In an effort to develop drug products that are more convenient to use and to address potential issues of patient compliance for certain product indications and patient populations, pharmaceutical manufacturers have developed products that can be ingested simply by placing them on the tongue. The products are designed to disintegrate or dissolve rapidly on contact with saliva, thus eliminating the need for chewing the tablet, swallowing an intact tablet, or taking the tablet with water. This mode of administration was initially expected to be beneficial to pediatric and geriatric patients, to people with conditions related to impaired swallowing, and for treatment of patients when compliance may be difficult (e.g., for psychiatric disorders).

As firms started developing additional products using different technology and formulations, many of these later products exhibited wide variation in product characteristics from the initial products. Because this shift in product characteristics can affect a product's suitability for particular uses, the agency developed this guidance for industry.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on orally disintegrating tablets. 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.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: March 30, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–6509 Filed 4–6–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Council on Graduate Medical Education; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Council on Graduate Medical Education (COGME).

Dates and Times: April 30, 2007, 8:30 a.m.– 5 p.m.; and May 1, 2007, 8:30 a.m.–2:30 p.m.

Place: Hilton Washington, DC/Rockville Executive Meeting Center, 1750 Rockville Pike, Rockville, Maryland 20852–1699.

Status: The meeting will be open to the public.

Agenda: The agenda for April 30 in the morning will include: Welcome and opening comments from the Chair and Executive Secretary of COGME and senior management staff of the Health Resources and Services Administration.

On April 30, following the welcoming remarks from the COGME Chair, the Executive Secretary of COGME, and Agency senior management, there will be a review and discussion of the draft paper ''Enhancing GME Flexibility,'' by Barbara Chang, M.D., and other writing group members. After lunch there will be a review and discussion of the draft paper ''New Paradigms for Physician Training for Improving Access to Healthcare'' by Earl Reisdorff, M.D. and other writing group members. At 3 p.m. there will be a breakout of Council members into the two draft writing groups for further report revisions.

On May 1 there will be reports to the Council and further discussion on writing group activities and reports. The Council will conclude with a discussion of the timeframe and next steps for producing the Reports.

Agenda items are subject to change as priorities dictate.

FOR FURTHER INFORMATION CONTACT: Jerald M. Katzoff, Executive Secretary, COGME, Division of Medicine and Dentistry, Bureau of Health Professions, Parklawn Building, Room 9A–27, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–6785.

Dated: April 2, 2007.

Caroline Lewis,

Acting Associate Administrator for Administration and Financial Management.

[FR Doc. E7–6597 Filed 4–6–07; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Reimbursement of Travel and Subsistence Expenses Toward Living Organ Donation Proposed Eligibility Guidelines

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Request for Public Comment.

SUMMARY: HRSA is soliciting comments on the proposed eligibility criteria for the *Reimbursement of Travel and Subsistence Expenses toward Living Organ Donations* Program. Eligibility criteria were proposed by the program grantee, the Regents of the University of Michigan, to HRSA. HRSA has determined that the proposed eligibility criteria constitute a proper interpretation of the authorizing statute's requirements, including determinations as to which individuals would otherwise be unable to meet the eligible expenses authorized under this Program. HRSA is soliciting public comment on the criteria outlined in this notice. HRSA will consider the comments in light of the authorizing statute and seek feedback from the Regents of the University of Michigan concerning the comments. HRSA will then approve final criteria. The final program eligibility criteria will be posted on the Reimbursement of Travel and Subsistence Expenses for Living Organ Donation Web site, *http://www.livingdonorassistance.org*.

DATES: Written comments must be submitted to the office in the address section below by mail or e-mail on or before May 24, 2007.

ADDRESSES: Please send all written comments to James F. Burdick, M.D., Director, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, Room 12C–06, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443–7577; fax (301) 594–6095; or e-mail: *jburdick@hrsa.gov*.

FOR FURTHER INFORMATION CONTACT: James F. Burdick, M.D., Director, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 12C–06, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443–7577; fax (301) 594–6095; or e-mail: *jburdick@hrsa.gov*.

SUPPLEMENTARY INFORMATION: Congress has provided specific authority under

section 377 of the Public Health Service (PHS) Act, as amended, 42 U.S.C. 274f, for providing reimbursement of travel and subsistence expenses for certain living organ donors, with preference for those for whom paying such expenses would create a financial hardship. On September 25, 2006, HRSA awarded a 4-year, $8,000,000, Cooperative Agreement to the Regents of the University of Michigan to establish this program.

The authorizing statute stipulates that the Secretary, in carrying out this program, shall give preference to those individuals that the Secretary determines are more likely to be otherwise unable to meet such expenses. HRSA asked the grantee to propose eligibility criteria to HRSA to satisfy this requirement.

The two main issues raised in developing the program eligibility criteria are:

(1) Which criteria should be used to identify potential living organ donors who may be unable to pay for travel and subsistence expenses associated with living organ donation? This issue is important because such donors are to receive priority under this program; and

(2) Which criteria should be established to assess the potential organ recipient's ability to pay the living donor's travel and subsistence expenses? This determination is significant because the authorizing statute provides that payments are not to be made if a donor's eligible expenses have been, or reasonably can be expected to be, paid by the organ recipient.

This program is intended for individuals with end stage organ failure for whom a transplant from a suitable living donor is a viable therapy. The purpose of this solicitation of comments is to obtain feedback from the public on the proposed eligibility criteria. These comments are important to assure that the needs and concerns of the general public, including its views as to the optimal means of carrying out the program's objectives, are addressed. After considering the comments, HRSA will approve final criteria, which will be posted on the Reimbursement of Travel and Subsistence Expenses for Living Organ Donation Web site, *http://www.livingdonorassistance.org.*

Proposed Eligibility Guidelines

The program's authorizing legislation explicitly states that funds ''will not be expended to pay the qualifying expenses of a donating individual to the extent that payment has been made, or can reasonably be expected to be made, with respect to such expenses:

(1) Under any State compensation program, under an insurance policy, or under any Federal or State health benefits program;

(2) By an entity that provides health services on a prepaid basis; or

(3) By the recipient of the organ.''

In implementing this authority, the proposed threshold of income eligibility for the recipient of the organ is 200% of the HHS Poverty Guidelines (described below). At any income above this measure, it can reasonably be expected that the recipient of the organ could pay for the donor's qualifying expenses. However, the transplant social worker or appropriate transplant center personnel involved in the potential transplant recipient's evaluation process can provide a written justification that notwithstanding the potential transplant recipient's income level, significant financial hardship is likely to be encountered by the potential transplant recipient of the organ for the payment of the donor's qualifying expenses in the course of the donation process. This justification will be given consideration by the program's Review Committee.

All live organ donors are eligible for reimbursement of qualifying expenses provided all the criteria for donor reimbursement are fulfilled. However, subject to availability of funds, preference will be given to donors who are more likely to be otherwise unable to meet the qualifying expenses, in the following proposed order of priority:

Preference Category 1: Donor income and recipient anticipated income each is ≤200% of the HHS Poverty Guidelines in their respective States of primary residence.

Preference Category 2: Donor income is ≤200% of the HHS Poverty Guidelines in the State of primary residence.

Preference Category 3: Recipient anticipated income is ≤200% of the HHS Poverty Guidelines in the State of primary residence.

Preference Category 4: Donors who can demonstrate that notwithstanding their income level, significant financial hardship is likely to be encountered for qualifying non-medical expenses in the course of the donation process.

Preference Category 5: Any live organ donor, notwithstanding income level or financial hardship, who meets the criteria for donor reimbursement.

Recipient anticipated income is the total income from all sources that the recipient is expected to receive in the year in which live donor organ transplantation will occur for the patient with previous existing organ failure or the subsequent calendar year after the year of onset of end stage organ failure for a new patient with end stage organ failure. The HHS Poverty Guidelines are updated periodically and the guidelines in effect at the time of application will be applied. As an illustration, the HHS Poverty Guidelines for 2006 (71 Fed. Reg. 3848) are shown in the table below.

2006 HHS POVERTY GUIDELINES

Persons in family or household	48 Contiguous states and DC	Alaska	Hawaii
1	$9,800	$12,250	$11,270
2	13,200	16,500	15,180
3	16,600	20,750	19,090
4	20,000	25,000	23,000
5	23,400	29,250	26,910
6	26,800	33,500	30,820
7	30,200	37,750	34,730
8	33,600	42,000	38,640
For each additional person, add	3,400	4,250	3,910

Source: 71 FR 3848 (Jan. 24, 2006).

Proposed Criteria for Donor Reimbursement

In addition to the eligibility and priority guidelines discussed above, the following criteria for donor reimbursement are proposed:

1. Any individual who in good faith incurs qualifying expenses toward the intended donation of an organ but with respect to whom, for such reasons as the Secretary determines to be appropriate, no donation of the organ occurs (see special provision). This criteria is specifically discussed in the authorizing statute.

2. Donor and recipient of the organ are either U.S. citizens or lawfully admitted residents of the U.S.

3. Donor and recipient have primary residence in the U.S. or its territories.

4. Travel is originating from the donor's primary residence.

5. Donor meets the criteria for informed consent for the planned procedure according to applicable State and Federal laws.

6. Donor and recipient are not participating in a paired exchange program or a living donor/deceased donor exchange for the particular donation procedure for which reimbursement is being sought unless the legality of such practices is clarified by the Federal Government.

7. Donor and recipient attest to full compliance with section 301 of the National Organ Transplant Act (NOTA), as amended (42 U.S.C. 274e) which stipulates in part that '' * * * [i]t shall be 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.''

8. The transplant center where the donation procedure occurs attests to its status of good standing with the Organ Procurement and Transplantation Network (*i.e.*, it is not a Member Not in Good Standing) and assurance that the program follows best practices for the health and safety of living donors such as the recommendations provided in the Consensus Statement of the Ethics Committee of the Vancouver Forum on living organ donation (Source: *Pruett TL, Tibell A, Alabdulkareem A, Bhandari M, Cronin DC, Dew MA, Dib-Kuri A, Gutmann T, Matas A, McMurdo L, Rahmel A, Rizvi SA, Wright L, Delmonico FL. The ethics statement of the Vancouver Forum on the live lung, liver, pancreas, and intestine donor.* Transplantation 81(10):1386–1387; (2006).

The public is invited to submit comments on these criteria.

Proposed Qualifying Expenses

For the purpose of the Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation Program, qualifying expenses presently include only travel, lodging, and meals and incidental expenses incurred by the donor and/or accompanying person(s) as part of:

(1) Donor evaluation clinic visit or hospitalization;

(2) Hospitalization for the living donor surgical procedure; and/or

(3) Medical or surgical follow-up clinic visit or hospitalization within 90 days after the living donation procedure.

The Program will pay for up to five trips per donation or intended donation. Three of these trips may be for the potential living donor and up to two trips may be for any accompanying person(s). The total Federal reimbursement for qualified expenses during the donation process for the donor and accompanying individuals shall not exceed $6,000.

The public is invited to submit comments on these criteria.

Special Provisions

The authorizing statute provides that the Secretary may consider as an eligible donating individual a person who in good faith incurs qualifying expenses toward the intended donation of an organ but with respect to whom, for reasons the Secretary determines to be appropriate, no donation of the organ occurs. Many factors may prevent the intended and willing donor from proceeding with the donation. Such circumstances include present health status of the intended donor or recipient that would prevent the transplant or donation from proceeding, perceived long-term risks to the intended donor, circumstances such as acts of God (e.g., major storms or hurricanes), or other unforeseen events outside of the intended donor's control. In such cases, the intended donor and accompanying persons may receive reimbursement for the qualified expenses incurred. In the case that a potential donor no longer wishes to donate, he or she may receive reimbursement for qualified expenses incurred. However, payments received for expenses that were not incurred by the intended donor and accompanying persons must be refunded. Otherwise, such payment will be treated as income to the intended donor, and in accordance with Internal Revenue Service (IRS) regulations, the Regents of the University of Michigan shall notify the IRS (Form 1099) that a payment has been made to the intended donor in the amount equivalent to the unexpended payment.

Dated: March 30, 2007.

Elizabeth M. Duke,

Administrator.

[FR Doc. E7–6598 Filed 4–6–07; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Establishment; Pursuant to the Federal Advisory Committee Act, as Amended (5 U.S.C. Appendix 2), the Director, National Institutes of Health (NIH), Announces the Establishment of the Council of Councils (Council)

The Council shall provide advice and recommendations to the Director, NIH, or other appropriate delegated officials on matters related to the policies and activities of the Division of Program Coordination, Planning, and Strategic Initiatives including making recommendations with respect to the conduct and support of research that represents important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that deserve special emphasis and would benefit from conducting or supporting additional research that involves collaboration between two or more national research institutes or national centers, or would otherwise benefit from strategic coordination and planning.

Duration of this committee is two years from the date the Charter is filed.

Dated: March 29, 2007.

Elias A. Zerhouni,

Director, National Institutes of Health.

[FR Doc. 07–1730 Filed 4–6–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and