

Attachment 1:
Proposed Change to Advertisement for OMB #0920-0961

Date: May 20, 2013

Change: CDC seeks to make a non-material change to OMB # 0920-0961 (Proficiency Testing in US Clinical Laboratories: Perception, Practices and Potential for Expanded Utility) but only to the survey advertisements that will appear in trade magazines; no change is proposed for the survey itself. The change will not affect any of the topics listed in the supporting statements in the original OMB submission. Therefore, there is no need to modify the supporting statements that have already been approved by OMB. Specifically, CDC seeks to add the sentence “Laboratory Directors or other persons directly responsible for the oversight of proficiency testing are invited to take the survey,” which is highlighted in yellow in the accompanying example.

Justification for the change: In order to acquire data that will be useful to HHS, the survey should be answered only by individuals who are responsible for proficiency testing in laboratories that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) with a Certificate of Compliance or Certificate of Accreditation. Although we have a mechanism to assure that surveys will only be allowed from these CLIA laboratories, we do not have a way to assure who completes the survey. To maximize the likelihood that we will only receive responses from laboratory directors or managers who are qualified to answer the questions, we have a two-stage plan to recruit respondents.

Initially, letters will be sent by our collaborator, the Association of Public Health Laboratory Directors (APHL), to CLIA laboratory directors, inviting them or someone else in the organization who is responsible for proficiency testing to take the survey. APHL will follow up with a reminder postcard, and then after sufficient time for a response, APHL will send conduct additional advertisement thorough trade magazines that target laboratory professionals who work in these CLIA laboratories. This second approach is intended to recruit laboratories that, for whatever reason, may not have been reached by the initial letters and follow-up postcard. We inadvertently omitted the new phrase (above) from the advertisement. Without it, there is a risk that individuals who are not qualified to answer the questions will take the survey. Although the two-stage plan will decrease the risk of inappropriate survey responses, addition of the new sentence will further reduce the risk. This non-material change will not result in any more individuals taking the survey.