DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Generic Program-Specific Performance Progress Report (0970–0490)

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

ACTION: Request for public comment.

SUMMARY: This Notice describes the proposal to extend data collection under the Administration for Children and Families (ACF) Generic Program-Specific Performance Progress Report (PPR) (0970–0490). This overarching generic allows ACF program offices to collect performance and progress data from recipients and sub-recipients who receive funding from ACF under a discretionary grant or cooperative agreement. This information is required under 45 CFR 75.342, monitoring and reporting program performance. The generic program-specific PPR was originally approved in January 2017.

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 emailing *OPREinfocollection@acf.hhs.gov.* Alternatively, copies can also 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, emailed or written should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: ACF is primarily a grant-making agency that promotes the economic and social well-being of families, children, individuals and communities with partnerships, funding, guidance, training and technical assistance. Prior to the use of this generic program-specific PPR, a standard ACF PPR (#0970–0406) was used for all ACF discretionary grant and cooperative agreement awards for post award reporting. Historically, on the standard ACF PPR form, ACF required grantees to only respond to a common set of broad questions, which often solicited qualitative or incomplete information. This one-size-fits-all approach did not adequately collect the specific data needed for particular grant programs or allow program offices to assess continuous quality improvement. Different grant programs vary in purpose, target population, and activities. Therefore, a need for program offices to customize performance measurements was identified and the generic program-specific PPR was developed.

ACF program offices have benefited from the ability to create and use a program-specific PPR that is more effective and includes specific data elements that reflects a specific program's indicators, demographics, priorities and objectives.

A generic program-specific PPR that can be tailored for program-specific needs allows program offices to collect useful data in a uniform and systematic manner. The reporting format allows program offices to gather uniform program performance data from each grantee, allowing aggregation at the program level to calculate outputs and outcomes, providing a snapshot and allowing for longitudinal analysis.

Data from a tailored program-specific PPR that demonstrates a program's successes and challenges have been useful for accountability purposes, such as required reports to Congress. Moreover, it has been useful for program management and oversight, such as identifying grantees' technical assistance needs and ensuring compliance with Federal and programmatic regulations and policies.

Respondents: ACF Grantees

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hour per response	Total burden hours
Program Specific PPRs	2,000	2	1	4,000

Estimated Total Annual Burden Hours: 4000.

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. 2019–16518 Filed 8–1–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Reallotment of FY 2019 Funds

AGENCY: Administration on Disabilities (AoD), Administration for Community Living (ACL), U.S. Department of Health and Human Services (HHS).

ACTION: Notice of reallotment of FY 2019 funds.

AOD intends to reallot funds under the authority of Section 122(e) and Section 142(a)(1) of the Development Disabilities Assistance and Bill of Rights Act of 2000, (Pub. L. 106–402) which states: ''If the Secretary determines that an amount of an allotment to a State for a period (of a fiscal year or longer) will not be required by the State during the period for the purpose for which the allotment was made, the Secretary may reallot the amount.''

AOD will be reallotting FY 2019 funds awarded to the State Council on Developmental Disabilities (SCDD) located within the Commonwealth of Puerto Rico. This determination is based on the limited reported expenditures

and requests for reimbursement over the last several years from the SCDD in the Commonwealth of Puerto Rico.

The Puerto Rico SCDD will have up to $2 million rescinded and proportionately redistributed to the remaining SCDDs. SCDDs that receive FY 2019 realloted funds will have through the end of FY 2020 to obligate the funds and until the end of FY 2021 to liquidate the funds.

Realloted funds for the SCDDs must be used according to the terms as outlined in the FY 2019 Notice of Award for each program.

DATES: Funds will be realloted after August 15, 2019 and before September 30, 2019.

FOR FURTHER INFORMATION CONTACT: Allison Cruz, Office of Intellectual and Developmental Disabilities, Administration on Disabilities, Administration for Community Living, 330 C St. SW, Washington, DC 20201. Telephone (202) 795–7408. Email *allison.cruz@acl.hhs.gov.* Please note the telephone number is not toll free. This document will be made available in alternative formats upon request. Written correspondence can be sent to Administration for Community Living, U.S. Department of Health and Human Services, 330 C St. SW, Washington, DC 20201.

Dated: July 25, 2019.

Julie E. Hocker,

Commissioner, Administration on Disabilities.

[FR Doc. 2019–16546 Filed 8–1–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1772]

Oncology Therapeutic Radiopharmaceuticals: Nonclinical Studies and Labeling Recommendations; 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 for industry entitled ''Oncology Therapeutic Radiopharmaceuticals: Nonclinical Studies and Labeling Recommendations.'' The purpose of this guidance is to assist sponsors in designing appropriate nonclinical studies before initiation of first-in-human (FIH) trials and through product approval. In addition, this guidance provides recommendations for product labeling, such as duration of contraception to minimize potential risk to a developing embryo or fetus, and recommendations for lactating women to minimize potential risk to a nursing child. This guidance is intended to provide recommendations for nonclinical programs in a unique and challenging area of product development, provide a more consistent approach in nonclinical studies and product labeling, and reduce the conduct of nonclinical studies that are not informative for product use.

DATES: The announcement of the guidance is published in the **Federal Register** on August 2, 2019.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–1772 for ''Oncology Therapeutic Radiopharmaceuticals: Nonclinical Studies and Labeling Recommendations.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for