

appointment to view public comments, phone 1 (800) 743-3951.

## I. Background

Organ Procurement Organizations (OPOs) are not-for-profit organizations that are responsible for the procurement, preservation, and transport of transplantable organs to transplant centers throughout the country. Qualified OPOs are designated by the Centers for Medicare & Medicaid Services (CMS) to recover or procure organs in CMS-defined exclusive geographic service areas, pursuant to section 371(b)(1) of the Public Health Service Act (42 U.S.C. 273(b)(1)) and our regulations at 42 CFR 486.306. Once an OPO has been designated for an area, hospitals in that area that participate in Medicare and Medicaid are required to work with that OPO in providing organs for transplant, pursuant to section 1138(a)(1)(C) of the Social Security Act (the Act) and our regulations at 42 CFR 482.45.

Section 1138(a)(1)(A)(iii) of the Act provides that a hospital must notify the designated OPO (for the service area in which it is located) of potential organ donors. Under section 1138(a)(1)(C) of the Act, every participating hospital must have an agreement to identify potential donors only with its designated OPO.

However, section 1138(a)(2)(A) of the Act provides that a hospital may obtain a waiver of the above requirements from the Secretary under certain specified conditions. A waiver allows the hospital to have an agreement with an OPO other than the one initially designated by CMS, if the hospital meets certain conditions specified in section 1138(a)(2)(A) of the Act. In addition, the Secretary may review additional criteria described in section 1138(a)(2)(B) of the Act to evaluate the hospital's request for a waiver.

Section 1138(a)(2)(A) of the Act states that in granting a waiver, the Secretary must determine that the waiver—(1) is expected to increase organ donations; and (2) will ensure equitable treatment of patients referred for transplants within the service area served by the designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement under the waiver. In making a waiver determination, section 1138(a)(2)(B) of the Act provides that the Secretary may consider, among other factors: (1) Cost-effectiveness; (2) improvements in quality; (3) whether there has been any change in a hospital's designated OPO due to the changes made in definitions for metropolitan statistical areas; and (4)

the length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO. Under section 1138(a)(2)(D) of the Act, the Secretary is required to publish a notice of any waiver application received from a hospital within 30 days of receiving the application, and to offer interested parties an opportunity to comment in writing during the 60-day period beginning on the publication date in the **Federal Register**.

The criteria that the Secretary uses to evaluate the waiver in these cases are the same as those described above under sections 1138(a)(2)(A) and (B) of the Act and have been incorporated into the regulations at § 486.308(e) and (f).

## II. Waiver Request Procedures

In October 1995, we issued a Program Memorandum (Transmittal No. A-95-11) detailing the waiver process and discussing the information hospitals must provide in requesting a waiver. We indicated that upon receipt of a waiver request, we would publish a **Federal Register** notice to solicit public comments, as required by section 1138(a)(2)(D) of the Act.

According to these requirements, we will review the request and comments received. During the review process, we may consult on an as-needed basis with the Health Resources and Services Administration's Division of Transplantation, the United Network for Organ Sharing, and our regional offices. If necessary, we may request additional clarifying information from the applying hospital or others. We will then make a final determination on the waiver request and notify the hospital and the designated and requested OPOs.

## III. Hospital Waiver Request

As permitted by § 486.308(e), the following hospital has requested a waiver in order to enter into an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located:

Pioneer Community Hospital (Medicare provider number 25-1302), of Aberdeen, Mississippi, is requesting a waiver to work with: Mississippi Organ Recovery Agency, 12 River Bend Place, Jackson, MS 39232.

The Hospital's Designated OPO is: Mid-South Transplant Foundation, Inc., 8001 Centerview Parkway, Suite 302, Memphis, TN 38018.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774, Medicare—Supplementary Medical Insurance, and Program No. 93.778, Medical Assistance Program)

Dated: December 14, 2011.

**Marilyn Tavenner,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Proposed Information Collection Activity; Comment Request

*Title:* Parents and Children Together (PACT) Evaluation.

*OMB No.:* New Collection.

*Description:* The Office of Planning, Research, and Evaluation (OPRE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing data collection activity as part of the Parents and Children Together (PACT) Evaluation.

The overall objective of the PACT evaluation is to document and evaluate Responsible Fatherhood (RF) and Healthy Marriage (HM) grants that were authorized under the 2010 Claims Resolution Act. This information will inform decisions related to future investments in this kind of programming as well as the design and operation of such services.

To meet the objective of the study, experimental impact studies with complementary implementation studies will be conducted, along with separate qualitative studies:

- *Impact studies, with complementary implementation studies.*

The goal of the impact component is to provide rigorous estimates of the effectiveness of the programs. This component will use an experimental design. Program applicants who are interested in and eligible for the RF or HM program will be randomly assigned to either a program group and be offered participation in the program, or a control group and not be offered participation in the program. Information will be collected twice for the impact component. First, baseline information will be collected from all fathers or couples prior to random assignment. Second, follow-up data will be collected from sample members at about 12 months after enrollment in the program. A wide range of outcomes (e.g., father involvement; parenting and co-parenting; economic self-sufficiency) will be evaluated. The goal of the complementary implementation component is to provide a detailed

description of the programs included in the impact study component—how they are implemented, their participants, the contexts in which they are operated, and their promising practices. The detailed descriptions will assist in interpreting program impacts and identifying program features and conditions necessary for effective program replication or improvement. Data collection for this component will include site visits, Management Information Systems (MIS), and partner organization surveys.

- *Qualitative studies.* The goal of the qualitative component is to provide a deeper understanding of the organizations operating RF and HM programs, as well as the lives of participants—their relationships, the challenges they face, the influences of the community in which they live, and how programs touch their lives. Data

collection for this component will include site visits, MIS, participant characteristics survey, partner organization surveys, nonparticipant telephone interviews, in-depth in-person conversations with program participants, and diary studies.

This 60-Day Notice covers (a) instruments for the impact studies' baseline, (b) site Management Information Systems (MIS) for the impact/implementation and qualitative studies, (c) program participant characteristics survey for the qualitative studies, and (d) a request for OMB to waive subsequent 60-day **Federal Register** notices pertaining to the PACT Evaluation.

#### Respondents

For the baseline, information will be collected from all fathers or couples prior to random assignment. Program

staff will be responsible for collecting and transferring the information.

For the Management Information Systems (MIS), program staff will be asked to record information on the services received by study participants in the impact/implementation and qualitative studies in the study MIS.

For the program participant characteristics survey in the qualitative studies, information will be collected from participants. Program staff will be responsible for collecting and transferring the information.

#### Annual Burden Estimates

A discussion guide, to assist in selecting sites for the impact/implementation and qualitative studies, is currently under review at OMB. A 60-Day **Federal Register** Notice for this instrument was published on August 12, 2011.

Instrument	Annual number of respondents	Number of responses per respondent	Average burden per response (minutes)	Total annual burden hours
Discussion guide for grantees and partner organization staff	150	1	60	150

The following instruments, part of the baseline data collection and site

Management Information Systems (MIS), are proposed for public comment

under this 60-Day **Federal Register** Notice.

Instrument	Annual number of respondents	Number of responses per respondent	Average burden per response (minutes)	Total annual burden hours
<b>Impact/Implementation Component</b>				
Baseline for program applicants .....	3,000	1	35	1,750
Baseline for grantee staff .....	30	100	35	1,750
Study MIS for grantee staff .....	30	5,200	2	5,200
<b>Qualitative Component</b>				
Study MIS for grantee staff .....	15	867	2	434
Program participant characteristics survey .....	250	1	25	104
Program participant characteristics survey for grantee staff ...	15	16.7	25	104
Total .....				9,342

Estimated Total Annual Burden Hours (for instruments currently under review and those associated with this 60-Day Notice): 9342.

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, 370 L'Enfant Promenade SW., Washington, DC 20447, 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.

**Robert Sargis,**

*Reports Clearance Officer.*

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