dietary interventions), we will include all studies that otherwise meet the selection criteria to allow us to make overarching comments about the status of the FI treatment-outcomes literature in the final report.

Setting

Any setting (community dwelling, long-term care, other).

Dated: December 30, 2014.

Richard Kronick,

AHRQ Director.

[FR Doc. 2015–00764 Filed 1–20–15; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Performance Measures for Community-Centered Healthy Marriage, Pathways to Responsible Fatherhood and Community-Centered Responsible Fatherhood Ex-Prisoner Reentry grant programs.

OMB No.: 0970–0365—Reinstatement with changes of a previously approved collection.

Description: The Office of Family Assistance (OFA), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), intends to request approval from the Office of Management and Budget (OMB) to renew OMB Form 0970–0365 for the collection of performance measures from grantees for the Community-Centered Healthy Marriage, Pathways to Responsible Fatherhood and Community-Centered Responsible Fatherhood Ex-Prisoner Reentry discretionary grant programs. The performance measure data obtained from the grantees will be used by OFA to report on the overall performance of these grant programs.

Data will be collected from all 60 Community-Centered Healthy Marriage, 54 Pathways to Responsible Fatherhood and 5 Community-Centered Responsible Fatherhood Ex-Prisoner Reentry grantees in the OFA programs. Grantees will report on program and participant outcomes in such areas as participants' improvement in knowledge skills, attitudes, and behaviors related to healthy marriage and responsible fatherhood. Grantees will be asked to input data for selected outcomes for activities funded under the grants. Grantees will extract data from program records and will report the data twice yearly through an on-line data collection tool. Training and assistance will be provided to grantees to support this data collection process.

Respondents: Office of Family Assistance Funded Community-Centered Healthy Marriage, Pathways to Responsible Fatherhood and Community-Centered Responsible Fatherhood Ex-Prisoner Reentry Grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Performance measure reporting form (for private sector affected public)	110	2	0.8	176
Performance measure reporting form (for State, local, and tribal government affected public)	9	2	0.8	14
Estimated Total Annual Burden Hours				190

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.* 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 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.

[FR Doc. 2015–00809 Filed 1–20–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0500]

Agency Information Collection Activities; Proposed Collection; Comment Request; Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's requirements on content and format of labeling for human prescription drug and biological products.

DATES: Submit either electronic or written comments on the collection of information by March 23, 2015.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA 305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: 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. ''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 (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products (OMB Control Number 0910–0572)—Extension

FDA's regulations governing the format and content of labeling for human prescription drug and biological products were revised in the **Federal Register** of January 24, 2006 (71 FR 3922), to require that the labeling of new and recently approved products contain highlights of prescribing information, a table of contents for prescribing information, reordering of certain sections, minor content changes, and minimum graphical requirements. These revisions were intended to make it easier for health care practitioners to access, read, and use information in prescription drug labeling; to enhance the safe and effective use of prescription drug products; and to reduce the number of adverse reactions resulting from medication errors due to misunderstood or incorrectly applied drug information.

Currently, § 201.56 (21 CFR 201.56) requires that prescription drug labeling contain certain information in the format specified in either § 201.57 (21 CFR 201.57) or § 201.80 (21 CFR 201.80), depending on when the drug was approved for marketing. Section 201.56(a) sets forth general labeling requirements applicable to all prescription drugs. Section 201.56(b) specifies the categories of new and more recently approved prescription drugs subject to the revised content and format requirements in §§ 201.56(d) and 201.57. Section 201.56(c) sets forth the schedule for implementing these revised content and format requirements. Section 201.56(e) specifies the sections and subsections, required and optional, for the labeling of older prescription drugs not subject to the revised format and content requirements.

Section 201.57(a) requires that prescription drug labeling for new and more recently approved prescription drug products include ''Highlights of Prescribing Information''. Highlights provides a concise extract of the most important information required under § 201.57(c) (the Full Prescribing Information (FPI)), as well as certain additional information important to prescribers. Section 201.57(b) requires a table of contents to prescribing information, entitled ''Full Prescribing Information: Contents,'' consisting of a list of each heading and subheading along with its identifying number to facilitate health care practitioners' use of labeling information. Section 201.57(c) specifies the contents of the FPI. Section 201.57(d) mandates the minimum specifications for the format of prescription drug labeling and establishes minimum requirements for key graphic elements such as bold type, bullet points, type size, and spacing.

Older drugs not subject to the revised labeling content and format requirements in § 201.57 are subject to labeling requirements at § 201.80. Section 201.80(f)(2) requires that within 1 year, any FDA-approved patient labeling be referenced in the ''Precautions'' section of the labeling of older products and either accompany or be reprinted immediately following the labeling.

Annual Burden for Prescription Drug Labeling Design, Testing, and Submitting to FDA for New Drug Applications (NDAs) and Biologics License Applications (BLAs) (§§ 201.56 and 201.57). New drug product applicants must: (1) Design and create prescription drug labeling containing ''Highlights'', ''Contents'', and FPI, (2) test the designed labeling (*e.g.,* to ensure that the designed labeling fits into carton-enclosed products), and (3) submit it to FDA for approval. Based on the projected data used in the January 24, 2006, final rule, FDA estimates that it takes applicants approximately 3,349 hours to design, test, and submit prescription drug labeling to FDA as part of an NDA or a BLA under the revised regulations. Currently, approximately 131 applicants submit approximately 196 new applications (NDAs and BLAs) to FDA annually, totaling 656,404 hours.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Part	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Labeling Requirements in §§ 201.56 and 201.57	131	1.5	196	3,349	656,404

Dated: January 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–00761 Filed 1–20–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Advisory Committee on Training in Primary Care Medicine and Dentistry Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (92), notice is hereby given of the following meeting:

Name: Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD).

Dates and Times: February 6, 2015 (10:00 a.m.–4:00 p.m.)

Place: Webinar and Conference Call Format.

Status: The meeting will be open to the public.

Purpose: The ACTPCMD provides advice and recommendations on a broad range of issues relating to grant programs authorized by sections 222 and 749 of the Public Health Service Act, as amended by section 5103(d) and re-designated by section 5303 of the Patient Protection and Affordable Care Act of 2010.

The ACTPCMD members will discuss health literacy and patient engagement for inclusion in the 12th ACTPCMD Report. The report will be submitted to the Secretary of the Department of Health and Human Services; the Committee on Health, Education, Labor, and Pensions of the Senate; and the Committee on Energy and Commerce of the House of Representatives.

Agenda: The ACTPCMD agenda provides opportunity for members to discuss health literacy and patient engagement for inclusion in the 12th ACTPCMD Report. An official agenda will be available 2 days prior to the meeting on the HRSA Web site (*http://www.hrsa.gov/advisorycommittees/bhpradvisory/actpcmd/index.html*). Agenda items are subject to change as priorities dictate.

Public Comment: Requests to make oral comments or provide written comments to the ACTPCMD should be sent to Dr. Joan Weiss, Designated Federal Official, using the address and phone number below. Individuals who plan to participate on the conference call or webinar should notify Dr. Weiss at least 3 days prior to the meeting, using the address and phone number below. Members of the public will have the opportunity to provide comments. Interested parties should refer to the meeting subject as the HRSA Advisory Committee on Training in Primary Care Medicine and Dentistry.

The conference call-in number is 800–369–1867. The passcode is: 8803797. The webinar link is *https://hrsa.connectsolutions.com/actpcmd/.*

FOR FURTHER INFORMATION CONTACT: Anyone requesting information regarding the ACTPCMD should contact Dr. Joan Weiss, Designated Federal Official within the Bureau of Health Workforce, Health Resources and Services Administration, in one of three ways: 1) Send a request to the following address: Dr. Joan Weiss, Designated Federal Official, Bureau of Health Workforce, Health Resources and Services Administration, Parklawn Building, Room 12C–05, 5600 Fishers Lane, Rockville, Maryland 20857; 2) call (301) 443–0430; or 3) send an email to *jweiss@hrsa.gov.*

Jackie Painter,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2015–00841 Filed 1–20–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Advisory Committee on Interdisciplinary, Community-Based Linkages; Notice of Meeting

In accordance with section 10(a) (2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Interdisciplinary, Community-Based Linkages (ACICBL).

Dates And Times: January 28, 2015 (10:00 a.m.–4:00 p.m.).

Place: Webinar and Conference Call Format.

Status: The meeting will be open to the public.

Purpose: The members of the ACICBL will discuss the legislatively mandated 15th Annual Report to the Secretary of Health and Human Services and Congress. The Committee members will discuss programmatic recommendations for each of the programs under Title VII Part D.

The programs under Title VII Part D include: 750—General Provisions; 751—Area Health Education Centers; 752—Continuing Education Support for Health Professionals Serving in Underserved Communities; 753—Education and Training Related to Geriatrics; 754—Quentin N. Burdick Program for Rural Interdisciplinary Training; 755—Allied Health and Other Disciplines; 756—Mental and Behavioral Health Education and Training Grants; 757—Advisory Committee on Interdisciplinary, Community-Based Linkages; and 759—Program for Education and Training in Pain Care. The logistical challenges of scheduling this meeting hindered an earlier publication of this meeting notice.

Agenda: The ACICBL agenda includes an opportunity for members to discuss the content of the 15th Annual Report and to listen to expert presentations to develop the report. The agenda will be available 2 days prior to the meeting on the Heath Resources and Services Administration (HRSA) Web site (*http://www.hrsa.gov/advisorycommittees/bhpradvisory/acicbl/acicbl.html*). Agenda items are subject to change as priorities dictate.

Public Comment: Requests to make oral comments or provide written comments to the ACICBL should be sent to Dr. Joan Weiss, Designated Federal Official, using the address and phone number below. Individuals who plan to participate on the conference call or webinar should notify Dr. Weiss at least 3 days prior to the meeting, using the

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