

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 § 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 comment period beginning on the publication date of the notice in the **Federal Register**.

On June 11, 2010, we published a **Federal Register** notice (75 FR 33313) that established a public process for hospitals that had previously been granted a waiver under section 1138(a)(2) of the Act. Under the notice, a hospital may request approval to work with a different OPO.

II. Procedures for Requesting a Change in OPOs

For hospitals that had previously been granted a waiver request under section 1138(a)(2) of the Act but are now seeking to enter into an agreement with a different OPO, the hospital may file a request, by letter, to CMS containing the information set forth in the June 11, 2010 notice (75 FR 33313). Upon receipt of a request, we publish a **Federal Register** notice to solicit public comments, modeled after the procedures set forth in section 1138(a)(2)(D) of the Act.

Under these procedures, 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 request to change the OPO and notify the hospital and the OPOs involved.

III. Hospital Requests To Change OPOs

As permitted by the June 11, 2010 notice (75 FR 33313), the following hospital has requested to work with an OPO other than the OPO it had been designated to work through based on a previous waiver request:

OSF St. Anthony Medical Center of Rockford, Illinois, Provider Number 14-0233, is requesting to work with: Gift of Hope Organ & Tissue Donor Network, 425 Spring Lake Drive, Itasca, IL 60143.

OSF St. Anthony Medical Center has an existing waiver to work with: UW Health Organ Procurement Organization, 450 Science Drive, Suite 220, Madison, WI 53711.

(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: July 21, 2010.

Marilyn Tavenner

Principal Deputy Administrator and Chief Operating Officer, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0260]

Report: A New Approach to Targeting Inspection Resources and Identifying Patterns of Adulteration: The Reportable Food Registry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a report entitled "A New Approach to Targeting Inspection Resources and Identifying Patterns of Adulteration: The Reportable Food Registry." The report presents FDA's experience with the Reportable Food Registry (RFR or the Registry) from the opening of the Reportable Food electronic portal on September 8, 2009, until March 31, 2010.

ADDRESSES: Submit written requests for single copies of the report to the Office of Food Defense, Communication and Emergency Response (HFS-005), Center for Food Safety and Applied Nutrition,

Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the report.

FOR FURTHER INFORMATION CONTACT: Kathy Gombas, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1807.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Reportable Food Registry was created by Public Law 110-85 which mandated that the FDA establish an electronic portal to which industry must and public health officials may report when there is a reasonable probability that an article of human food or animal food/feed (including pet food) will cause serious adverse health consequences or death to humans or animals. The Congressional intent of the Registry is to help FDA better protect public health by tracking patterns of food and feed adulteration and targeting inspection resources. This report presents FDA's experience with the RFR from the opening of the Reportable Food electronic portal on September 8, 2009, until March 31, 2010. Because the Registry has been operational for only a short period, FDA cautions that it is too early to draw inferences concerning patterns of food and feed adulteration.

II. Background

The RFR was established by section 1005 of the Food and Drug Administration Amendments Act of 2007 (Public Law 110-85) which amended the Federal Food, Drug, and Cosmetic Act by creating a new section 417, Reportable Food Registry (21 U.S.C. 350f), and required FDA to establish an electronic portal by which reports about instances of reportable food must be submitted to FDA within 24 hours by responsible parties and may be submitted by public health officials. These reports may be *primary*, the initial submission about a reportable food, or *subsequent*, a report by either a supplier (upstream) or a recipient (downstream) of a food or food ingredient for which a primary report has been submitted.

The RFR covers all human and animal food/feed (including pet food) regulated by FDA except infant formula and dietary supplements. Other mandatory reporting systems exist for problems with infant formula and dietary supplements. Submissions to the

Reportable Food electronic portal provide early warning to FDA about potential public health risks from reportable foods and increase the speed with which the agency and its partners at the State and local levels can investigate the reports and take appropriate followup action, including ensuring that the reportable foods are removed from commerce when necessary.

The RFR does not receive reports about drugs or other medical products, reports about products under the exclusive jurisdiction of the U.S. Department of Agriculture, or reports from consumers.

The RFR is helping FDA better protect public health by tracking patterns of adulteration in human and animal food/feed (including pet food). The report presents FDA's experience with the RFR from the opening of the Reportable Food electronic portal on September 8, 2009, until March 31, 2010.

III. Electronic Access

Persons with access to the Internet may obtain the report at <http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/RFR/ucm200958.htm>.

Dated: July 12, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Intent To Request Renewal From OMB of One Current Public Collection of Information: Sensitive Security Information Threat Assessments

AGENCY: Transportation Security Administration, DHS.

ACTION: 60-day notice.

SUMMARY: The Transportation Security Administration (TSA) invites public comment on one currently approved Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652-0042, abstracted below that we will submit to OMB for renewal in compliance with the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. The collection involves TSA determining whether the party or representative of a party seeking access to sensitive security information (SSI) in

a civil proceeding in federal court may be granted access to the SSI.

DATES: Send your comments by September 28, 2010.

ADDRESSES: Comments may be e-mailed to TSAPRA@dhs.gov or delivered to the TSA PRA Officer, Office of Information Technology (OIT), TSA-11, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598-6011.

FOR FURTHER INFORMATION CONTACT: Joanna Johnson at the above address, or by telephone (571) 227-3651.

SUPPLEMENTARY INFORMATION:

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation is available at www.reginfo.gov. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

TSA is seeking to renew the control number (1652-0042) for the maximum three-year period in order to continue compliance with sec. 525(d) of the Department of Homeland Security Appropriations Act of 2007 (DHS Appropriations Act, Public Law 109-295, 120 Stat 1382), as reenacted, and to continue the process TSA developed whereby a party seeking access to SSI in a civil proceeding in federal court who demonstrates a substantial need for relevant SSI in the preparation of the party's case, and who is unable without undue hardship to obtain the substantial equivalent of the information by other means, may request that the party or party's representative be granted conditional access to the SSI at issue in the case. The procedures also apply to