

10.10.01-10.10.08; 10.10.12 - Medical Labs

Name of Submitter and Organization	Comment(s)	OHCQ Response
Roxy Kozyckyj, AdvaMed	Do the proposed changes eliminate the Laboratory Advisory Committee (LAC) or remove their authority over CLIA-waived tests?	The LAC is built into the annotated Health General code of Maryland and will remain unchanged in purpose -- to advise the Health Secretary regarding clinical laboratories.
Roxy Kozyckyj, AdvaMed	Could a CLIA-waived test that receives federal approval with Emergency Use Authorization (EUA) also be administered in qualified Maryland labs without an emergency order being issued by the Maryland Secretary of Health?	Yes. CLIA-waived tests that receive federal approval with EUA have already been "administered" or in use in Maryland laboratories since the Pandemic in 2020 with the first EUA's issued for Covid tests.
Roxy Kozyckyj,	Comment letter is attached.	Thank you for your participation.
Lorrie C Mills, Diamond Medical Laboratories	Diamond Medical Labs in Owings Mills. Here to gather information.	Thank you for your participation.
Michael Paddy,	No comments at this time.	Thank you for your participation.
Jeanne Mumford, Johns Hopkins Hospital	No specific comments at the moment. We are here listen. I have a question what would be the impact of repealing the single use test device ? how will this language it affects us?	OHCQ cannot predict the future impact of these regulations. Our intent is to streamline and address concerns of the industry, while maintaining minimum standards for patient safety and quality through licensing.
Andrew Diamond, Diamond Medical Labs	Appears there are three things that are being added. Based on our reading it looks like the single device test requirements is a minimum of weekly QC, which was already a requirement for IQCP, and then there are a couple other things. We are here to listen as well.	Weekly controls will not apply to all labs. CLIA requires an IQCP (individual quality control plan) for non-waived labs, and for some labs, it will be weekly controls, but that does not apply to all labs.
Roxy Kozyckyj, AdvaMed	I am with Advamed, a Med Tech Association that represents over 500 medical device, diagnostic, digital health, health technology innovators around the world and across the country. We have closely looked at this issue over the years. Broadly we are in support of the changes, in particular, sections 10.10.01.03 (definitions & general) and 10.10.02.01 which is the responsibility of the department for medical labs, so broadly speaking we are in support of the changes as they align Maryland with almost all other states that already allow CLIA waived test approved by HHS to be performed without further state review. We think this is positive streamlining and will increase patient access to important critical test like COVID, better point of care for example. We support Maryland Governor Moore's overall efforts to streamline, make access more equitable for all Marylanders, will help with reducing disparities, and more importantly cut out the red tape where possible. It will make access easier, yet keep it safe for patients. Thank you.	Thank you for your participation.
Owen Voutsinas-Klose, Viohl & Associates	Just observing. No questions or comments at this point. thank you.	Thank you for your participation.
Jonathan Medeiros, Cepheid	Good afternoon. Just listening and thank you for the opportunity to participate.	Thank you for your participation.
T. Tompsett, Quest	10.10.03.01: Suggest that the state remove A(1)(b) and not require out of state licensure: Specifically, A(1)(b) Offering to perform or performing a medical laboratory test or examination on a specimen acquired from a health care provider in this State at a laboratory located outside this State; or	We will keep the requirements for out of state licensure. The process to apply for a Maryland lab license is not onerous and there is no fee. It is important that OHCQ have a mechanism to hold the out of state labs responsible with information such as contact updates, as well as ensuring directors are qualified and don't exceed the directorship maximum of five nonwaived labs. OHCQ must also ensure that their pathology technical supervisors hold a Maryland medical license for oncology diagnoses.
T. Tompsett, Quest	10.10.05.01. Participation and Evaluation: 1)Maryland should be in alignment with CLIA when describing PT Performance (Unsuccessful and Unsatisfactory). Maryland uses the term Marginal PT Performance (At the outer or lower limits; minimal for the requirements; almost insufficient.) and Unsatisfactory PT Performance (Failing PT scores in three of four consecutive testing events in a subdiscipline, specialty, or individual constituent or analyte, for example, Na, RBC, cholesterol,); CLIA uses Unsuccessful and Unsatisfactory. This would require updates to C(1)(f) of this section to read (f) Performance Records. A laboratory's marginal unsuccessful or unsatisfactory PT performance may not be changed to reflect satisfactory performance when and replace the word marginal with unsuccessful in C(4), C(4)(a), C(4)(b)(i), and C(4)(b)(ii) 2)Maryland should align the scores for satisfactory performance with CLIA. This would require a change to C(2)(b)(xiii) of this section to read: (xiii) Immunohematology, antibody identification, equal to or greater than 90 80 percent;	The state's PT monitoring system is separate from CLIA and will remain at the present time.

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T. Tompsett, Quest	Sec. 10.10.07.01. Permitted POL and POCL — Director and Associate Director: Suggest that on-site visits by the laboratory director described in B(4)(b) be updated to align with CLIA requirements 493.1707(c)(1) and 493.1445(c)(1) going into effect December 2024 which states: Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits.	The state requirement is more stringent, and is allowed to be such, per CMS. It will remain in place at the present time.
T. Tompsett, Quest	Sec. 10.10.07.04. Permitted Laboratory Other than a POL or POCL — Director: Comment: Suggest that on-site visits by the laboratory director described in B(5) be updated to align with CLIA requirements 493.1707(c)(1) and 493.1445(c)(1) going into effect December 2024 which states: Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits.	The state requirement is more stringent, and is allowed to be such, per CMS. It will remain in place at the present time.
T. Tompsett, Quest	Sec. 10.10.07.05. Permitted Laboratories — Technical Supervisors: Comment – Experience for individuals qualifying with a doctoral degree is not defined for disciplines other than genetics and forensic toxicology. Suggest that the State allow for technical supervisors with a doctoral degree to qualify with 1 year experience in the discipline. Example: [specialty] A technical supervisor shall possess a bachelor's or higher degree including significant studies in chemistry and have at least 4 years post-baccalaureate, or 2 years post-master's, or 1-year post-doctoral medical laboratory experience in clinical [specialty]. This would apply to the specialties of Chemistry, Hematology, Immunology, Microbiology, and Molecular Biology	The state qualifications may change in the future. CMS is changing requirements per the "final rule" in 2025, and that will first be monitored by the state.
T. Tompsett, Quest	Sec. 10.10.07.06. Permitted Laboratory Other than a POL or POCL — Supervisors: Comments: Suggest that the state align years of experience requirement with CLIA and allow for an individual to qualify as a general supervisor with at least a bachelor's degree and 1-year of experience or an associates degree and 2-years experience OR refer to CLIA standard 493.1461 Standard; General Supervisor qualifications. This would require an update to B(1) of this section and would help to address staffing shortages.	The state qualifications may change in the future. CMS is changing requirements per the "final rule" in 2025, and that will first be monitored by the state.
Thomas Tompsett Jr,	Comments are in blue throughout the attached document.	Reviewed.