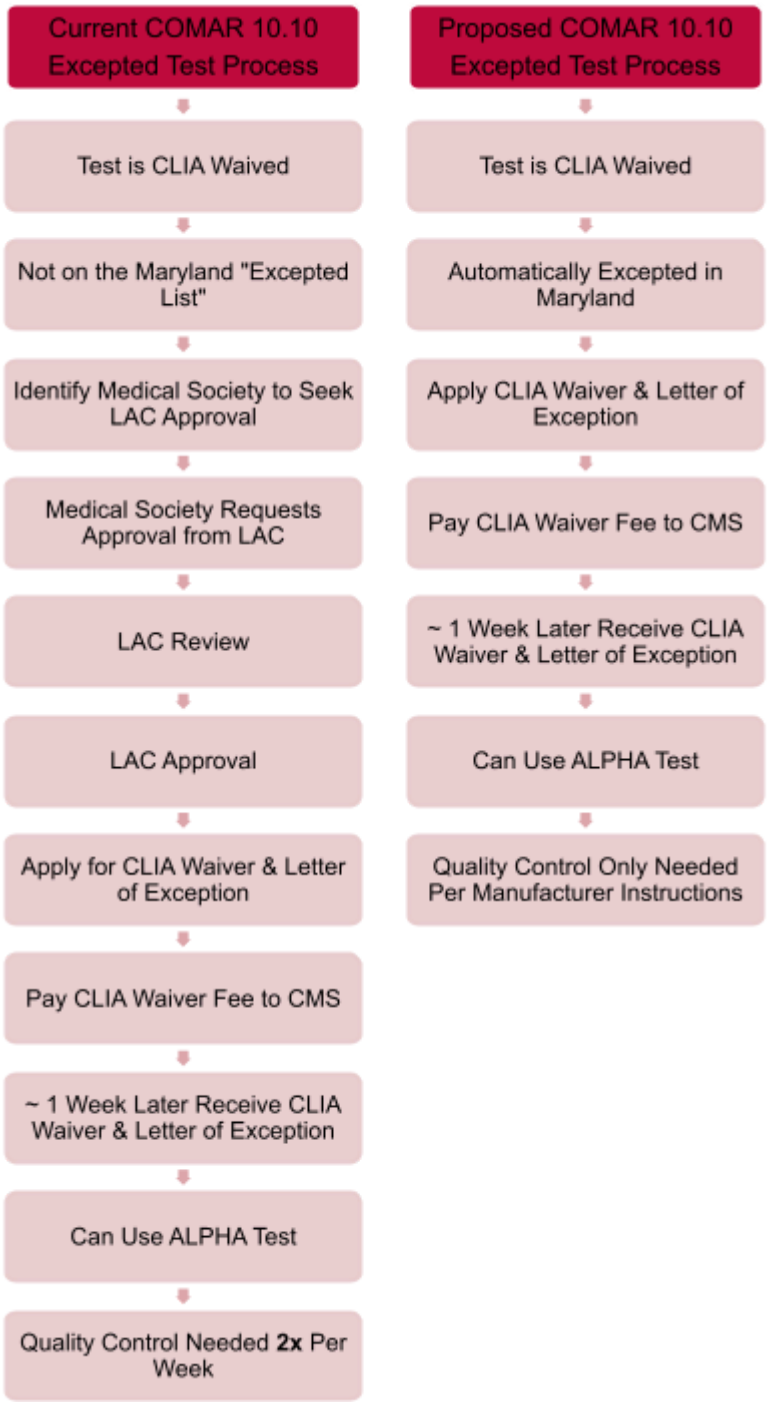
MDH believes that these revised regulations are a great step forward in improving the process. If there are technical questions regarding the revised regulations, stakeholders are encouraged to submit their questions using this link. OHCQ will respond within 30 days after review and consultation with our internal policy team.

Should you have any further questions or concerns, please contact Paul.Celli@Maryland.gov

Hypothetical Test Example: Guidance Document for OHCQ's Proposed Revisions to COMAR 10.10.01 - 10.10.08

What is ALPHA? ALPHA (hypothetical test) is a **single-use clinical laboratory test** used in physician offices. It is deemed by FDA as **CLIA-waived**, meaning the test is simple and has a low risk of an incorrect result.

- **Understanding the New Proposed Regulations (COMAR 10.10)**



- **Summary:**
  - The new, proposed regulations streamline the procedure for small physician offices to use ALPHA. There's no longer a need for Laboratory Advisory Committee (LAC) special approval, and the quality control requirements are determined by the manufacturer.
  - **If a test is CLIA waived, it is now automatically an Excepted Test in Maryland.** This applies to all CLIA waived tests. Maryland will continue to require all labs to notify OHCQ when adding tests to their license, so that OHCQ can confirm the CLIA test complexity (waived versus non-waived).

- **ALPHA under the Old Procedure <u>BEFORE</u> the Proposed Regulatory Changes**
  - Even though ALPHA is a **CLIA-waived test**, Maryland has potential **additional steps** to use ALPHA in small practices under a Letter of Exception. The non-Excepted ALPHA test would require a full laboratory permit. A full permit would require the facility to **enroll in Proficiency Testing (PT),** where a PT company would send them five unknown samples to be tested for accuracy twice a year. As a single use test, **2 levels of external quality control (QC) testing are required per week**.[1]
- **Old Procedure:**

1. **ALPHA not on the "Excepted" List**
   - Maryland has a list of tests called "Excepted Tests".
   - Only these Excepted Tests could be used without a full laboratory permit.
   - ALPHA is not on the list.

[1] Historically, Maryland required two levels of external quality control (QC) testing per week for certain tests to ensure the accuracy and reliability of clinical test results. This stringent protocol was implemented by the Maryland Laboratory Advisory Committee, citing concerns about the accuracy of qualitative tests and the potential impact on patient care. The weekly requirement for two levels of external QC was a safeguard to verify the device was performing as expected and to catch any degradation in the test system before inaccurate results could be reported to a patient.

2. **Requesting to Add ALPHA**
    - The test manufacturing company has to ask a **medical society** (like Med Chi or the American Board of Family Medicine) to request its addition to the Excepted list. The Maryland Laboratory Advisory Committee (LAC) does not accept requests directly from manufacturers.
    - The Med Chi request goes to the **LAC** to determine whether the test should be added.
    - OHCQ does not have any input on whether the test is added by the LAC as an Excepted Test.
3. **LAC Approval**
    - The LAC meets once or twice over several weeks, reviews the request, and decides whether ALPHA can be added to the "Excepted" list.
    - They agree it can.
    - The process for LAC approval can take several months.
4. **QC (Quality Control) Requirements**
    - Even though it's single-use and CLIA waived, Maryland still requires 2 levels of external QC testing per week.
5. **Licensing Process**
    - After LAC approval and COMAR update deeming ALPHA Excepted:
        - The physician's office applies for a CLIA Waiver (Federal).
        - Simultaneously, they apply for a Letter of Exception (Maryland lab license).
        - Both applications are reviewed and processed by the Office of Health Care Quality (OHCQ).
        - The lab office pays the Centers for Medicare and Medicaid Services (CMS) the fee for the CLIA waiver.
        - Both the CLIA waiver (renewal needed every two years) and Letter of Exception (non-expiring) are mailed to the OHCQ Lab office. With about one week turnaround. A full laboratory permit takes the same amount of time.
        - Once the requester receives the CLIA waiver and the Letter of Exception, the requester can perform ALPHA in the office in compliance with CMS and state of Maryland. This process takes about 3-6 months from the request to add ALPHA as an excepted test. The QC requirement is still weekly.

- **ALPHA under the New Procedure <u>AFTER</u> the Proposed Regulatory Changes**
    - Proposed regulations change the definition of "Excepted Test" so that a medical laboratory test that is a CLIA waived test, is automatically an Excepted Test.
    - The Single-Use Test requirements for QC are removed.
    - LAC is no longer needed to review tests for Excepted test status.
        - LAC remains available to advise the Secretary of Health on laboratory matters, per the Annotated Health Code.
        - Letters of Exception and the LAC are written in the Annotated Code and would require a statutory change to remove them entirely.

- **<u>What has changed under the proposed regulations (COMAR 10.10)?</u>**

1. **Automatic Approval for CLIA Waived Tests**
    - ALPHA is *now automatically "an Excepted Test"* in Maryland because it is CLIA waived.
    - No LAC involvement is needed.
    - No more waiting for LAC meetings or special requests from medical societies.
2. **No Extra QC for Single-Use Tests**
    - The old regulation requiring *extra external QC* has been *repealed.*
    - Offices now just follow the *manufacturer's QC instructions for all CLIA waived tests (that are likewise Excepted).*
3. **Licensing Process**
    - The office applies for:
        a. **CLIA Waiver** (Federal)
        b. **Letter of Exception** (Maryland lab license)
    - Applications go to *OHCQ for review and approval.*
    - The office *pays CMS* for the waiver.
    - They receive both documents in the mail (Around one week. Letter of Exception is *still free*).
    - They are now fully authorized to perform ALPHA in compliance with CMS and OHCQ requirements.

COMPARISON OF PROCEDURES		
	Current COMAR 10.10 Regulations	*Proposed* COMAR 10.10 Regulations
Is a CLIA waived test automatically "Excepted"?	**NO**	**YES**
Is LAC approved needed for Excepted Tests?	**YES**	**NO**
Quality Control Requirements	2x Per Week	Based on Manufacturer's Instructions
OHCQ Requirements for Utilization	Full Laboratory Permit	Letter of Exception
Application Process	CLIA Waiver & Letter of Exception *~ 1 Week Processing Time*	CLIA Waiver & Letter of Exception ~1 Week Processing Time
Cost	Cost of CMS CLIA Waiver	Cost of CMS CLIA Waiver