

| 21 CFR part; guidance; or FDA form | Topic | OMB control No. |
|------------------------------------|---|-----------------|
| 820 | Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation. | 0910-0073 |

Dated: December 14, 2018.
Leslie Kux,
Associate Commissioner for Policy.
 [FR Doc. 2018-27433 Filed 12-18-18; 8:45 am]
BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0955-new]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.
ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before January 18, 2019.

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

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795-7714. When submitting comments or requesting information, please include the document identifier 0955-New-30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: National Survey of Health Information Exchange Organizations (HIO)

Abstract: Electronic health information exchange (HIE) is one of three goals specified by Congress in the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act to ensure that the \$30 billion federal investment in electronic health records (EHRs) results in higher-quality, lower-cost care. The ability of providers to share data electronically is a core goal of HITECH and a central feature of a high-performing healthcare delivery system. Greater EHR adoption without data flowing between systems substantially limits quality and efficiency gains as well as reduces the value of the health IT investment.

There is growing consensus that achieving broad-based HIE is one of the most difficult components of HITECH. This is because successful HIE at scale involves coordination between many stakeholders, including but not limited to federal and state policymakers, healthcare delivery organizations, EHR and HIE vendors, and specific organizations supporting HIE, such as health information organizations (HIOs) and health information service providers (HISPs). Further, the issues requiring coordination are diverse, spanning technical standards, consent regulations, business models and incentives, workflow integration, trust and governance, and information privacy and security.

Three HIE issues have proven particularly challenging: Implementation of and use of standards, information blocking, and sustainability. The ultimate goal of our project is to administer a survey instrument to HIOs in order to generate the most current national statistics and associated actionable insights on electronic health information exchange to inform policy efforts.

Need and Proposed Use of the Information: Collecting timely, national data from HIOs in the three domains of standards, information blocking, and sustainability is valuable to inform both HIE-specific policy efforts as well as broader health system reform efforts.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

| Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden hours |
|------------------|-----------------------|------------------------------------|--|--------------------|
| HIO Survey | 200 | 1 | 20/60 | 67 |
| Total | | | | 67 |

Terry Clark,
Assistant Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.
 [FR Doc. 2018-27469 Filed 12-18-18; 8:45 am]
BILLING CODE 4150-45-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-new]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.
ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before January 18, 2019.

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

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795-7714. When submitting comments or requesting information, please include the document identifier 0990-New-30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information

collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Cohort 3 Teen Pregnancy Prevention Performance Measure Data.

Type of Collection: New, 0990-NEW—Office of Adolescent Health.

Abstract: The Office of Adolescent Health Requests a new clearance for the collection of performance measures from the cohort 3 Teen Pregnancy Prevention (TPP) grant recipients, awarded in Fall 2018. Phase 1 cohort 3 TPP grants shall be issued in for an anticipated 2 year period of performance. A subset of successful Phase 1 grantees will be selected for Phase 2 grants. A 3 year clearance is requested. FY2018 TPP phase 1 grant recipients will be expected to report data twice each year.

ESTIMATED ANNUALIZED BURDEN TABLE

| Type of respondent | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden hours |
|--------------------------------------|-----------------------|------------------------------------|--|--------------------|
| TPP Grantee (Grantee Form) | 19 | 2 | 7 | 266 |
| TPP Grantee (Participant Form) | 19 | 2 | 8 | 304 |
| TPP Program Participant | 14,250 | 2 | 10/60 | 4,750 |
| Total | 14,269 | 2 | 15 | 5,320 |

Terry Clark,
Office of the Secretary, Asst Paperwork Reduction Act Reports Clearance Officer.
 [FR Doc. 2018-27470 Filed 12-18-18; 8:45 am]
BILLING CODE 4168-11-P

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.
Contact Person: Richard C. Palmer, DRPH, Health Scientist Administrator, National Institute on Minority Health and Health Disparities, National Institutes of Health, 6707 Democracy Blvd., Suite 800, Bethesda, MD 20906, (301) 451-2432, *richard.palmer@nih.gov*.

Dated: December 13, 2018.
Ronald J. Livingston, Jr.,
Program Analyst, Office of Federal Advisory Committee Policy.
 [FR Doc. 2018-27375 Filed 12-18-18; 8:45 am]
BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Minority Health and Health Disparities Special Emphasis Panel; Minority Health and Health Disparities Research Training Program.

Date: February 7-8, 2019.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Name of Committee: National Institute on Minority Health and Health Disparities Special Emphasis Panel; NIMHD Mentored Career Development Awards (Ks).

Date: March 4, 2019.

Time: 12:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Gateway Building, 533K, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Xinli Nan, M.D., Ph.D., Scientific Review Officer, National Institute on Minority Health and Health Disparities, National Institutes of Health Scientific Review Branch, OERA, 6707 Democracy Blvd., Suite 800, Bethesda, MD 20892, (301) 594-7784, *Xinli.Nan@nih.gov*.

Any interest person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; Center for Translational ImmunoEngineering (2019/05).

Date: March 6, 2019.