DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–417]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by October 10, 2017.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov*. Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*.

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–417 Hospice Request for Certification and Supporting Regulations

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Hospice Request for Certification and Supporting Regulations; *Use:* The Hospice Request for Certification Form is the identification and screening form used to initiate the certification process and to determine if the provider has sufficient personnel to participate in the Medicare program. *Form Number:* CMS–417 (OMB Control number: 0938–0313); *Frequency:* Annually; *Affected Public:* Private Sector—Business or other for-profits; *Number of Respondents:* 851; *Total Annual Responses:* 851; *Total Annual Hours:* 213. (For policy questions regarding this collection contact Sarah Fahrendorf at 410–786–3112.)

Dated: August 3, 2017.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2017–16704 Filed 8–7–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Personal Responsibility Education Program (PREP) Promising Youth Programs (PYP).

OMB No.: New Collection.

Description: The Personal Responsibility Education Program (PREP) grantees provide education to adolescents on both abstinence and contraception for the prevention of pregnancy and sexually transmitted infections, as well as education on additional topics to prepare youth for adulthood. PREP programs are overseen by the Family and Youth Services Bureau (FYSB), in the Administration for Children and Families (ACF), in the U.S. Department of Health and Human Services (HHS).

The Promising Youth Programs (PYP) project supports PREP programming in two ways. First, it supports PREP grantees as they collaborate with independent evaluators to conduct evaluations of their programs. Second, it is working to develop curricula to address PREP-related needs for underserved youth. PYP is overseen by ACF's Office of Planning, Research, and Evaluation (OPRE). To support the PYP project, FYSB and OPRE seek approval to collect the following information:

(1) *Abstract template:* We will annually ask grantees and their independent evaluators to develop/update abstracts about their evaluations.

(2) *CONSORT (CONsolidated Standards of Reporting Trials) diagram template:* We will bi-annually ask grantees and their independent evaluators for information about study recruitment, enrollment, and retention.

(3) *Baseline equivalence template:* We will bi-annually ask grantees and their independent evaluators for information that demonstrates whether program and comparison groups are comparable.

(4) *Youth discussions topic guide:* We will hold discussions with youth from target populations about their perceptions of PREP-related programming.

Respondents: Grantees and their independent evaluators; and youth from target populations.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent (annually)	Average burden hours per response	Annual burden hours
(1) Abstract template	29	29	1	3	87
(2) CONSORT diagram template	29	29	2	1	58
(3) Baseline equivalence template	16	16	2	2	64
(4) Youth discussions topic guide	64	21	*1	1.5	32

*Total.

Estimated Total Annual Burden Hours: 241.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Mary Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2017–16671 Filed 8–7–17; 8:45 am]

BILLING CODE 4184–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0349]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Providing Waiver-Related Materials in Accordance With the Guidance for Industry on Providing Post-Market Periodic Safety Reports in the International Conference on Harmonisation E2C(R2) Format

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 7, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0771. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Providing Waiver-Related Materials in Accordance With the Guidance for Industry on Providing Post-Market Periodic Safety Reports in the International Conference on Harmonisation E2C(R2) Format (Periodic Benefit-Risk Evaluation Report); OMB Control Number 0910–0771—Extension

The International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use issued, on November 15, 2012, the ICH harmonized tripartite guideline entitled ''Periodic Benefit-Risk Evaluation Report (PBRER) E2C(R2)'' (the PBRER guideline) (available at *https://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html*). The PBRER guideline is intended to promote a consistent approach to periodic post-marketing safety reporting among the ICH regions, to enhance efficiency and reduce burden by reducing the number of reports generated for submission to the regulatory authorities. The PBRER is intended to provide a common standard for periodic reporting on approved drugs or biologics among the ICH regions.

FDA currently has OMB approval for the required submission of periodic adverse drug experience reports (PADER) for drugs subject to a new drug application (NDA) or an abbreviated new drug application (ANDA) (§ 314.80(c)(2) (21 CFR 314.80(c)(2)) (OMB control number 0910–0230), and for the required submission of periodic adverse experience reports (PAER) for drugs subject to a biologics license application (BLA) (§ 600.80(c)(2) (21 CFR 600.80(c)(2)) (OMB control number 0910–0308).