Image-Assisted Cytology Workload Assessment and Measure

Request for Approval of New Data Collection

Supporting Statement B

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1. Respondent Universe of Information

All cytology laboratories will receive an advance request to participate in the survey from a CDC contractor that has been selected to collect the survey data and conduct the time measure study. Respondents will be from the 1,245 cytology laboratories in the United States. Since a response to this survey is voluntary we are inviting all laboratories to participate. We expect an 80% response rate or approximately 996 laboratories. Responses would be submitted in written format. In addition, individual cytotechnologists working in the laboratory will be asked to fill out a portion of the survey. There are 6,064 cytotechnologists in the United States. Response to this survey is voluntary, so we would expect an 80% response rate or approximately 4,581 cytotechnologists. Responses would be submitted in written format.

2. Procedures for Collection of Information

The survey will be distributed and the information collected by a contractor that has on-site access to cytology laboratories, as a CMS approved accrediting agency, CMS approved proficiency testing program, or has a formal arrangement with CMS to conduct on-site laboratory inspections or surveys. A notice that the survey questionnaire is being conducted to collect laboratory and individual workload information will be mailed (via paper) to all cytology laboratories listed in the CLIA database as having a certificate in cytology. Additional reminder postcards may also be mailed.

A pilot test will be conducted at nine sites. We do not anticipate many changes to be needed to our collection form since we consulted with a panel of experts that are peers of the population from which we expect to collect the information.

3. Methods to Maximize Response Rates and Deal with No Response

Non-responders will be contacted by the contractor to try and get them to complete the survey. The contractor will be an organization that has on-site access to cytology laboratories, as a CMS approved accrediting agency, CMS approved proficiency testing program, or has a formal arrangement with CMS to conduct on-site laboratory inspections or surveys. This status allows them to ask the laboratories to provide this type of information.

4. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

We consulted with Marina Kondratovich at the Food and Drug Administration.

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