

ACLA Principles for Oversight of Laboratory Developed Tests Revised August 2008

1. Stakeholder/ Agency Interaction:

CMS and FDA should continue consultation with relevant stakeholders, including clinical laboratories, patients, physicians, and other agencies such as FTC and AHRQ, before proceeding with new regulatory approaches relevant to laboratory testing, to ensure that such approaches are consistent with identified goals, represent the least burdensome regulatory means to achieve those goals, and have been selected after thorough consideration of alternative proposals.

2. CLIA Regulations

a. CMS should conduct routine monitoring of compliance with CLIA regulations and enforce them. ACLA supports the hiring, if necessary, of additional personnel to carry out compliance and enforcement activities relevant to the current regulations.

b. ACLA supports clarifying CLIA as follows:

i. That CMS' authority is applicable to all testing providing "information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings" including laboratory-developed tests and tests offered directly to consumers.

ii. That the laboratory medical director is responsible for ensuring that tests offered by the laboratory are clinically relevant and based on sound science.

3. Direct to consumer tests:

a. The Centers for Medicare and Medicaid Service should:

i. Identify laboratories that are performing any direct to consumer tests for purposes of examining material derived from the human body to provide information for the diagnosis, monitoring, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings.

ii. Take appropriate enforcement action against those laboratories that are not CLIA certified to perform the tests being performed.

- iii. In the course of performing the required inspection under CLIA, determine whether all direct to consumer tests offered by these laboratories for the purposes described in Section 3(a)(i) above are capable of providing the quality of results required for patient care and are clinically relevant and based on sound science and take appropriate regulatory action consistent with CLIA.

b. The Federal Trade Commission and comparable State agencies should investigate complaints of false or misleading claims made with respect to genetic tests marketed directly to consumers and enforce existing consumer fraud laws as appropriate.

4. Registry of IVDMA and Direct to Consumer Genetic Tests

- a. The Agency for Healthcare Research and Quality (AHRQ) or the National Library of Medicine (NLM), after consultation with relevant stakeholders, including clinical laboratories, patients, and physicians, should itself or through a public-private entity, establish and maintain a mandatory registry to enhance public transparency of genetic testing services. Examples of services where there has been an expression of enhanced public transparency include IVDMA and Direct to Consumer genetic tests. Elements of the registry could include basic information about the tests, published in the Federal Register and on the AHRQ, NLM or public-private web site accessible by the public, and updated regularly. The registry would exclude FDA-cleared/approved tests.

b. Information for the Laboratory to Report to Registry

- i. Interactive workshop process will define the tests subject to the Registry and the appropriate content and format for the Registry within six months. Laboratories will have an additional 12 months to submit information to the Registry.
- ii. Laboratory performing the test is responsible for submitting the information using the agreed to standard reporting format including the following information:
 - a. Summary of data supporting;
 - 1. Indications for testing
 - 2. Analytical performance
 - 3. Clinical Validity
- iii. Updated summary to be submitted if the intended use undergoes significant revision that materially affects clinical performance

e. Additional Features of Registry

- i. Should be pilot tested (like PGx dossier submissions)
 - a. To assess feasibility of operation
 - b. To evaluate usefulness of information collected
 - c. To assess burden to laboratories to submit and to update
 - d. To assess burden on the entity maintaining the registry to collect information and maintain database