

hospitalizations for asthma (objective RD-2), reducing hospital emergency department visits for asthma (objective RD-3), reducing activity limitations among persons with asthma (objective RD-4), reducing the number of school or

work days missed by persons with asthma because of asthma (objective RD-5), increasing the proportion of persons with asthma who receive formal patient education (objective RD-6), and increasing the proportion of persons

with asthma who receive appropriate asthma care according to the NAEPP guidelines (objective RD-7). There are no costs to the respondents other than their time. The total estimated annual burden hours are 40 hours total.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Physician and Nurse .....	Screener .....	48	1	5/60
Physician .....	Interview .....	24	1	30/60
Nurse .....	Focus Group .....	24	1	1

Dated: December 14, 2011.

**Daniel Holcomb,**

*Reports Clearance Officer, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[CMS-1598-NC]

**Medicare and Medicaid Programs; Announcement of Application From Hospital Requesting Waiver for Organ Procurement Service Area**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice with comment period.

**SUMMARY:** This notice with comment period announces a waiver request from Pioneer Community Hospital to participate in an Organ Procurement Organization (OPO) outside of its designated OPO. The request was made in accordance with section 1138(a)(2) of the Social Security Act (the Act) which provides that a hospital may obtain a waiver from the Secretary under certain conditions. This notice solicits comments from OPOs and the general public for our consideration in determining whether we should grant the requested waiver.

**DATES:** *Comment Date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 21, 2012.

**ADDRESSES:** In commenting, please refer to file code CMS-1598-NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.
2. *By regular mail.* You may mail written comments to the following address *only*: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1598-NC, P.O. Box 8010, Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address *only*: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1598-NC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments only to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and

Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

*Submission of comments on paperwork requirements.* You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Kwana Johnson, (410) 786-3171.

**SUPPLEMENTARY INFORMATION:**

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an

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