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Prevention.

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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES****Administration for Children and
Families****Proposed Information Collection
Activity; Comment Request**

Title: Pathways for Advancing Careers
and Education (PACE): Third Follow-Up
Data Collection.

OMB No.: 0970-0397.

Description: The Administration for
Children and Families (ACF), U.S.
Department of Health and Human
Services (HHS), is proposing a data
collection activity as part of the
Pathways for Advancing Careers (PACE)
evaluation. PACE is an evaluation of
nine promising career pathways
strategies to promote education,
employment, and self-sufficiency. The
major goal of PACE is to increase the

empirical knowledge about the
effectiveness of programs for low-
income individuals and families to
achieve educational credentials, attain
employment, and advance to positions
that enable self-sufficiency.

PACE is one project within the
broader portfolio of research that the
ACF Office of Planning, Research, and
Evaluation (OPRE) is utilizing to assess
the success of career pathways programs
and models. In addition to PACE, this
strategy includes a multi-pronged
research and evaluation approach for
the Health Profession Opportunity
Grants (HPOG) Program to better
understand and assess the activities
conducted and their results. In order to
maximize learning across this portfolio,
survey development for the HPOG and
PACE baseline and follow up surveys
has been coordinated, and the majority
of the data elements collected in these
surveys are similar. (See OMB Control
#0970-0394 for HPOG data collection.)

Three data collection efforts have
been approved for PACE: One for
baseline data collection (approved
November 2011); a second for data
collection activities to document
program implementation, data
collection activities for an initial follow-
up survey of participants administered

approximately 15 months after random
assignment, and data collection through
in-depth interviews for a small sample
of study participants (approved August
2013); and a third for a second follow-
up survey of participants administered
36 months after random assignment
(approved December 2014).

This **Federal Register** Notice provides
the opportunity to comment on a
proposed new information collection
activity for PACE—a third follow-up
survey for PACE participants
approximately 72 months after program
enrollment. The purpose of the survey
is to follow-up with study participants
to document their education and
training experiences; employment
experiences including their
advancement in their career; economic
well-being; student debt and repayment
status; and parenting practices and child
outcomes for participants with children.

Previously approved collection
activities under 0970-0397 will
continue under this new request,
specifically the 36-Month Follow-Up
Survey and Follow-Up Survey Contact
Information Update Letters.

Respondents: Individuals enrolled in
the PACE study at programs selected for
long-term follow-up.

ANNUAL BURDEN ESTIMATES

[This information request is for a three-year period]

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
72-Month Follow-Up Survey	3,600	1,200	1	0.75	1,125.

*Estimated Total Annual Burden
Hours:* 1,125.

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.
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](mailto:OPREinfocollection@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 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 Jones,

ACF/OPRE Certifying Officer.

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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES****Administration for Children and
Families****Statement of Organization, Functions,
and Delegations of Authority**

AGENCY: Administration for Children
and Families, HHS.

ACTION: Notice.

SUMMARY: Statement of Organizations,
Functions, and Delegations of
Authority. The Administration for
Children and Families (ACF) and the
National Treasury Employees Union
(NTEU) have renewed the ACF Labor
Management Committee Charter.

FOR FURTHER INFORMATION CONTACT:
Benjamin Goldhaber, Deputy Assistant
Secretary for Administration, 330 C
Street SW., Washington, DC 20201,
(202) 795-7790.

The ACF Labor Management Committee Charter is being published as follows:

Cooperation Agreement and Charter for the Labor Management Committee (LMC) the Administration for Children and Families (ACF) and National Treasury Employees Union (NTEU)

The Administration for Children and Families (ACF) and the National Treasury Employees Union (NTEU) jointly establish the ACF/NTEU Labor Management Committee (Committee or LMC). The parties recognize that a strong relationship between labor and management as true and equal partners is essential in order for ACF to continue to deliver high quality human services to the American people as well as continue to recognize and value its employees and their union representation. This cooperative relationship envisions the open sharing of information at the earliest pre-decisional stage thereby engendering mutual trust and respect.

Purpose and Objectives

The Committee's goal is to establish an ACF/NTEU labor-management culture that fosters the full development and utilization of employees' skills, knowledge, expertise and capabilities through cooperative dialogue and endeavors with ACF employees and their union representative.

In pursuit of this goal, the Committee sets forth the following objectives:

- Focus on ACF mission achievement by serving the public interest first;
- Promote a quality workplace through improved working conditions and enhanced working relationships;
- Provide a communication and information sharing channel for all bargaining-unit employees through their union representatives;
- Enhance and establish policy and program improvement initiatives through pre-decisional involvement of NTEU without regard to whether those matters are negotiable subjects of bargaining under 5 U.S.C. § 7106;
- Make a good-faith effort to resolve issues concerning proposed changes in conditions of employment as it relates to numbers, types, and grades of employees and positions assigned to any organizational subdivision, work product, or tour of duty; and the technology, methods, and means of performing work;
- Identify and target mutual interests and shared problems and craft solutions;
- Respect each other as equal partners in order to address issues from a problem-solving, interest based, and cooperative perspective;
- Promote cooperative labor-management working relationships across the Agency; and
- Provide a forum from which to build mutual trust, respect, and understanding between the partners.

Scope

The ACF LMC will implement the purposes and objectives on which it is founded by:

- Identifying issues impacting ACF's mission, labor-management relations, and

others of mutual interest to committee members and providing proposed recommendations to ACF and NTEU leadership;

- Discussing issues and developing proposed recommendations on items referred to the Committee by ACF or NTEU leadership;
- Exchanging facts and information about agency-wide issues affecting management, labor and mission achievement, and serving as a forum for discussion of such issues; and
- Promoting and facilitating labor-management cooperation throughout ACF, including cooperative relationships at all appropriate levels.

The Parties recognize that although the work of the Committee may reduce the need for formal bargaining, the discussion of issues by the Committee does not relieve the Agency of its bargaining obligations under the Federal Labor-Management Relations Statute (the Statute), absent explicit agreement by the Union.

Principles

1. ACF allows employees through their union representatives to have pre-decisional involvement in workplace matters to the fullest extent practicable without regard to whether those matters are negotiable subjects of bargaining pursuant to 5 U.S.C. § 7106. Pre-decisional involvement takes place before the bargaining process.

2. The basic principles that underlie pre-decisional involvement are as follows:

- a. The pre-decisional process begins early: as soon as management identifies an issue or problem that it intends to address but before the scope of the problem has been defined or potential solutions are evaluated.
- b. Information is shared freely during the entire process.
- c. There is an understanding of confidentiality.
- d. The parties use interest-based problem solving.
- e. The parties must have a high degree of commitment to the process and to achieving their shared goals.

3. The Committee is responsible for reaching a common understanding on the structure of their pre-decisional involvement process.

4. Pre-decisional involvement does not waive management's statutory right to make decisions under 5 U.S.C. § 7106, nor does it waive the NTEU's right to engage in bargaining prior to implementation consistent with 5 U.S.C. § 7106. Either party retains the right to reject any recommendations and/or proposed agreements arrived at during discussions. It is understood that no agreement will become final and binding until the parties have signed a written agreement to memorialize the terms. Pre-decisional involvement may result in an agreement on an issue, which should be memorialized in a Memorandum of Understanding (MOU) that eliminates the need for further bargaining on the matter. Agency head review is required for any MOU that the parties propose.

5. ACF recognizes that bargaining unit employees represented by NTEU are an essential source of ideas and information

about the realities of achieving the ACF's mission. Their input generated through the Committee will assist management in making better informed decisions before making changes in working conditions that affect them. It is the intent of the parties that collaboration will result in less formal bargaining and/or fewer issues that must be referred to the collective bargaining process.

Structure

Composition

1. *Membership:* The Committee will consist of eight members, four NTEU representatives and four management representatives. All members of the Committee must be current and active employees of ACF. In addition, an Executive Secretary will be appointed by the Co-Chairs to perform administrative duties as directed by the Committee. The ACF Deputy Assistant Secretary for Administration and the NTEU National President, or their designees, will be considered ex officio members of the Committee. NTEU representatives will be appointed by the NTEU National President and management representatives will be appointed by the ACF Deputy Assistant Secretary for Administration or his/her designee. The parties will provide the names of appointed committee members and alternates as soon as possible, but no later than 30 days from the date of execution of this Charter. In the event that a committee member is no longer able to serve, a replacement member will be appointed as soon as possible, but no later than 30 days after the original committee member resigns. NTEU and ACF may each appoint one alternate. Alternates can participate fully in discussions but not in decisions. NTEU's representatives will be allocated appropriate official time to prepare for and participate in in the Committee, to include travel time to and from each meeting.

2. *Co-Chairs:* NTEU and ACF will each appoint a Committee Co-Chair for a term to be established individually by each entity.

3. *Guests:* NTEU and ACF may each invite two non-member guests per committee meeting. Guests may provide information and their individual views to the Committee and may fully participate in committee discussions, but will not be involved in the decision making process of the Committee and shall not be involved in making final recommendations to ACF management. Guests may vary per meeting, and may include, but are not limited to, individuals from NTEU's national office, retired/former federal government employees, and the Department's National Labor Relations Office.

Decision Making: All Committee members have equal status during Committee deliberations. The Committee has authority to recommend action to ACF management and NTEU. However, the Committee can only make decisions regarding recommendations when a quorum is present. A quorum exists when at least three representatives from labor and three representatives from ACF are present. When there is no quorum, meetings may still be held to discuss issues, however no decisions may be made. All decisions must be made by consensus. If consensus is

not reached, each party may use its statutory and other rights as specified in the "Preservation of Rights" section below. This decision making process will be evaluated by the Committee after one full year of its operation.

Meeting Schedule and Logistics: The Committee will meet on a quarterly basis or more frequently by consensus of its members. The Committee will normally meet at ACF Central Office in Washington, DC, but may also meet at another location by consensus. If a Committee member is unable to physically attend a meeting, he/she may participate by phone or video teleconferencing. The date and time for any meetings will be established by mutual agreement. Committee meetings may be held in conjunction with other meetings where it is deemed cost effective and there is consensus.

Working Groups: The Committee has the authority to form workgroups that may include individuals who are not members of the Committee. Any such workgroups will be given their charge and/or responsibilities from the LMC in writing. Non-Committee member bargaining unit participants on such groups will be appointed by NTEU and will be provided appropriate official time to participate in workgroup activities.

Support: The Committee will use the services of a facilitator trained in interest-based bargaining techniques as needed. The appointed Executive Secretary will provide administrative support to the Committee. Such support shall include creation and dissemination of meeting agenda and minutes, announcements of meetings, and other matters as determined by the Committee. The Agency will make available the use of video and telephone conferencing for the participation of all committee members at meetings. The Agency will provide meeting rooms for LMC meetings.

Participation: The Agency encourages the use of video and telephone conferencing for the participation of those members who are domiciled outside the 50 mile radius of Washington, DC, and will provide the necessary equipment to facilitate the process. Union representatives will be granted official time for preparation and participation in the meetings, pursuant to Article 10 of the Collective Bargaining Agreement. The Agency will pay for all reasonable local travel expenses, namely transportation and parking. For those participants domiciled outside the 50 mile radius, the Agency agrees to reimburse the Union representatives 50 percent of reasonable travel expenses, including transportation, lodging, and per diem.

In the interest of facilitating the working relations among the members, the Agency agrees to assume the full costs associated with travel, including transportation, lodging and per diem for participants for the first scheduled meeting of the Committee. For all subsequent meetings, the Agency will reimburse the Union representatives for 50 percent as stated above.

Agenda Development and Dissemination: The LMC's potential agenda items will be submitted to the Co-Chairs who will mutually establish a formal agenda for the

next LMC meeting. The formal agenda will be distributed to all LMC members at least three work days prior to the next LMC meeting. For issues requiring a decision by the LMC, all proposals or related materials will be distributed to the LMC members as soon as possible but no later than seven work days prior to the meeting at which the decision will need to be made.

Communication: Final, approved minutes of the Committee will be disseminated and made available to all ACF employees via methods determined by the Committee.

Evaluation

The Committee will evaluate its progress on an annual basis. It will determine whether to renew its procedures and/or to make changes in any aspect of the LMC.

Preservation of Rights

Cooperation is not intended to supplant the decision-making authority, or to usurp the responsibility of agency management, but to further involve ACF employees in developing ACF decisions through the active and systematic participation of NTEU and those it represents who perform ACF's work. This LMC is based on the belief that NTEU participation in ACF decision-making will promote decisions of such a nature that the need for formal bargaining will be reduced and, where bargaining becomes necessary, will inform and facilitate the negotiations.

Accordingly, subject to statute, executive orders, and the collective bargaining agreement, ACF reserves the right to determine whether to implement recommendations arising from the cooperation endeavor, and NTEU reserves the right to bargain concerning the substance, impact and implementation of final ACF decisions prior to implementation. The ACF recognizes its statutory, regulatory, and/or contractual obligations to provide notification to NTEU and to bargain.

Effective Date, Duration, and Modifications

This LMC shall be instituted upon the date the parties have signed the Charter. The partners may amend or supplement this Agreement at any time upon consensus. This Agreement may be terminated by either of the parties to this Agreement. Termination by either party shall be provided in writing and shall be considered effective exactly 30 calendar days after receipt by the recipient party. Notification of termination shall be sent out in a written notice to all ACF staff within 10 days of the termination and shall be published in the **Federal Register** within 30 days of the termination.

On behalf of NTEU and ACF, the undersigned execute this Agreement on this 30th day of December, 2016, by Anthony Reardon, NTEU National President; Mark H. Greenberg, Acting Assistant Secretary for Children and Families; and Benjamin Goldhaber, Deputy Assistant Secretary for Administration, Administration for Children and Families.

Dated: January 6, 2017.

Mark H. Greenberg,

Assistant Secretary for Children and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-1524]

Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities; Final Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a final guidance for industry entitled "Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities." This guidance describes the conditions under which FDA does not intend to take action for violations of certain provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), when a State-licensed pharmacy, a Federal facility, or an outsourcing facility repackages certain human drug products.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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").