DIAGNOSTIC
LABORATORY
SERVICES,INC.

Diagnostic Laboratory Services, Inc. (DLS) is pleased to provide a response to the September 27, 2018 Federal Register notice seeking public input to the Clinical Laboratory Improvement Advisory Committee (CLIAC) regarding proposed revisions to Clinical Laboratory Improvement Amendments (CLIA) standards. DLS has over 700 employees in Hawaii, Guam, and the U.S. Affiliated Pacific Islands, and is a major employer of laboratorians in the Pacific. Some of the most important proposed changes deal with Personnel Requirements. Current language requires degrees in chemical, physical, biological or clinical laboratory science and/or medical laboratory technology degree as the educational requirement for moderate and high complexity testing personnel. Modifications under review consider applicability of nursing degrees, physical science degrees, and non-traditional degrees. Laboratory science talent is scarce at all levels in the Pacific making recruitment and retention difficult, so DLS supports changes that offer employers more flexibility to develop the workforce that we have.

1. Nursing degrees: Is a bachelor's degree in nursing equivalent to a bachelor's degree in biological sciences or it should be considered a separate qualifying degree to meet the CLIA requirements for moderate and high complexity testing personnel and technical consultants?

Response: Nursing degrees should be considered non-traditional degrees (discussed below) for the purposes of qualifying to meet CLIA requirements.

Rationale: Degree category/title alone is not an adequate credential, and must be taken into consideration with other qualifications. Most laboratorians will argue a degree in nursing is inferior to one biological sciences for the purposes of CLIA qualification, and in many cases this is true. However the opposite is true when the biological science degree is in subject such as forestry, marine biology, botany, ecology, zoology, etc.

2. Physical Science Degrees: What is considered a physical science degree and do physical science degrees provide the educational background needed such that all or some should be considered a qualifying degree to meet the intent of CLIA?

Response: Physical science degrees should be considered non-traditional degrees (discussed below) for the purposes of qualifying to meet CLIA requirements.

Rationale: Degree category/title alone is not an adequate credential, and must be taken into consideration with other qualifications. By definition, physical sciences is the study of non-living things. Like biological sciences and nursing, it includes degrees that do not relate well to medical laboratory science (astronomy, geology, soil science, theoretical physics, etc.).

3. Personnel Competencies: Should general supervisors be allowed to perform competency assessments for testing personnel performing moderate complexity testing in laboratories that perform both moderate and high complexity testing?

Response: Yes.

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Rationale: This corrects an oversight in the current CLIA regulation, which allows general supervisors with associate's degrees to perform competency assessment on high complexity testing personal; however, general supervisors cannot perform competency assessments on moderate complexity testing personnel unless they can meet the regulatory qualifications of a technical consultant.

4. Personnel Experience, Training and Skills: What comprises appropriate documentation to verify the training, experience and skills for personnel positions?

Response: For the purposes of the regulation, it will probably be specified timeframe during which training occurs (e.g., internship, CEUs), experience is gained (e.g., on-the-job), and skills are demonstrated (competency assessments, presentations, publications). This gains considerable importance if/when appropriate training, experience and skills provide a pathway for personnel with non-traditional degrees to qualify for CLIA regulated positions.

Rationale: Timeframe is the most manageable from a regulatory standpoint; however, it is unlikely there is a tidy answer to the timeframe length. Perhaps this could be a task for CLIAC. Ultimately there will need to be good judgement on the part of experienced employers and auditors as to what qualifies.

5. Non-Traditional Degrees: Should non-traditional type degrees (e.g., Regents Bachelor of Arts, MBA, Ph.D in Public Administration, Nursing, Physical Science) combined with training, experience, and skills be considered to meet the requirements for a CLIA personnel qualifying degree?

Response: Yes.

Rationale: Post-secondary education has changed significantly since CLIA 88. Students can earn community college credit during high school. People need to work just to afford college. Graduate degrees in science don't necessarily prepare laboratorians to be managers, directors, and administrators. While it is important to be able to audit credentials during a compliance inspection, it's equally (more) important for employers to attract talent that may not meet a 20th century mold. Although the original intent of this proposal probably had a narrower scope of considering distance learning and adult education programs, insightful application of this concept to degree programs that may not necessarily be synonymous with lab science could open up appropriate talent pools that are not available currently because of the language in the regulation.

Sincerely,

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