

CLIA FINAL RULE

Personnel Regulations

ASHI Town Hall Meeting
July 10, 2024



CLIA FINAL RULE-TOWNHALL MEETING

- On December 28, 2023, new/revised CLIA regulations were signed into Final Rule.
- Changes affect ALL CLIA positions including lab Director, Technical Supervisor, Clinical Consultant, General Supervisor, and Technologists.
- Changes focus on:
 1. New degree requirements and creation of “alternative assessment pathway”.
 2. New definition for training and experience.
 3. Removal and restructuring of grandfathering clauses.
 4. Clarification of existing regulations.
- Most new/revised regulations for personnel qualifications go into effect December 28, 2024. Exceptions are for existing regulations which were clarified. Those were immediately effective as of December 28, 2023.

CHANGES AT A GLANCE

- A new definition for doctoral degree was added.
- CLIA clarified that doctoral degree **DOES NOT** include MD, DO, DPM, DVM, or honorary degrees. MD, DO, DPM must follow the designated MD, DO, and/or DPM track and **HAVE A LICENSE TO PRACTICE MEDICINE IN THE STATE WHERE THE lab IS LOCATED.**
- DVM and honorary degrees are **NO LONGER ACCEPTABLE DEGREES.**
- DCLS now qualifies as an “acceptable doctoral degree”.
- A new definition of Training and Experience was added to CLIA. lab Training or Experience means that the training or experience **MUST** be obtained in a facility that meets the definition of a lab under sub-section 493.2 and is NOT except from CLIA.
- Addition of **20 CE hours** covering lab director responsibility added for Ph.D and M.D. that are not board certified in pathology (one time activity).
- Historic grandfathering clauses have been removed and replaced by a single grandfathering clause. You are grandfathered until you have a break in service. After a break in service you must qualify under the revised CLIA regulation. Break in service = loss of grandfathering

ASHI AND CMS: THE LAST 6 MONTHS

Since CMS released the revised CLIA regulations in December 2023, ASHI has had several rounds of communication with CMS:

1. CMS meeting (webinar): January 2024. Included all accreditation agencies. CMS presented the revised regulations to all partners with a very brief Q&A session.
2. ACHI Portfolio Chair/CMS conversation: Following the partner's meeting, ACHI Portfolio Chair met with Penney Keller focusing on foreign MD and DITs.
3. Email from ACHI Portfolio Chair to CMS lab excellence portal and to CMS liaison: Questions from ASHI members, DIT, portfolio committee, and others were submitted (as instructed in the CMS partners webinar) and email to the ASHI CMS liaison.
***Most questions were left unanswered.
4. CMS meeting with ASHI: May 30, 2024. Participants included Gregg Brandush (CLIA director) and several other CMS/CLIA consultants, liaisons, technical advisors, and attorneys. Attendee for ASHI were: ASHI President, President Elect, CEO, ACHI Portfolio Committee Dean, ASHI Accreditation Manager, Representative from Wheat and Shroyer Government Relations, and ASHI's Lawyer.
5. Following ASHI's meeting with CMS, written follow up questions were submitted to CMS. CMS responded to the questions in mid June 2024-some vaguely or asking for clarification. ASHI will submit answers and additional follow up questions.

WORK IN PROGRESS

1. We have completed the CMS crosswalk document (85 pages document). This is now at the revision stage.
2. New ASHI standards have been written and are being reviewed by key members of the BOD, QAS, and ARB.
3. The ASHI Educational committee/ASHI U committee have developed a curriculum for the 20 CE hours covering lab directors' responsibilities.
4. Next step is to revise ACHI and ACHI Portfolio Committee operations manuals.
5. As operations manuals are being revised, the ACHI examination handbook will also need to undergo revision.

**THANKS TO ALL ASHI VOLUNTEERS AND
STAFF MEMBERS!!!**

OUTSTANDING QUESTIONS

1. Can pre-doctoral training/experience in HLA be counted for up to 2 yrs of HLA training/experience as lab director and technical supervisor? **CMS has answered this question with a question to ASHI. We will reply to CMS and hopefully get a full answer on this question.
2. How to properly assess degrees on the alternative pathway? ***CMS will release a guidance document. They are not answering questions about doctoral degree/transcripts until this document comes out.
3. Is there a list of Ph.D. degree fields of study that meets the traditional pathway? **We already know from the introduction to the new regulation some of the acceptable fields of study (genetics, molecular biology...) but the list is minimal and for many degrees we do not know if the field of study qualifies under the traditional pathway or must be evaluated under the alternative pathway. We expect this information to be released in the forthcoming CMS guidance document.
4. Can HLA director training/experience in an international ASHI-accredited lab be used toward the 4 yrs of training/experience to qualify as a US lab director? **CMS has answered this question vaguely and clarification is needed. ASHI is seeking clarification.

ANSWERS TO COMMONLY ASKED QUESTIONS

1. Can foreign MDs serve as lab Director/Technical Supervisor and/or Clinical Consultant in the US without a medical license? **No**
2. Are current foreign MDs with no US license grandfathered? **ASHI only has 1 CLIA lab Director that is a foreign MD with no US license. This is the ONLY individual that will be grandfathered until a break of service. No other foreign MD, even if ASHI accredited as lab Director can practice in the US without a US medical license and appropriate training.**
3. Are DIT with foreign MD but no US license grandfathered? **No. They will be accredited to direct international lab ONLY until they either have a US license or meet other CLIA personnel qualification requirements.**
4. Can my yrs of pre-doctoral experience as an HLA supervisor be counted toward 4 yrs of training/experience for lab director's qualifications? **We do not have an answer from CMS to this yet. However, we know that it will not count for more than 2 of the 4 yrs and likely less.**
5. Does my Ph.D degree in Health Science, Pharmacology, Medical Science, Parasitology qualify under the traditional pathway? **Many of those fields of study do not directly qualify and must be evaluated under the alternative pathway. Further information is expected in the CMS guidance document.**

ANSWERS TO COMMONLY ASKED QUESTIONS (CONTINUED)

6. I am an AP/CP board certify pathologist. Can I count my AP/CP residency time as part of the 4 yrs of experience for technical supervisor? **In most cases No. However, some exceptions exist eg. if you are a CP only pathologist who used their elective CP time to perform HLA training. Some CP only residents perform up to 1 year of HLA training as part of their residency if they choose to do HLA in all of their elective rotations. Only work directly in the subspecialty of HLA or clinical immunology can be counted and must be well documented.**
7. I worked in research doing HLA work for the last 5 yrs can some of that time be counted? **No. CLIA regulation is clear that the work must be clinical. Time in research positions is not counted toward clinical time.**
8. I hired a DIT last year on a 2 yrs training plan, are they now required to do 4 years? **Yes, for US labs. Unless DIT is employed in a CLIA position prior to Dec. 28/2024, they must qualify using the new CLIA requirements. NO EXCEPTION for US labs.**
9. I submitted my US degree equivalency that shows a US Ph.D equivalent. Why does ASHI need additional information to register me as a DIT? **To evaluate whether you meet the CLIA requirement we need more information than just the fact that you have a US Ph.D equivalent degree. The field of study for your degree and the course-by-course evaluation (with credit hours) for your graduate level courses must be provided to ASHI directly from a NACES accredited agency.**

ANSWERS TO COMMONLY ASKED QUESTIONS (CONTINUED)

10. I did my Ph.D abroad and my US equivalency shows I have a Ph.D but my university's transcript where I studied does not include a subject or course content so that information cannot be provided for educational assessment. Can you make an exception? **No. Unfortunately, if your university cannot provide this information for educational assessment, there is nothing ASHI, or any other accreditation agency, can do. We cannot assess whether your degree meets CLIA requirements, even if you graduated from a top university.**
11. I have a degree in Biotechnology will this work? **CMS has clearly indicated that biotechnology is not an acceptable degree under the traditional path. Your degree will need to be evaluated under the alternative pathway and many biotechnology degrees will not meet the requirement.**
12. When will new ASHI standards for personnel be presented for public comment? **They will not undergo a public comment period due to time constraint. The standards are drafted and are being revised for submission to CMS shortly.**

ANSWERS TO COMMONLY ASKED QUESTIONS (CONTINUED)

13. I don't see in CLIA that the lab director/technical supervisor training is increasing from 2 to 4 yrs why do I now have to do 4 years? **It was always 4 yrs however now CLIA has redefined what "training and experience" means as such ASHI can not use 2 yrs of post-doctoral work or pathology residency to offset 2 of the 4 years.**
14. I am registering as a DIT today and the CLIA changes go into effect only in December 2024, why do I need to do 4 yrs and not 2 if I register before December 2024? **You must do 4 yrs because the law is not about DIT registration, it is about what training you must have when you are hired as lab director. Anyone who is not in a position prior to the new regulations going into effects will need 4 yrs to be hired as a LD/TS in the US.**

QUESTIONS ???

