on the process for updating ANDA labeling after approval of the NDA for the RLD has been withdrawn. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

### II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in § 314.94(a)(8) and 21 CFR 314.97 have been approved under OMB Control No. 0910–0001.

### III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: June 21, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–16157 Filed 7–8–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

**[Document Identifier: HHS–OS–0990–0221–30D]**

### Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for renewal of the approved information collection assigned OMB control number 0990–0221, scheduled to expire on September 30, 2016. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

**DATES:** Comments on the ICR must be received on or before August 10, 2016.

**ADDRESSES:** Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

**FOR FURTHER INFORMATION CONTACT:** Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the OMB control number 0990–0221 and document identifier HHS–OS–0990–0221–30D for reference.

*Information Collection Request Title:* Family Planning Annual Report: Forms and Instructions.

*Abstract:* The Office of Population Affairs within the Office of the Assistant Secretary for Health seeks to renew the currently approved Family Planning Annual Report (FPAR) data collection and reporting tool (OMB No. 0990–0221). This annual reporting requirement is for family planning services delivery projects authorized and funded by the title X Family Planning Program [''Population Research and Voluntary Family Planning Programs'' (Pub. L. 91–572)], which was enacted in 1970 as title X of the Public Health Service Act (section 1001; 42 U.S.C. 300). The FPAR data collection and reporting tool remains unchanged in this request to renew OMB approval to collect essential, annual data from title X grantees.

*Likely Respondents:* Respondents for this annual reporting requirement are centers that receive funding directly from OPA for family planning services authorized and funded under the title X Family Planning Program [''Population Research and Voluntary Family Planning Programs'' (Pub. L. 91–572)], which was enacted in 1970 as title X of the Public Health Service Act (section 1001 of title X of the Public Health Service Act, 42 United States Code [U.S.C.] 300).

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

| Type of respondent | Form name | Number of respondents | Number of responses per respondent | Average annualized burden per response (hours) | Annualized total burden (hours) |
|---|---|---|---|---|---|
| Grantees | FPAR | 93 grantees | 1 | 36 | 3,348 |
| Totals | | 93 | | | 3,348 |

**Terry S. Clark,**

*Asst. Information Collection Clearance Officer.*

[FR Doc. 2016–16300 Filed 7–8–16; 8:45 am]

**BILLING CODE 4150–34–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

### Request for Public Comment: 30-Day Proposed Information Collection: Indian Health Service Medical Staff Credentials and Privileges Files

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995 which requires 30 days for public comment on proposed information collection projects, the Indian Health Service (IHS) is submitting to the Office of Management and Budget (OMB) a request for an extension of a previously approved collection of information titled, ''Indian Health Service Medical Staff Credentials and Privileges Files,'' OMB Control Number 0917–0009, which expires August 31, 2016. This

proposed information collection project was previously published in the **Federal Register** (81 FR 23318) on April 20, 2016, and allowed 60 days for public comment. The IHS received no public comments regarding this collection. The purpose of this notice is to allow 30 days for public comment to be submitted directly to OMB.

*Proposed Collection:* Title: 0917–0009, ''Indian Health Service Medical Staff Credentials and Privileges Files.'' Type of Information Collection Request: Extension, without revision, of currently approved information collection, 0917–0009, ''Indian Health Service Medical Staff Credentials and Privileges Files.'' Form Numbers: 0917–0009. Need and Use of Information Collection: This collection of information is used to evaluate individual health care providers applying for medical staff privileges at IHS health care facilities. The IHS operates health care facilities that provide health care services to American Indians and Alaska Natives. To provide these services, the IHS employs (directly and under contract) several categories of health care providers including: Physicians (M.D. and D.O.), dentists, psychologists, optometrists, podiatrists, audiologists, physician assistants, certified registered nurse anesthetists, nurse practitioners, and certified nurse midwives. IHS policy specifically requires physicians and dentists to be members of the health care facility medical staff where they practice. Health care providers become medical staff members, depending on the local health care facility's capabilities and medical staff bylaws. There are three types of IHS medical staff applicants: (1) Health care providers applying for direct employment with IHS; (2) contractors who will not seek to become IHS employees; and (3) employed IHS health care providers who seek to transfer between IHS health care facilities.

National health care standards developed by the Centers for Medicare and Medicaid Services, the Joint Commission, and other accrediting organizations require health care facilities to review, evaluate and verify the credentials, training and experience of medical staff applicants prior to granting medical staff privileges. In order to meet these standards, IHS health care facilities require all medical staff applicants to provide information concerning their education, training, licensure, and work experience and any adverse disciplinary actions taken against them. This information is then verified with references supplied by the applicant and may include: Former employers, educational institutions, licensure and certification boards, the American Medical Association, the Federation of State Medical Boards, the National Practitioner Data Bank, and the applicants themselves.

In addition to the initial granting of medical staff membership and clinical privileges, the Joint Commission standards require that a review of the medical staff be conducted not less than every two years. This review evaluates the current competence of the medical staff and verifies whether they are maintaining the licensure or certification requirements of their specialty.

The medical staff credentials and privileges records are maintained at the health care facility where the health care provider is a medical staff member. The establishment of these records at IHS health care facilities is a Joint Commission requirement. Prior to the establishment of this Joint Commission requirement, the degree to which medical staff applications were maintained at all health care facilities in the United States that are verified for completeness and accuracy varied greatly across the Nation.

The application process has been streamlined and is using information technology to make the application electronically available on the Internet. The application may be found at the *IHS.gov* Web site address: *http://www.ihs.gov/IHM/index.cfm?module=dsp_ihm_pc_p3c1_ex#ManualExhibit3-1-A.*

*Affected Public:* Individuals and households.

*Type of Respondents:* Individuals.

*The table below provides:* Types of data collection instruments, Estimated number of respondents, Number of annual number of responses, Average burden per response, and Total annual burden hours.

| Data collection instrument(s) | Estimated number of respondents | Responses per respondent | Average burden hour per response * | Total annual burden hours |
|---|---|---|---|---|
| Application to Medical Staff | 570 | 1 | 1.00 (60 mins) | 570 |
| Reference Letter | 1,710 | 1 | 0.33 (20 mins) | 570 |
| Reappointment Request | 190 | 1 | 1.00 (60 mins) | 190 |
| Ob-Gyn Privileges | 20 | 1 | 1.00 (60 mins) | 20 |
| Internal Medicine | 325 | 1 | 1.00 (60 mins) | 325 |
| Surgery Privileges | 20 | 1 | 1.00 (60 mins) | 20 |
| Psychiatry Privileges | 13 | 1 | 1.00 (60 mins) | 13 |
| Anesthesia Privileges | 15 | 1 | 1.00 (60 mins) | 15 |
| Dental Privileges | 150 | 1 | 0.33 (20 mins) | 50 |
| Psychology Privileges | 30 | 1 | 0.17 (10 mins) | 5 |
| Audiology Privileges | 7 | 1 | 0.08 (5 mins) | 1 |
| Podiatry Privileges | 7 | 1 | 0.08 (5 mins) | 1 |
| Radiology Privileges | 8 | 1 | 0.33 (20 mins) | 3 |
| Pathology Privileges | 3 | 1 | 0.33 (20 mins) | 1 |
| Total | 3,068 | | | 1,784 |

* For ease of understanding, burden hours are provided in actual minutes.

There are no capital costs, operating costs and/or maintenance costs to respondents.

*Request for Comments:* Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry out an agency function; (b) whether the agency processes the information collected in a useful and timely fashion; (c) the accuracy of public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information); (d) whether the methodology and assumptions used to determine the estimate is logical; (e) ways to enhance the quality, utility, and clarity of the information being collected; and (f) ways to minimize the public burden

through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**ADDRESSES:** To request additional information, please contact Lisa Neel by one of the following methods:

- *Mail:* Lisa Neel, Program Manager, HIV Program, Office of Clinical and Preventive Services, Indian Health Service, 5600 Fishers Lane, Mail Stop: 08N06–A, Rockville, MD 20857.
- *Phone:* 301–443–4305.
- *Email: Lisa.Neel@ihs.gov.*
- *Fax:* 301–443–4305.

*Direct Your Comments to OMB:* Send your comments and suggestions regarding the proposed information collection contained in this notice, especially regarding the estimated public burden and associated response time to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for IHS.

*Comment Due Date:* Your comments regarding this information collection is best assured of having full effect if received within 30 days of the date of this publication.

Dated: June 29, 2016.

**Elizabeth A. Fowler,**

*Deputy Director for Management Operations, Indian Health Service.*

[FR Doc. 2016–16207 Filed 7–8–16; 8:45 am]

**BILLING CODE 4165–16–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

### Notice of Meeting

**AGENCY:** Center for Substance Abuse Prevention, Substance Abuse and Mental Health Services Administration, HHS.

Pursuant to Public Law 92–463, notice is hereby given that the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention (CSAP) Drug Testing Advisory Board (DTAB) will meet on July 26 and July 27, 2016. The DTAB will convene in both open and closed sessions over these two days.

On July 26, 2016 from 9:00 a.m. to 5:00 p.m. EDT, the meeting will be open to the public to provide an update on the status of the Mandatory Guidelines for Federal Workplace Drug Testing Programs for urine and oral fluid. A description of technical issues associated with hair testing will also be provided.

The public is invited to attend the open session in person or to listen via web conference. Due to the limited seating space and call-in capacity, registration is requested. Public comments are welcome. To register, make arrangements to attend, obtain the teleconference call-in numbers and access codes, submit written or brief oral comments, or request special accommodations for persons with disabilities, please register at the SAMHSA Advisory Committees' Web site at *http://nac.samhsa.gov/Registration/meetingsRegistration.aspx* or contact the CSAP DTAB Designated Federal Official, Brian Makela (see contact information below).

On July 27, 2016 between 9:00 a.m. and 2:00 p.m. E.D.T., the Board will meet in closed session to discuss proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs. This portion of the meeting is closed to the public as determined by the Administrator, SAMHSA, in accordance with 5 U.S.C. 552b(c)(9)(B) and 5 U.S.C. App. 2, Section 10(d).

Substantive program information, a summary of the meeting, and a roster of DTAB members may be obtained as soon as possible after the meeting by accessing the SAMHSA Advisory Committees Web site, *http://www.nace.samhsa.gov/MeetingList.aspx,* or by contacting Brian Makela. The transcript for the open meeting will also be available on the SAMHSA Committee Web site within three weeks after the meeting.

*Committee Name:* Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Prevention, Drug Testing Advisory Board.

*Dates/Time/Type:* July 26, 2016 from 9:00 a.m. to 5:00 p.m. E.D.T.: OPEN; July 27, 2016 from 9:00 a.m. to 2:00 p.m. E.D.T.: CLOSED.

*Place:* 7500 Old Georgetown Rd., Bethesda, Maryland 20814.

*Contact:* Brian Makela, Designated Federal Official, CSAP Drug Testing Advisory Board, 5600 Fishers Lane, Room 16N02B, Rockville, Maryland 20857, *Telephone:* 240–276–2600, *Email: brian.makela@samhsa.hhs.gov.*

**Summer King,**

*Statistician.*

[FR Doc. 2016–16358 Filed 7–8–16; 8:45 am]

**BILLING CODE 4162–20–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

### Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are 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.

**Proposed Project: Confidentiality of Alcohol and Drug Abuse Patient Records—(OMB No. 0930–0092)—Revision**

Statute (42 U.S.C. 290dd–2) and regulations (42 CFR part 2) require federally conducted, regulated, or directly or indirectly assisted alcohol and drug abuse programs to keep alcohol and drug abuse patient records confidential. Information requirements are (1) written disclosure to patients about Federal laws and regulations that protect the confidentiality of each patient, and (2) documenting ''medical personnel'' status of recipients of a disclosure to meet a medical emergency. Annual burden estimates for these requirements are summarized in the table below: