

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 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 only with its designated OPO to identify potential donors.

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 submit comments during the 60-day comment 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 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 42 CFR 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:

Transplant Institute at Methodist Le Bonheur Healthcare of Memphis, Tennessee, is requesting a waiver to work with: Tennessee Donor Services, 1600 Hayes Street, Suite 300, Nashville, TN 37203.

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: April 18, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2012-9977 Filed 4-23-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: TANF Quarterly Financial Report, ACF-196.

OMB No.: 0970-0247.

Description: This information collection is authorized under Section 411(a)(3) of the Social Security Act. This request is for renewal of approval to use the Administration for Children and Families' (ACF) 196 form for periodic financial reporting under the Temporary Assistance for Needy Families (TANF) program. States participating in the TANF program are required by statute to report financial data on a quarterly basis. This form meets the legal standard and provides essential data on the use of Federal funds. Failure to collect the data would seriously compromise ACF's ability to monitor program expenditures, estimate funding needs, and to prepare budget submissions required by Congress. Financial reporting under the TANF program is governed by 45 CFR part 265. This renewal removes columns for reporting Emergency Contingency Fund and Supplemental Grant expenditures, as those funding streams are no longer available, and includes a requirement to

provide an addendum to the fourth quarter report to describe estimates used

in deriving any expenditures reported in any category.

Respondents: TANF Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF-196	51	4	8	1,632

Estimated Total Annual Burden Hours: 1,632.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: infocollection@acf.hhs.gov.

OMB Comment: 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. 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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012-9759 Filed 4-23-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage

for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT:

Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301-496-7057; fax: 301-402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Small-Molecule Modulators of Lipid Storage for Treatment of Obesity, Atherosclerosis, Metabolic Syndrome and Lipid Storage Diseases

Description of Technology: Lipid droplets are key organelles involved in lipid homeostasis. In normal physiology, these droplets are formed in response to elevated fatty acid levels, and are broken down when needed for energy production. Imbalances in lipid homeostasis trigger compensatory alterations in metabolism that can lead to diseases such as obesity, atherosclerosis, and metabolic syndrome. There are also a number of inherited lipid storage diseases that result in harmful buildup of various lipids, such as Gaucher disease, Fabry disease, and others. Reducing the accumulation of lipid droplets is a promising potential strategy for treatment of such disorders.

This technology describes three novel structural classes of small-molecule compounds that significantly reduce the accumulation of lipid droplets. These compounds hold promise for the treatment of diseases associated with aberrant lipid deposition.

Potential Commercial Applications:

- Treatment of inherited metabolic diseases such as Gaucher disease, Fabry disease, and Tay Sachs disease.
- Treatment of obesity and metabolic disease.
- Treatment of atherosclerosis.

Competitive Advantages: Modulation of lipid droplet accumulation is a novel mechanism for treatment of lipid storage diseases.

Development Stage:

- Early-stage
- In vitro data available

Inventors: Matthew Boxer et al. (NCATS).

Intellectual Property: HHS Reference No. E-277-2011/0—U.S. Provisional Patent Application No. 61/562,894 filed 22 Nov 2011.

Licensing Contact: Tara L. Kirby, Ph.D.; 301-435-4426; tarak@mail.nih.gov.

A Broadly Neutralizing Human Anti-HIV Monoclonal Antibody (10E8) Capable of Neutralizing Most HIV-1 Strains

Description of Technology: This Human Anti-HIV Monoclonal Antibody (10E8) has great potential to provide passive protection from infection, as a therapeutic vaccine, or as a tool for the development of vaccine immunogens. 10E8 is one of the most potent HIV-neutralizing antibodies isolated thus far and it can potentially neutralize up to 98% of genetically diverse HIV-1 strains. 10E8 is specific to the membrane-proximal external region (MPER) of the HIV envelope protein, GP41. It is anticipated that 10E8 could be used in combination with another human anti-HIV-1 monoclonal antibody to provide an antibody response that neutralizes nearly all strains of HIV-1. Additionally, 10E8 is a useful tool for the design of vaccine immunogens that can elicit an adaptive immune response to produces 10E8 like antibodies. This technology also includes monoclonal antibodies from the same germ line as 10E8.

Potential Commercial Applications:

- Passive protection to prevent HIV infection
- Passive protection to prevent mother-to-infant HIV transmission
- Topical microbicide to prevent HIV infection
- Gene-based vectors for anti-gp41 antibody expression
- Therapeutic for the elimination of HIV infected cells that are actively producing virus

Competitive Advantages: