CLIAC Meeting Public Comment Registration Form

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Issue Blood Lead PT limits

PUBLIC COMMENT FORM

Patrick Parsons

- Why is NYS so interested in Blood Lead PT limits
  - Childhood Lead Poisoning remains a major public health problem in NYS. From 2002-2003, >4000 children in NYS has elevated BLLs.
  - NYS DOH has operated a Blood lead PT program for >30 years. Currently, ~100 laboratories participate in this CMS-approved program from across the US and from >10 countries.
  - At the current NYS public health action level of 10 µg/dL the total allowable error under CLIA 88 is ±40%. At a BLL of 5 µg/dL (current 95% tile), the total allowable error is ±80%. This performance standard is no longer protective of children's health.
  - NYS DOH also participates in an international network of EQAS organizers providing PT for blood lead. This network has proposed tighter limits for blood lead PT, that have been implemented in some EC countries.

- Impact of changing PT limits for blood lead
  - We were asked by the CDC to evaluate different grading criteria on current laboratory performance for blood lead.
  - With our colleagues in WSLH, we examined previous PT performance data and have concluded that most blood lead laboratories could easily meet ±2, ±10%. Some lab techniques (ASV) would probably have to be replaced with AAS or ICP-MS. Since bench top ASV is no longer manufactured, this transition will occur anyway.
  - Waived testing devices (LeadCare), while not subject to PT under CLIA, may be required by some states to participate in PT for Medicaid reimbursement.
  - A consensus exists among PT program providers that ±2 or ± 10% (whichever is greater) is feasible with approximately 10% of current labs needing to improve or change methods.