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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-13-13OE]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639-7570 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Image-Assisted Cytology Workload Assessment and Measure – New – Office of Surveillance, Epidemiology, and Laboratory Services (OSELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC provides technical guidance to the Department of Health and Human Services (HHS) in coordination with the Centers for

Medicare & Medicaid Services (CMS) and the Food and Drug Administration (FDA) for the implementation of the Clinical Laboratory Improvement Amendments (CLIA). The Clinical Laboratory Improvement Amendments of 1988 (CLIA) directed the Secretary of Health and Human Services to establish the maximum number of cytology slides that any individual may screen in a 24 hour period; to establish certain quality assurance standards; to set personnel standards; and to provide for periodic proficiency testing of cytotechnologists and pathologists involved in screening and interpreting cytological preparations.

The regulations implementing CLIA, published in the *Federal Register* of February 28, 1992, established that the maximum number of slides examined by an individual in each 24 hour period was not to exceed 100 slides and could not be examined in less than an eight hour day. The regulation further established that the technical supervisor is required to evaluate the performance of cytotechnologists at least every six months and determine their individual maximum daily workload limit.
In 1992, when the regulation was published, all Pap slides were conventional "Pap smears." In a conventional Pap smear, samples are smeared directly onto a glass microscope slide after collection. The cells are often obscured by blood or the smear may be too thick and contain contaminating artifacts. Today,

almost all Pap tests in the U.S. are collected with a liquid-based method. Instead of "smearing" cervical cells directly onto a glass microscope slide, the cells are sent to the laboratory in a liquid preservative and processed by an automated processor. This processor disperses a uniform thickness representative sample on the slide that is free of obscuring blood, mucus, and non-diagnostic debris in a circle that covers less than one half of the slide.

CLIA's Federal Advisory Committee, the Clinical Laboratory Improvement Advisory Committee (CLIAC), has discussed cytology workload on numerous occasions from 1996 until present. On August 29, 2011 the American Society of Cytopathology's (ASC) Executive Board approved an ASC task force recommendation that the average laboratory cytotechnologist productivity should not exceed 70 slides and that an individual's screening time should not exceed seven (7) hours in a 24 hour period.

Each laboratory will receive an advance request to participate in the Image-Assisted Cytology Workload Practices Survey from a DLSS contractor that has been selected to collect the survey data and conduct the time measure study. Respondents will be cytology supervisors from the 1,245 cytology laboratories in the Unites States. Since a response to this survey is voluntary we would expect an 80% response rate or approximately 996

laboratories. Responses would be submitted in written format. The estimated burden per response is one half hour. In addition, individual cytotechnologists working in the laboratory will be asked to complete the Image-Assisted Cytology Workload Assessment 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. The estimated burden per response is one half hour. CDC requests OMB approval to collect information for one year.

There are no costs to respondents other than their time. The total estimated annual burden hours are 2,789.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)
Cytology Supervisor	Image-Assisted Cytology Workload Practices	996	1	30/60
Cytotechnologists	Image-Assisted Cytology Workload Assessment	4,581	1	30/60

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