

facility has demonstrated full compliance with all requirements.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we approve TJC as a national accreditation organization for psychiatric hospitals that request participation in the Medicare program, effective February 25, 2019 through February 25, 2023.

To verify TJC's continued compliance with the provisions of this final notice, CMS expects to conduct a follow-up corporate on-site visit and survey observation within 18 months of the publication date of this notice.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: February 7, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2019-02673 Filed 2-15-19; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; ACF's Generic Clearance for Grant Reviewer Recruitment Forms (OMB #0970-0477)

AGENCY: Office of Planning, Research, and Evaluation; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF), Office of Planning, Research, and Evaluation (OPRE) is proposing an extension of a currently approved generic clearance (OMB no. 0970-0477) for Grant Reviewer Recruitment (GRR) forms. The GRR forms will be used to select reviewers who will participate in the grant review process for the purpose of selecting successful applications.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(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.

ADDRESSES: 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, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov*. All requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Under this generic approval, ACF conducts and proposes to continue to conduct more than one information collection that is very similar, voluntary, low-burden and uncontroversial. The purpose is to select qualified reviewers for the grant peer review process based on professional qualifications using data entered by candidates and the uploaded writing sample and/or curriculum vitae and/or resume. The grant review process is in accordance with the U.S. Department of Health and Human Services' (DHHS) Grants Policy Directive (GPD) 2.04 "Awarding Grants", the DHHS Awarding Agency Grants Administration Manual (AAGAM), Chapter 2.04.104C "Objective Review of Grant Applications", and the Public Health Service (PHS) Act, Sections 799(f) and 806(e).

Respondents: Individuals who may apply to review ACF grant applications.

ANNUAL BURDEN ESTIMATES

| Instrument | Total number of respondents | Number of responses per respondent | Average burden hours per response | Annual burden hours |
|---------------------------------------|-----------------------------|------------------------------------|-----------------------------------|---------------------|
| Grant Reviewer Recruitment Form | 3,000 | 1 | .5 | 1,500 |

Estimated Total Annual Burden Hours: 1,500.

Comments: 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 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.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019-02624 Filed 2-15-19; 8:45 am]

BILLING CODE 4184-79-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Strengthening Relationship Education and Marriage Services (STREAMS) Evaluation (OMB#0970-0481)

AGENCY: Office of Planning, Research, and Evaluation; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Family Assistance (OFA) within the Administration for Children and Families (ACF) at the U.S. Department of Health and Human Services has issued grants to organizations to provide healthy marriage and relationship education (HMRE) services. Under a previously approved data collection activity (OMB#0970-0481), the Office of Planning, Research, and Evaluation (OPRE) within ACF is conducting the Strengthening Relationship Education and Marriage Services (STREAMS) evaluation with five HMRE grantees. The purpose of STREAMS is to measure the effectiveness and quality of HMRE programs designed to strengthen intimate relationships. This data collection request is for an extension of

previously approved data collection instruments and for two additional data collection instruments.

DATES: Comments due within 30 days of publication. 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.

ADDRESSES: 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.

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*.

SUPPLEMENTARY INFORMATION:

Description: The STREAMS evaluation includes two components, an impact study and a process study. The evaluation will examine HMRE programs for youth in high school, adult couples, and adult individuals.

1. Impact Study. The goal of the impact study is to provide rigorous estimates of the effectiveness of program services and interventions to improve program implementation. The impact study uses an experimental design. Eligible program applicants are randomly assigned to either a program group that is offered program services or a control group that is not. STREAMS collects baseline information from eligible program applicants prior to random assignment and administers a follow-up survey to participants 12 months after random assignment.

2. Process study. The goal of the process study is to support the interpretation of impact findings and document program operations to support future replication. STREAMS

conducts semi-structured interviews with program staff and selected community stakeholders, conducts focus groups with program participants, administers a survey to program staff, and collects data on adherence to program curricula through an add on to an existing program MIS (nFORM, OMB no. 0970-0460).

This data collection request is for an extension of previously approved data collection instruments for the impact study and for two additional data collection instruments associated with the impact study. The two additional instruments will allow for longer-term follow-up in two of the five evaluation sites. (1) The second follow-up survey for youth will be administered approximately 24 to 36 months after random assignment to study participants in the STREAMS site serving youth. (2) The second follow-up survey for adults will be administered approximately 30 months after random assignment to study participants in one of the STREAMS evaluation sites serving adults.

Respondents: Study participants.

ANNUAL BURDEN ESTIMATES

| Instrument | Total number of respondents | Annual number of respondents | Number of responses per respondent | Average burden hours per response | Annual burden hours |
|--|-----------------------------|------------------------------|------------------------------------|-----------------------------------|---------------------|
| Previously Approved Burden that Remains | | | | | |
| Introductory script, grantee staff | 8 | 8 | 25 | 0.08 | 16 |
| Introductory script, program applicants | 600 | 200 | 1 | 0.08 | 16 |
| Add-on to nFORM to conduct random assignment | 8 | 8 | 25 | 0.08 | 16 |
| Follow-up survey for youth | 690 | 230 | 1 | 0.5 | 115 |
| Baseline survey for adults | 600 | 200 | 1 | 0.5 | 100 |
| Follow-up survey for adults | 2,300 | 767 | 1 | 0.75 | 575 |
| Current Request for Approval | | | | | |
| Second follow-up survey for youth | 1,500 | 500 | 1 | 0.5 | 250 |
| Second follow-up survey for adults | 800 | 267 | 1 | 0.75 | 200 |

Estimated Total Annual Burden Hours: 1,288.

Authority: 42 U.S.C. 603; Sec. 811 (b) Healthy Marriage Promotion and Promoting Responsible Fatherhood Grants of the Claims Resolution Act of 2010, Pub. L. 111-291, 124 Stat. 3064.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019-02693 Filed 2-15-19; 8:45 am]

BILLING CODE 4184-73-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-6154]

Evaluation of Devices Used With Regenerative Medicine Advanced Therapies; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled “Evaluation of

Devices Used with Regenerative Medicine Advanced Therapies; Guidance for Industry.” The guidance document provides manufacturers, applicants, and sponsors engaged in the development of regenerative medicine therapies, with our current thinking regarding evaluation of devices used in the recovery, isolation or delivery of regenerative advanced therapies, which FDA generally refers to as “regenerative medicine advanced therapies” or “RMATs.” Specifically, the guidance addresses how FDA intends to simplify and streamline its application of regulatory requirements for combination device and cell or tissue products; what, if any, intended uses or specific attributes would result in a device used