

confidentiality requirements. In particular, under § 3.404, a person who discloses identifiable PSWP in knowing or reckless violation of the Patient Safety Act and 42 CFR part 3 shall be subject to a civil money penalty (CMP) of not more than \$10,000 for each act constituting a violation.

Congress enacted the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note, as amended by the Debt Collection Improvement Act of 1996 (31 U.S.C. 3701)) (Inflation Adjustment Act), based on its findings that the impact of CMPs had been reduced by inflation and that reducing the impact of CMPs had weakened their deterrent effect. Inflation Adjustment Act section 2, 28 U.S.C. 2461 note. In general, the Inflation Adjustment Act requires Federal agencies to issue regulations to adjust for inflation each CMP provided by law within their jurisdiction. The Inflation Adjustment Act applies to civil penalties found within the Public Health Service Act, such as the Patient Safety Act's CMP provision. The Inflation Adjustment Act directs agencies to issue regulations to adjust CMPs under their authority by October 23, 1996, and to make additional adjustments at least once every four years thereafter based on a specific calculation set forth in the Act. While the Inflation Adjustment Act CMP adjustment requirements apply to most federal statutes, they do not apply to CMPs included in the Social Security Act. The CMPs for title II, subtitle F (Administrative Simplification) of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) are found at section 1176 of the Social Security Act. Thus, the Inflation Adjustment Act does not require, or provide authority for, the Department to adjust the HIPAA administrative simplification CMPs.

Because the Patient Safety Act was enacted after October 23, 1996, we interpret the Inflation Adjustment Act as requiring the Department to determine whether an adjustment for inflation is necessary for the Patient Safety Act's CMP amount at least once every four years, beginning from the Patient Safety Act's date of enactment, which was July 29, 2005. Accordingly, on August 25, 2009, we published a direct final rule to amend the Patient Safety and Quality Improvement Rule by adjusting for inflation the maximum CMP amount for violations of the confidentiality provisions of the Rule. (74 FR 42777 (Aug. 25, 2009).) We chose to use direct final rulemaking because we did not expect to receive any adverse comment on the rule. The Department did not receive any adverse comments,

and the direct final rule became effective and the Patient Safety and Quality Improvement Rule was amended on November 23, 2009. The amendment increased the maximum CMP amount from \$10,000 to \$11,000.

II. No Adjustment is Necessary

In accordance with the Inflation Adjustment Act, the Office for Civil Rights (OCR) has determined that an adjustment to the maximum CMP amount for violations of the confidentiality provisions of the Patient Safety and Quality Improvement Rule is not required at this time.

The Inflation Adjustment Act provides for the adjustment of a penalty amount through a three-step process.¹ First, we calculate an increase in the penalty amount by a "cost-of-living adjustment." Inflation Adjustment Act section 5(a), 28 U.S.C. 2461 note. The Inflation Adjustment Act defines the cost-of-living adjustment as "the percentage (if any) for each civil monetary penalty by which—(1) the Consumer Price Index for the month of June of the calendar year preceding the adjustment, exceeds (2) the Consumer Price Index for the month of June of the calendar year in which the amount of such civil monetary penalty was last set or adjusted pursuant to law." Inflation Adjustment Act section 5(b), 28 U.S.C. 2461 note. Second, we round the adjustment amount pursuant to the methodology set forth in section 5(a) of the Inflation Adjustment Act, which rounds the increase based on the size of the underlying penalty, as follows:

Any increase determined under this subsection shall be rounded to the nearest—

- (1) multiple of \$10 in the case of penalties less than or equal to \$100;
- (2) multiple of \$100 in the case of penalties greater than \$100 but less than or equal to \$1,000;
- (3) multiple of \$1,000 in the case of penalties greater than \$1,000 but less than or equal to \$10,000;
- (4) multiple of \$5,000 in the case of penalties greater than \$10,000 but less than or equal to \$100,000;
- (5) multiple of \$10,000 in the case of penalties greater than \$100,000 but less than or equal to \$200,000; and
- (6) multiple of \$25,000 in the case of penalties greater than \$200,000.

¹ Pursuant to the Debt Collection Improvement Act's amendment to the Federal Civil Penalties Inflation Adjustment Act of 1990, the third-step in adjusting a penalty amount requires that the first adjustment of the penalty be limited to ten percent of the penalty amount. This step is not applicable here because the first adjustment to the CMP with respect to the Patient Safety Act occurred on September 24, 2009.

With respect to step 1 of the adjustment, the Consumer Price Index (CPI) for June of 2012 (the calendar year preceding publication of this Notice) was 229.478. The CPI for June of 2009 (the calendar year the CMP was last adjusted for inflation) was 215.693. The percent change in these CPIs is an increase of 6.39 percent. This leads to an unrounded increase in the Patient Safety Act's CMP of \$702.90.

With respect to step 2 of the adjustment, we rounded the amount of the increase (\$702.90) to the nearest multiple of \$5,000 because the current maximum CMP is \$11,000, which places it in tier (4) above (i.e., penalties greater than \$10,000 but less than or equal to \$100,000). The nearest multiple of \$5,000 for the \$702.90 increase is zero.

Thus, based on the above, we are not amending 42 CFR 3.404(b) at this time, and the current maximum CMP remains at \$11,000. As required by the Inflation Adjustment Act, we will consider whether an adjustment is needed again in four years.

Dated: September 3, 2013.

Leon Rodriguez,
Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30-Day-13-130E]

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 United 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 4,811 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	Number of respondents	Number of responses per respondent	Average 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

Leroy Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day-13-0199]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and

instruments, call 404-639-7570 and send comments to LeRoy Richardson, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should