DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Interest Rate on Overdue Debts

Section 30.18 of the Department of Health and Human Services' claims collection regulations (45 CFR part 30) provides that the Secretary shall charge an annual rate of interest, which is determined and fixed by the Secretary of the Treasury after considering private consumer rates of interest on the date that the Department of Health and Human Services becomes entitled to recovery. The rate cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the ''Schedule of Certified Interest Rates with Range of Maturities.'' The Secretary of the Treasury may revise this rate quarterly. The Department of Health and Human Services publishes this rate in the **Federal Register**.

The current rate of 10 7/8%, as fixed by the Secretary of the Treasury, is certified for the quarter ended September 30, 2009. This interest rate is effective until the Secretary of the Treasury notifies the Department of Health and Human Services of any change.

Dated: October 30, 2009.

Molly P. Dawson,

Director, Office of Financial Policy and Reporting.

[FR Doc. E9–27022 Filed 11–9–09; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; HIT Standards Committee Advisory Meeting; Notice of Meeting

AGENCY: Office of the National Coordinator for Health Information Technology, HHS.

ACTION: Notice of meeting.

This notice announces a forthcoming meeting of a public advisory committee of the Office of the National Coordinator for Health Information Technology (ONC). The meeting will be open to the public.

Name of Committee: HIT Standards Committee.

General Function of the Committee: To provide recommendations to the National Coordinator on standards, implementation specifications, and certification criteria for the electronic exchange and use of health information for purposes of adoption, consistent with the implementation of the Federal Health IT Strategic Plan, and in accordance with policies developed by the HIT Policy Committee.

Date and Time: The meeting will be held on November 19, 2009, from 9 a.m. to 5:15 p.m. Eastern Time.

Location: The Holiday Inn-Capitol, 550 C Street, SW., Washington, DC 20008. The hotel telephone number is 202–479–4000.

Contact Person: Judy Sparrow, Office of the National Coordinator, HHS, 330 C Street, SW., Washington, DC 20201, 202–205–4528, Fax: 202–690–6079, e-mail: *judy.sparrow@hhs.gov.* Please call the contact person for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

Agenda: The Committee will discuss a report from its Implementation Workgroup. In addition, to inform the Committee they will hear testimony from stakeholder groups on security standards. ONC intends to make background material available to the public no later than two (2) business days prior to the meeting. If ONC is unable to post the background material on its Web site prior to the meeting, it will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on ONC's Web site after the meeting, at *http://healthit.hhs.gov.*

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 16, 2009. Oral comments from the public will be scheduled between approximately 4:30 and 5 p.m. Time allotted for each presentation will be limited. If the number of speakers requesting to comment is greater than can be reasonably accommodated during the scheduled open public hearing session, ONC will take written comments after the meeting until close of business.

Persons attending ONC's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

ONC welcomes the attendance of the public at its advisory committee meetings. Seating is limited at the location, and ONC will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Judy Sparrow at least seven (7) days in advance of the meeting.

ONC is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://healthit.hhs.gov* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App. 2).

Dated: October 30, 2009.

Judith Sparrow,

Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

[FR Doc. E9–26981 Filed 11–9–09; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Full Committee Meeting.

Time and Date:

November 19, 2009 9 a.m.–3:30 p.m.

November 20, 2009 9:30 a.m.–12:30 p.m.

Place: National Center for Health Statistics, 3311 Toledo Road, Hyattsville, MD 20782, Telephone: 301 458–4200.

Status: Open.

Purpose: At this meeting the Committee will hear presentations and hold discussions on several health data policy topics. On the morning of the first day, the Committee will hear updates from the Department, the HHS Data Council, and the Centers for Medicare and Medicaid Services. A discussion of the Meaningful Measures letter action item led by the Quality Subcommittee will also take place. There will also be a briefing on the Department's work on comparative effectiveness research under the Recovery Act. In the afternoon, a discussion is scheduled regarding enhancing health information capacity in the 21st century.

On the morning of the second day, an action item is scheduled on the Meaningful Measures letter. Updates are planned from the Office of the National Coordinator (ONC) and the Office for Civil Rights (OCR), and a review of a draft of the biannual report to Congress on the implementation of the Administrative Simplification Provisions of HIPAA. Also scheduled are an update from NCHS Board of Scientific Counselors and a status report regarding the NVCHS 60th Anniversary Symposium.

The times shown above are for the full Committee meeting. Subcommittee breakout sessions can be scheduled for late in the afternoon of the first day and second day and in the morning prior to the full Committee

meeting on the second day. Agendas for these breakout sessions will be posted on the NCVHS Web site (URL below) when available.

Contact Person for More Information: Substantive program information as well as summaries of meetings and a roster of committee members may be obtained from Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, telephone (301) 458–4245. Information also is available on the NCVHS home page of the HHS Web site: *http://www.ncvhs.hhs.gov/,* where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458–4EEO (4336) as soon as possible.

Dated: November 2, 2009.

James Scanlon,

Deputy Assistant Secretary for Planning and Evaluation, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. E9–27023 Filed 11–9–09; 8:45 am]

BILLING CODE 4151–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0528]

International Conference on Harmonisation; Draft Guidance on E7 Studies in Support of Special Populations; Geriatrics; Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''E7 Studies in Support of Special Populations: Geriatrics; Questions & Answers.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft questions and answers (Q&A) guidance addresses the representation of geriatric patients in the clinical database, including representation of special characteristics of the geriatric patient population. The Q&As are intended to provide guidance on this issue.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance by January 11, 2010.

ADDRESSES: Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the draft 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; or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Nisha Jain, Center for Biologics Evaluation and Research (HFM–392), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20850, 301–827–6110; or Robert Temple, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4212, 301–796–2270.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In September 2009, the ICH Steering Committee agreed that a draft guidance entitled ''E7 Studies in Support of Special Populations: Geriatrics; Questions & Answers'' should be made available for public comment. The draft guidance is the product of the E7(R1) Implementation Working Group of the ICH. Comments about this draft will be considered by FDA and the E7(R1) Implementation Working Group.

The draft Q&A guidance addresses the representation of geriatric patients in the clinical database, including special characteristics of the geriatric patient population. In view of the growing geriatric population (elderly and very elderly, i.e., over 75 years of age) and the recent advances in the field of geriatrics since the ICH E7 guidance issued (59 FR 39398, August 2, 1994), the importance of geriatric data (including data for the very elderly) in a drug evaluation program has increased. The Q&As are intended to provide guidance on this issue.

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 this topic. 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