TRANSACTION GRANTED EARLY TERMINATION—Continued

ET date	Trans. No.	ET req status	Party name
		G	Northrop Grumman Corporation.
		G	TASC, Inc.
	20100177	G	The Edward W. Scripps Trust.
		G	TCM Parent, LLC.
		G	TCM Parent, LLC.
	20100210	G	TeleCommunication Systems, Inc.
		G	Networks in Motion, Inc.
		G	Networks in Motion, Inc.
	20100218	G	Odyssey Investment Partners Fund IV, L.P.
		G	TA IX L.P.
		G	One Call Medical, Inc.
	20100219	G	Excellere Capital Fund, L.P.
		G	Med Tech Holdings, Inc.
		G	Med Tech College, L.L.C.
	20100225	G	Mitsui Sumitomo Insurance Group Holdings, Inc.
		G	Aioi Insurance Company, Limited.
		G	Aioi Insurance Company, Limited.
	20100226	G	Odyssey Investment Partners Fund IV, L.P.
		G	New S Corp. I, Inc.
		G	Wencor Holdings LLC.
	20100230	G	JPMorgan Chase & Co.
		G	HTS Stiftung.
		G	Constantia Packaging AG.
	20100232	G	Trow Global Holdings Inc.
		G	Ivan Dvorak.
		G	Teng & Associates, Inc.
	20100233	G	Carl C. Icahn.
		G	Tropicana Entertainment Inc.
		G	Tropicana Entertainment Inc.
	20100235	G	H.I.G Capital Partners IV, LP.
		G	Tennessee Valley Ventures, L.P.
		G	Food Holdings, Inc.
		G	Southern Quality Meats, Inc.
	20100236	G	People's United Financial, Inc.
		G	Financial Federal Corporation.
		G	Financial Federal Corporation.
11–DEC–09	20100238	G	Berkshire Hathaway Inc.
		G	American Electric Power Company, Inc.
		G	AEP Texas Central Company.
		G	AEP Texas North Company.
	20100242	G	The Procter & Gamble Company.
		G	MDVIP, Inc.
		G	MDVIP, Inc.

FOR FURTHER INFORMATION CONTACT: Sandra M. Peay, Contact Representative or Renee Hallman, Contact Representative, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room H–303, Washington, DC 20580, (202) 326–3100.

By Direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. E9–31207 Filed 1–5–10; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Extramural Support Reimbursement of Travel and Subsistence Expenses Toward Living Organ Donation Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Request for Information.

SUMMARY: Congress has provided specific authority under section 377 of the Public Health Service (PHS) Act, 42 U.S.C. 274f, as amended by Public Law 108–216 for providing reimbursement of travel and subsistence expenses for certain individuals donating their organs. Additionally, Congress authorized the Secretary to provide reimbursement for other incidental non-medical expenses as the Secretary determines by regulation to be appropriate.

Accordingly, under the existing Program launched in October 2007, individuals who meet Program eligibility guidelines may receive reimbursement for qualifying travel and subsistence expenses related to live organ donation. The existing Program

structure is based on Section 377(a)(1) of the PHS Act. This section explicitly allows the Secretary to provide reimbursement of travel and subsistence expenses incurred by living organ donors. HRSA wishes to implement Section 377(a)(2) of the PHS Act which authorizes the Secretary to issue regulations describing other incidental nonmedical expenses appropriate for reimbursement under this Program. The Department is considering initiating rulemaking proposing that reimbursement be extended to additional expenses incurred by living donors as ''incidental nonmedical expenses'' under 42 U.S.C. 274f(a)(2).

Before initiating such rulemaking, HRSA is soliciting input from the community on specific incidental nonmedical expenses to be considered for reimbursement. HRSA is looking for guidance from the community on the mechanism(s) to determine the appropriate reimbursement amount for these additional expenses and to validate that donors incurred or will incur these additional expenses as a result of making living donations of their organs. For example, if the community thinks lost wages and childcare expenses are incidental nonmedical expenses the Program should consider for reimbursement, how much the Program should reimburse donors for these expenses and on what basis should this determination be made?

Individuals can send their comments either by mail, fax, or email to the Division of Transplantation at the address listed below. In addition, the Division plans to sponsor three conference calls to discuss the Program.

DATES: To be considered, written comments must be postmarked no later than March 22, 2010. The conference calls will be held on Tuesday, February 23, 2010 from 10 a.m. to 11:30 a.m.; Wednesday, February 24, 2010 from 2:30 p.m. to 4 p.m.; and Friday, March 5, 2010 from 1 p.m. to 2:30 p.m. All listed times are eastern standard times. Participants must register for the conference calls by contacting Richard Laeng, Public Health Analyst, at (301) 443–5410 or e-mail *rlaeng@hrsa.gov.* The registration deadline is Thursday, February 18, 2010. Because the same information will be discussed on all the calls, it is not necessary to register for multiple calls. Registration is not guaranteed; it is on a first come basis.

ADDRESSES: Please send all written comments to Mesmin Germain, Public Health Analyst, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, Department of Health and Human Services, Room 12C–06, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; telephone: (301) 443–0053; fax: (301) 594–6095; e-mail: *mgermain@hrsa.gov.*

FOR FURTHER INFORMATION CONTACT: Mesmin Germain, Public Health Analyst, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, Department of Health and Human Services, Room 12C–06, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; telephone: (301) 443–0053; fax: (301) 594–6095; e-mail: *mgermain@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

Background

On September 14, 2006, HRSA awarded a 4-year cooperative agreement to the Regents of the University of Michigan to establish a national Program to provide reimbursement to living donors for travel and subsistence expenses, as well as additional expenses authorized by any future regulations issued by the Secretary. The Regents of the University of Michigan in partnership with the American Society of Transplant Surgeons (ASTS) established the National Living Donor Assistance Center (NLDAC) to operate this national Program.

On October 17, 2007, The Regents of the University of Michigan and ASTS officially launched NLDAC. NLDAC is located at the ASTS Headquarter in Arlington, Virginia. NLDAC has officially partnered with 299 living transplant programs throughout the United States to submit applications for reimbursement on behalf of their living donors. Applications are filed through the transplant centers and reviewed by a committee at NLDAC. Program eligibility is based on donor and recipient incomes of 300 percent or less of the HHS Poverty Guidelines. Applicants who do not meet eligibility guidelines may request a waiver. All waiver requests are reviewed for approval by HRSA. The Program provides prospective reimbursement to living donors based on the estimated travel expenses related to the donation process. Funds are provided through a controlled value card, giving NLDAC the ability to add and subtract funds as needed. All expenses are monitored in real time by NLDAC to ensure that donors are using funds according to Program guidelines.

HRSA sought input from the public from the conceptual stage of the Program through the determination of the Program's final eligibility criteria to ensure that the Program addresses the needs of the public:

- On October 13, 2005, HRSA published a Request for Public Comments on the proposed Program to provide reimbursement of travel and subsistence expenses in the **Federal Register** (70 FR 59760).
- On April 9, 2007, HRSA published a Request for Public Comments concerning the proposed Program eligibility criteria in the **Federal Register** (72 FR 17564).
- On October 5, 2007, HRSA published a Response to Solicitation of Comments and Final Program Eligibility Guidelines in the **Federal Register** (72 FR 57049).
- On March 5, 2008, HRSA published a Request for Public Comments on proposed changes to the reimbursement of travel and subsistence expenses Program eligibility criteria (concerning additional follow-up visits for donors) in the **Federal Register** (73 FR 11930).
- On June 20, 2008, HRSA published a change to Program eligibility guidelines to provide reimbursement for additional follow-up visits for donors in the **Federal Register** (73 FR 35143).
- On March 4, 2009, HRSA published a Request for Public Comments on a proposed change to the Program eligibility criteria (concerning the follow-up period) in the **Federal Register** (74 FR 9407).
- On June 19, 2009, HRSA published an amendment to Program eligibility guidelines to extend follow-up period that donors may receive reimbursement for qualifying expenses in the **Federal Register** (74 FR 29218).

Through September 30, 2009, the Program has facilitated 370 living organ transplants. Overall, 697 applications have been approved for funding under the established Program eligibility guidelines. The average reimbursement per living donor is approximately $2,600.

HRSA initiated this Program to address the travel and subsistence expenses faced by potential donors, recipients, and family alike. Even with this support, living donors still face other financial barriers related to the donation process.

Reimbursement of other incidental nonmedical expenses being considered would further diminish the financial barriers faced by many donors. Reimbursement for the additional expenses would be provided while maintaining the existing Program guidelines, including capping total reimbursement per donor and companions at $6,000. The expansion will be provided under the Qualified

Expenses Section of the Program Eligibility Guidelines.

Any payment permitted under this authority must not violate section 301 of the National Organ Transplant Act of 1984, which makes it ''unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.'' 42 U.S.C. 274e(a). Certain expenses are excluded from the scope of valuable consideration, including ''expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ.'' 42 U.S.C. 274e(c)(2). As the Secretary considers rulemaking, she will consider this criminal prohibition in evaluating which expenses are appropriate for reimbursement under this Program.

HRSA is seeking public comment as to whether the Secretary should initiate rulemaking to allow reimbursement under this Program for specific incidental nonmedical expenses and concerning which incidental nonmedical expenses should be included in such rulemaking.

Dated: December 29, 2009.

Mary K. Wakefield,

Administrator.

[FR Doc. E9–31312 Filed 1–5–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0525]

Guidance for Industry on New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products,'' dated December 2009. As part of the Medical Device User Fee Amendments of 2007 (MDUFA) Commitment for the Performance Goals and Procedures commitment letter, FDA agreed to publish guidance for medical imaging devices for use with imaging contrast agents or radiopharmaceuticals. FDA intends this guidance to assist developers of medical imaging devices and imaging drug/biological products that provide image contrast enhancement. The final guidance announced in this document fulfills FDA's commitment to issue guidance called for by the commitment letter. The guidance supercedes the draft guidance of the same title dated September 30, 2008.

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

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Patricia Y. Love, Office of Combination Products (HFG–3), Office of the Commissioner, Food and Drug Administration, 15800 Crabbs Branch Way, Rockville, MD 20855, 301–427–1934.

SUPPLEMENTARY INFORMATION:

I. Background

As part of the Medical Device User Fee Amendments of 2007 (MDUFA) Commitment for the Performance Goals and Procedures, Item I.N of the September 27, 2007, commitment letter, FDA agreed to publish draft guidance by September 30, 2008, for medical imaging devices for use with imaging contrast agents or radiopharmaceuticals. Further, the agreement stated that the ''draft guidance will be published by the end of FY 2008, and will be subject to a 90-day comment period. FDA will issue a final guidance within one year of the close of the public comment period.'' The draft guidance was dated September 30, 2008 (73 FR 58604, October 7, 2008); the comment period closed on January 5, 2009. FDA held meetings with imaging industry stakeholders in July 2008 and August 2009. The final guidance announced in this document fulfills FDA's commitment to issue final guidance called for by the commitment letter. The guidance supercedes the draft guidance of the same title dated September 30, 2008.

FDA is announcing the availability of guidance for industry entitled ''New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products.'' FDA intends this guidance to assist developers of medical imaging devices and imaging drug/biological products that provide image contrast enhancement. Particularly, this guidance focuses on the following topics: (1) When the imaging device developers may add certain new imaging contrast indications to their device for use with already approved imaging drugs without a need for a modification of the drug labeling, (2) when the imaging drug developers may add certain new imaging contrast indications to their drug for use with already approved imaging devices without a need for a modification of the device labeling, and (3) what type of marketing submission(s) imaging drug or imaging device developers should submit to FDA to request approval/clearance to add a new imaging contrast indication. FDA intends for the recommendations in this guidance to promote timely and effective review of, and consistent and appropriate regulation and labeling for imaging drugs and devices.

FDA notes that during the comment period, certain topics identified in the docket were beyond the scope of the guidance document. These comments included requests for guidance on developing specific medical imaging indications (e.g., myocardial perfusion or breast cancer imaging) and offered suggestions for the type of acceptable data. FDA will consider whether separate guidance would be appropriate.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on ''New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products''. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 807 have been approved under