



National Society for Histotechnology
3545 Ellicott Mills Drive, PMB 204
Ellicott City, MD 20143
P: 443-535-4060 ♦ F: 443-535-4055
E: histo@nsh.org
www.nsh.org

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Heather Stang MS, MLS (AMT)
Executive Secretary
Clinical Laboratory Improvement Advisory Committee
Centers for Disease Control and Prevention

RE: Oral Comments for November 8-9, 2023 Fall Clinical Laboratory Improvement Advisory Committee Meeting, CLIA Regulations Assessment Workgroup

Hello, my name is Dr. Luis Chiriboga, PhD, HT(ASCP), QIHC. I have worked in a CLIA certified histology laboratory for over 10 years and am currently the Director of an Accredited Biorepository-Histology Laboratory. I am here to comment on the CLIA Regulations Assessment Workgroup interim report on behalf of the National Society for Histotechnology (NSH). Additionally, NSH provided written comments to the CMS RFI ¹ *"Histopathology, Cytology and Clinical Cytogenetics Regulations Under the Clinical Laboratory Improvement Amendments (CLIA) of 1988"* referenced in the report.

NSH was extremely pleased to see the working group's assessment. NSH strongly agrees with the workgroups appraisal and commends the group on their effort to bring anatomic pathology in line with other medical laboratory disciplines. We agree that any recommendations should not place undue burden on an already compromised workforce. However, NSH strongly believes that standards should not be lowered solely because of the workforce shortage. NSH recommends a phased approach to regulation implementation that will create a pipeline with appropriate educational requirements, relevant training and experience in order to build a strong anatomic pathology laboratory workforce. Histology personnel must be trained to be competent for the laboratory work they perform now and in the future. This is even more important as new and emerging technology, which does not fall into current workflow models, begins to enter laboratory operational space. We support the ASCP certification structure and educational requirements as a mechanism for laboratory professionals to demonstrate competency and proficiency. We strongly support the expansion of accredited educational programs to promote all the laboratory sciences. Moreover, we should seek to leverage the current non-traditional student pool (those with previous science degrees that meet CLIA criteria) by cultivating career pathways into the professional laboratory sciences. To make these pathways more attractive, personnel requirements should graduate as roles and responsibilities increase.

NSH would like to thank CLIA for providing the opportunity to comment on this important issue. We look forward to CLIA's recommendations and welcome continued collaborative discussion in order to advance the histotechnology and anatomic pathology professions in order to provide the highest quality care to the patients we serve. We thank the committee for the prior work, ongoing efforts, and consideration.

¹File Code CMS-1784-P Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program



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Respectfully

Luis Chiriboga

Luis Chiriboga PhD, HT (ASCP) QIHC

CC:

Jerry Santiago, PhD, HTL (ASCP) QIHC

NSH president

Clare Thornton, BS HTL (ASCP) QIHC