

2. Common Carrier

Title: 2000 Biennial Regulatory Review—Comprehensive Review of the Accounting Requirements and ARMIS Reporting Requirements for Incumbent Local Exchange Carriers: Phase 2 and Phase 3.

Summary: The Commission will consider a Notice of Proposed Rule Making concerning issues regarding the accounting rules and ARMIS reporting requirements for incumbent local exchange carriers.

3. Wireless Telecommunications

Title: Promotion of Competitive Networks in Local Telecommunications Markets (WT Docket No. 99–217); Wireless Communications Association International, Inc., Petition for Rule Making to Amend Section 1.400 of the Commission's Rules to Preempt Restrictions on Subscriber Premises Reception or Transmission Antennas Designed to provide Fixed Wireless Services; Implementation of the Local Competition Provisions in the Telecommunications Act of 1996 (CC Docket No. 96–98); and Review of Sections 68.104, and 68.213 of the Commission's Rules Concerning Connection of Simple Inside Wiring to Telephone Network (CC Docket No. 88–57).

Summary: The Commission will consider a First Report and Order and Further Notice of Proposed Rule Making in WT Docket No. 99–217, a Fourth Report and Order and Memorandum Opinion and Order in CC Docket No. 96–98, and a Memorandum Opinion and Order in CC Docket No. 88–57, regarding obstacles to consumer's choice of telecommunications providers in multiple tenant environments.

4. Office of General Counsel

Title: Amendment of Section 19.735–203 of the Commission's Rules Concerning Nonpublic Information.

Summary: The Commission will consider an Order governing the misuse of nonpublic information (47 CFR 19.735–203).

Additional information concerning this meeting may be obtained from Maureen Peratino or David Fiske, Office of Media Relations, telephone number (202) 418–0500; TTY (202) 418–2555.

Copies of materials adopted at this meeting can be purchased from the FCC's duplicating contractor, International Transcription Services, Inc. (ITS, Inc.) at (202) 857–3800; fax (202) 857–3805 and 857–3184; or TTY (202) 293–8810. These copies are available in paper format and alternative media, including large print/type;

digital disk; and audio tape. ITS may be reached by e-mail:

its_inc@ix.netcom.com. Their Internet address is <http://www.itsdocs.com/>

This meeting can be viewed over George Mason University's Capitol Connection. The Capitol Connection also will carry the meeting live via the Internet. For information on these services call (703) 993–3100. The audio portion of the meeting will be broadcast live on the Internet via the FCC's Internet audio broadcast page at <<http://www.fcc.gov/realaudio/>>. The meeting can also be heard via telephone, for a fee, from National Narrowcast network, telephone (202) 966–2211 or fax (202) 966–1770. Audio and video tapes of this meeting can be purchased from Infocus, 341 Victory Drive, Herndon, VA 20170, telephone (703) 834–0100; fax number (703) 834–0111.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

[FR Doc. 00–26186 Filed 10–6–00; 1:19 pm]

BILLING CODE 6712–01–M

GENERAL SERVICES ADMINISTRATION

Office of Communications; Cancellation of Optional Forms

AGENCY: General Services Administration.

ACTION: Notice.

SUMMARY: The Department of Agriculture and the Department of Interior are cancelling the following Optional Forms because they do not collect the correct information:

OF 285, Warehouse Supplies Order

OF 290, Receipt for Property, Fire Suppression

Both of these forms are replaced with the following new Optional Forms:

OF 316, Interagency Incident Waybill (NSN 7540–01–475–4307)

OF 326A, Interagency Incident Waybill—Continuation (NSN 7540–01–475–4306)

You can order the above mentioned forms from the Federal Supply Service, General Products Commodity Center, Fort Worth, TX (817) 978–2508.

DATES: Effective October 11, 2000.

FOR FURTHER INFORMATION CONTACT: Ms. Barbara Williams, General Services Administration, (202) 501–0581.

Dated: September 1, 2000.

Barbara M. Williams,

Deputy Standard and Optional Forms Management Officer.

[FR Doc. 00–25988 Filed 10–10–00; 8:45 am]

BILLING CODE 6820–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Public Meeting on Medicare Coverage of Clinical Trials

AGENCY: Agency for Healthcare Research and Quality (AHRQ) formerly known as the Agency for Health Care Policy and Research (AHCPR).

ACTION: Notice of public meeting.

SUMMARY: In the past, Medicare has not paid for health care services provided as part of clinical trials because of their experimental nature. To carry out an executive memorandum from the President of the United States to the Secretary of Health and Human Services received on June 7, 2000 directing Medicare to provide for payment of routine patient care costs incurred by Medicare beneficiaries in connection with participation in clinical trials, the Health Care Financing Administration (HCFA) has issued a National Coverage Decision. In order to implement this new coverage policy for routine costs in clinical trials, HCFA must define the clinical trials for which payment of routine costs would be appropriate. Therefore, HCFA requested AHRQ to convene a multi-agency Federal group to develop readily verifiable criteria by which to identify trials that meet an appropriate standard of quality. The qualifying criteria will be developed under the authority to support health care research in § 1142 of the Social Security Act (Act). This notice announces a public meeting for the purpose of receiving oral and written comments on easily verifiable qualifying criteria for identifying sound clinical trials appropriate for Medicare coverage.

DATES: The meeting will take place on October 20, 2000, from 9 a.m.–12 p.m.

ADDRESSES: The meeting will be held at the Agency for Healthcare Research and Quality Conference Center, 6010 Executive Blvd., 4th Floor, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Nilam Patel, M.P.H., Center for Practice and Technology Assessment, AHRQ, 6010 Executive Blvd., Suite 300, Rockville, MD 20852; phone: (301) 594–

0236; Fax: (301) 594-4027; E-mail: npatel@ahrq.gov.

Arrangements for the Public Meeting: All representatives of organizations and other individuals who wish to attend, provide relevant written comments and information to AHRQ, and/or make a brief (10 minutes or less) oral statement at the meeting, must register with Nilam Patel, AHRQ, at the above address no later than three days prior to the date of the meeting. A copy of written materials should also be submitted to Ms. Patel. On the day of the meeting, presenters are requested to bring 25 copies of their written materials for distribution.

If sign language interpretation or other reasonable accommodations for a disability is needed, please contact Linda Reeves, Assistant Administrator for Equal Opportunity, AHRQ, at (301) 594-6662 no later than three days before the meeting date.

SUPPLEMENTARY INFORMATION:

1. Background

In June, 2000, the President of the United States issued an executive memorandum directing the Secretary of Health and Human Resources to "explicitly authorize Medicare payment for routine patient care costs * * * and costs due to medical complications associated with participation in clinical trials." In keeping with the President's directive, HCFA has developed and added a new section in the Medicare Coverage Issues Manual that will implement national coverage of routine costs of qualified clinical trials. For the purposes of this national coverage decision, routine costs of clinical trials include all items and services that are otherwise generally available to Medicare beneficiaries (conventional care); for example, hospital services, physician services, and diagnostic tests that are not statutorily excluded from coverage. Certain costs, such as costs for the investigational item or service itself, data collection-related costs, and items and services provided free of charge by the sponsor will not be covered.

In order to implement the coverage policy, a system must be in place to help identify trials that meet an appropriate standard of quality and for which it is appropriate for Medicare to pay the associated routine costs. HCFA requested AHRQ to form a multi-agency Federal group to develop qualifying criteria that would indicate a high probability that a trial has the following desirable characteristics of a scientifically sound clinical trial:

(1) The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;

(2) The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;

(3) The trial does not unjustifiably duplicate existing studies;

(4) The trial design is appropriate to answer the research question being asked in the trial;

(5) The trial is sponsored by a credible organization or conducted by an individual capable of executing the proposed trial successfully;

(6) The trial is in compliance with Federal regulations relating to the protection of human subjects; and

(7) The trial is conducted according to appropriate standards of scientific integrity.

Certain trials are presumed by AHRQ, and the other members of the multi-agency panel that it has convened, to be of sound quality and to have these desirable characteristics. Guided by the assumptions of the multi-agency group and discussions with AHRQ, HCFA announced both long term and short term types of automatic qualification for Medicare coverage of the routine costs of clinical trials in its related NCD.

"Effective September 19, 2000, clinical trials that are deemed to be automatically qualified are:

1. Trials funded by NIH, CDC, AHRQ, HCFA, DOD, and VA;

2. Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, HCFA, DOD and VA;

3. Trials conducted under an investigational new drug application (IND) reviewed by the FDA; and

4. Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) will be deemed automatically qualified until the qualifying criteria are developed and the certification process is in place. At that time the principal investigators of these trials must certify that the trials meet the qualifying criteria in order to maintain Medicare coverage of routine costs. This certification process will only affect the future status of the trial and will not be used to retroactively change the earlier deemed status."

The Federal multi-agency group will be developing criteria for identifying other trials that are likely to have the seven desirable characteristics of clinical trials. (From HCFA's Final National Coverage Decisions posted on HCFA's website (<http://www.hcfa.gov/quality/8d.htm>).

2. Purpose

To gather pertinent information and views that would contribute to defining the qualifying criteria used to identify sound clinical trials appropriate for Medicare coverage, AHRQ is holding this meeting. We are soliciting comments about what qualifying criteria might be appropriate and adequate to capture the desirable characteristics of sound clinical trials. The criteria should be easily verifiable and, where possible, dichotomous (that is, objective yes/no responses). Some examples might be:

Is the trial approved by an investigational review board (IRB)?

Does the trial have a written protocol?

Has the trial been approved by a Federal agency?

Has the trial received any external, non-Federal funding?

Has the trial been reviewed by any external, non-Federal group?

Does a data safety and monitoring board provide independent oversight of the trial?

AHRQ is also interested in receiving information on the availability of relevant literature (citations or copies if possible) that might assist the panel in its formulation of the qualifying criteria.

Agenda

The meeting will begin at 9 a.m. and continue through 12 p.m. If more requests to make oral statements are received than can be accommodated at this meeting, the chair person will allocate speaking time in a manner that attempts, to the extent possible, to have a range of information, findings and views presented orally. Those who cannot be granted speaking time because of time constraints are assured that their written comments will be considered along with other evidence during the course of further discussions and report preparation.

Due to time constraints, this Notice is published within the recommended 15 days prior to holding this public meeting.

Dated: October 4, 2000.

John M. Eisenberg,

Director.

[FR Doc. 00-25993 Filed 10-10-00; 8:45 am]

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