• § 208.24(e) (21 CFR 208.24(e))—Each authorized dispenser of a prescription drug product for which a Medication Guide is required must provide a Medication Guide directly to each patient when dispensing the product to the patient or to the patient's agent, unless an exemption applies under § 208.26 (21 CFR 208.26).

• § 208.26(a)—Requests may be submitted for an exemption or a deferral from particular Medication Guide content or format requirements.

In the **Federal Register** of October 26, 2018 (83 FR 54110), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received encouraging the use of ''provider-neutral language'' in places where terms such as ''doctor'' or ''physician'' are used suggesting that these terms may cause some confusion for patients. We are appreciative of this recommendation; however, we decline to implement such changes.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Content and Format of a Medication Guide—§ 208.20	61	1	61	320	19,520
Supplements and Other Changes to an Approved Application—§§ 314.70(b)(3)(ii) and 601.12(f)	155	1	155	72	11,160
Exemptions and Deferrals—§ 208.26(a)	1	1	1	4	4
Total					30,684

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Distributing Medication Guide to Authorized Dispenser—§ 208.24(c)	191	9,000	1,719,000	1.25	2,148,750
Distributing and Dispensing a Medication Guide to Patient—§ 208.24(e)	88,736	5,705	506,238,880	0.05 (3 minutes)	25,311,944
Total					27,460,694

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated annual reporting burden for the information collection reflects an overall increase of 4,664 total hours. We attribute this adjustment to an increase in the number of submissions we received over the last few years. Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our annual third-party disclosure burden estimate.

Dated: August 15, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–18000 Filed 8–20–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0221]

Agency Information Collection Request; 60-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 October 21, 2019.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990-New-60D, and project title for reference, to Sherrette Funn, the Reports Clearance Officer, *Sherrette.funn@hhs.gov,* or call 202–795–7714.

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: Family Planning Annual Report (FPAR).

Type of Collection: Renewal with change.

OMB No.: 0990–0221.

Abstract: The Office of Population Affairs within the Office of the Assistant Secretary for Health is requesting an extension on a 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'' (Public Law 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 will include a new module to collect

substance use disorder (SUD) screening data in this request to extend an OMB approval to collect essential, annual data from Title X grantees.

Need and Proposed Use of the Information: The Title X Family Planning Program (''Title X program'' or ''program'') is the only Federal grant program dedicated solely to providing individuals with comprehensive family planning and related preventive health services (*e.g.,* screening for breast and cervical cancer, sexually transmitted diseases (STDs), and human immunodeficiency virus). By law, priority is given to persons from low-income families (Section 1006[c] of Title X of the Public Health Service Act, 42 U.S.C. 300). The Office of Population Affairs (OPA) within the Office of the Assistant Secretary for Health administers the Title X program.

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.

This weighted average hour burden accounts for differences in reporting burden by type of grantee agency grantee (*e.g.,* public health department or private agency), as found in the *2009 FPAR Burden Study.* For purposes of this estimate, the average hour burden ranges between 39 hours (public health department) and 32 hours (private agency).

ANNUALIZED BURDEN HOUR TABLE

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

Terry Clark,

Asst. Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2019–18046 Filed 8–20–19; 8:45 am]

BILLING CODE 4150–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting 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: Center for Scientific Review Special Emphasis Panel; Member Conflicts: Respiratory Sciences.

Date: September 13, 2019.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Ghenima Dirami, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4122, MSC 7814, Bethesda, MD 20892, 240–498–7546, *diramig@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 15, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–17989 Filed 8–20–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute Of General Medical Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 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 General Medical Sciences Special Emphasis Panel; Review of NIGMS Support of Competitive Research (SCORE) Award Applications.

Date: October 11, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Brian R. Pike, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN18, Bethesda, MD 20892 301–594–3907, *pikebr@mail.nih.gov.*

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; Review of NIGMS Support of Competitive Research (SCORE) Award Applications.

Date: November 1, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Manas Chattopadhyay, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12, Bethesda, MD 20892, 301–827–5320, *manasc@mail.nih.gov.*

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; Review of NIGMS Support of Competitive Research (SCORE) Award Applications.

Date: November 20, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Nina Sidorova, Ph.D., Scientific Review Officer, Office of Scientific