

#### D. Subpart K—Quality System for Nonwaived Testing

The A2LA requirements are equal to the CLIA requirements at §§ 493.1200 through 493.1299.

#### E. Subpart M—Personnel for Nonwaived Testing

We have determined that the A2LA's requirements are equal to the CLIA requirements at §§ 493.1403 through 493.1495 for laboratories that perform moderate and high complexity testing.

#### F. Subpart Q—Inspections

We have determined that the A2LA requirements for the submitted subspecialties and specialties are equal to or more stringent than the CLIA requirements at §§ 493.1771 through 493.1780. The A2LA requires annual review of all accredited laboratories. The laboratory is required to submit any updates on information about its organization, facilities, key personnel and results of any proficiency testing. Laboratories may be required to undergo an onsite surveillance visit if they do not submit their annual review documentation to the A2LA by the established 30 day deadline, if significant changes to the facility or organization have occurred, or if proficiency testing results have been consistently poor. The CLIA regulations do not have this requirement.

#### G. Subpart R—Enforcement Procedures

The A2LA meets the requirements of subpart R to the extent that it applies to accreditation organizations. The A2LA policy sets forth the actions the organization takes when laboratories it accredits do not comply with its requirements and standards for accreditation. When appropriate, the A2LA will deny, suspend, or revoke accreditation in a laboratory accredited by the A2LA and report that action to us within 30 days. The A2LA also provides an appeals process for laboratories that have had accreditation denied, suspended, or revoked.

We have determined that the A2LA's laboratory enforcement and appeal policies are equal to the requirements of part 493, subpart R as they apply to accreditation organizations.

#### IV. Federal Validation Inspections and Continuing Oversight

The Federal validation inspections of laboratories accredited by the A2LA may be conducted on a representative sample basis or in response to substantial allegations of

noncompliance (that is, complaint inspections). The outcome of those validation inspections, performed by CMS or our agents, or the State survey agencies, will be our principal means for verifying that the laboratories accredited by the A2LA remain in compliance with CLIA requirements. This Federal monitoring is an ongoing process.

#### V. Removal of Approval as an Accrediting Organization

Our regulations provide that we may rescind the approval of an accreditation organization, such as that of the A2LA, for cause, before the end of the effective date of approval. If we determine that the A2LA has failed to adopt, maintain and enforce requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its monitoring, inspection or enforcement processes, we may impose a probationary period, not to exceed 1 year, in which the A2LA would be allowed to address any identified issues. Should the A2LA be unable to address the identified issues within that timeframe, we may, in accordance with the applicable regulations, revoke A2LA's deeming authority under CLIA.

Should circumstances result in our withdrawal of the A2LA's approval, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

#### VI. Collection of Information Requirements

This notice does not impose any information collection and record keeping requirements subject to the Paperwork Reduction Act (PRA). Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the PRA. The requirements associated with the accreditation process for clinical laboratories under the CLIA program, codified in 42 CFR part 493 subpart E, are currently approved by OMB under OMB approval number 0938-0686.

#### VII. Executive Order 12866 Statement

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

Dated: March 8, 2018.

**Seema Verma,**

*Administrator, Centers for Medicare & Medicaid Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Proposed Information Collection Activity; Comment Request

##### *Proposed Projects:*

*Title:* Initial Medical Exam Form and Initial Dental Exam Form.

*OMB No.:* 0970-0466.

##### *Description:*

The Administration for Children and Families' Office of Refugee Resettlement (ORR) places unaccompanied minors in their custody in licensed care provider facilities until reunification with a qualified sponsor. Care provider facilities are required to provide children with services such as classroom education, mental health services, and health care. Pursuant to Exhibit 1, part A.2 of the *Flores Settlement Agreement* (Jenny Lisette Flores, *et al.*, v. Janet Reno, Attorney General of the United States, *et al.*, Case No. CV 85-4544-RJK (C.D. Cal. 1996), care provider facilities, on behalf of ORR, shall arrange for appropriate routine medical and dental care and emergency health care services, including a complete medical examination and screening for infectious diseases within 48 hours of admission, excluding weekends and holidays, unless the minor was recently examined at another facility; appropriate immunizations in accordance with the U.S. Public Health Service (PHS), Center for Disease Control; administration of prescribed medication and special diets; appropriate mental health interventions when necessary for each minor in their care.

The forms are to be used as worksheets for clinicians, medical staff, and health departments to compile information that would otherwise have been collected during the initial medical or dental exam. Once completed, the forms will be given to shelter staff for data entry into ORR's secure, electronic data repository known as 'The UAC Portal'. Data will be used to record UC health on admission and for case management of any identified illnesses/conditions.

*Respondents:* Office of Refugee Resettlement Grantee staff.

## ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Initial Medical Exam Form (including Appendix A: Supplemental TB Screening Form) .....	150	297	0.20	8,910
Initial Dental Exam Form .....	150	30	0.07	315

*Estimated Total Annual Burden Hours: 9,225.*

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments 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) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Robert Sargis,**

*Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Submission for OMB Review; 30-Day Comment Request; Division of Cancer Epidemiology and Genetics (DCEG) (National Cancer Institute)

**AGENCY:** National Institutes of Health, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

**DATES:** Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

**ADDRESSES:** Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974, Attention: Desk Officer for NIH.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Jackie Lavigne, Ph.D., MPH, Chief, Office of Education, Division of Cancer Epidemiology and Genetics, 9609 Medical Center Drive, MSC, Bethesda, Maryland 20892 or call non-toll-free number 240.276.7237 or Email your request, including your address to: [lavignej@mail.nih.gov](mailto:lavignej@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** This proposed information collection was previously published in the **Federal Register** on December 20, 2017, page 60407 (82 FR 60407) and allowed 60 days for public comment. No public comments were received. The National Cancer Institute (NCI), National Institutes of Health, may not conduct or

sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

**Proposed Collection:** Fellowship Program and Summer Student Applications OMB No. 0925-0716 Expiration Date 05/31/2018 Extension, National Cancer Institute (NCI), National Institutes of Health (NIH).

**Need and Use of Information Collection:** The National Cancer Institute, Division of Cancer Epidemiology and Genetics (DCEG) Office of Education administers a variety of programs and initiatives to recruit pre-college through post-doctoral educational level individuals into the Intramural Research Program to facilitate their development into future biomedical scientists. DCEG trains post-doctoral, doctoral candidates, graduate and baccalaureate students, through full time fellowships, summer fellowships, and internships in preparation for research careers in cancer epidemiology and genetics. The proposed information collection involves brief online applications completed by applicants to the full time and the summer fellowship programs. Full-time fellowships include: Full-time Equivalent (FTE) and non-FTE fellowships for US citizens, permanent residents and international fellows. These applications are essential to the administration of these training programs as they enable OE to determine the eligibility and quality of potential awardees; to assess their potential as future scientists; to determine where mutual research interests exist; and to make decisions regarding which applicants will be proposed and approved for traineeship awards. In each case, completing the application is voluntary, but in order to receive due consideration, the