

health. In Cycle 6, both women and men will be interviewed. The interviews with males 15–44 will address (1) Factors that affect entry into marriage, cohabitation, and fatherhood; (2) factors that affect the spread of Sexually Transmitted Diseases (STDs) and HIV (Human Immunodeficiency Virus, the virus that causes AIDS); and (3) factors that affect men’s ability and willingness to carry out their fatherhood roles, including child support.

In 2002, the NSFG will interview a nationally representative sample of 11,500 women and 7,500 men 15–44 years of age. Black, Hispanic, and 15–

24-year-old men and women will be sampled at a higher rate than others. A pretest has been conducted. All participation is completely voluntary and confidential. NSFG data help measure the demographics, health status, and behavior of the population of reproductive age (as well as those responsible for most STDs). The NSFG data from the 1995 survey have already been published in more than 60 published NCHS reports and articles in scientific journals. Besides NCHS, users of NSFG data include the Department of Health and Human Services (HHS) Office of Population Affairs, the

National Institute for Child Health and Human Development, the CDC HIV/AIDS Prevention program, the CDC’s Division of Reproductive Health, the Office of the Assistant Secretary for Planning and Evaluation (OASPE), and the Children’s Bureau. Other users include Congress (for Section 905 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, among others); the Healthy People 2000 and 2010 initiatives; private researchers in demography, public health, maternal and child health, and state governments. The total annual burden for this data collection is 27,624 hours.

Respondents	Number of respondents	Number of responses/ respondent	Avg. burden/ response (in hrs.)
Survey: screener	55000	1	5/60
Survey: males	7500	1	1
Survey: females	11500	1	80/60
Verification	2500	1	5/60

Dated: December 19, 2001.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services (CMS)

Notice of Hearing: Reconsideration of Disapproval of Ohio State Plan Amendment 98–020

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice of hearing.

SUMMARY: This notice announces an administrative hearing to reconsider the decision to disapprove Ohio State Plan Amendment (SPA) 98–020, on February 21, 2002, at 10:00 a.m., Chicago Regional Office Federal Building; Fifth Floor; Minnesota Room; 233 North Michigan Avenue; Chicago, Illinois 60601.

CLOSING DATE: Requests to participate in the hearing as a party must be received by the presiding officer by January 15, 2002.

FOR FURTHER INFORMATION CONTACT:

Kathleen Scully-Hayes, Office of Hearings, CMS Suite L, 2520 Lord Baltimore Drive, Baltimore, Maryland 21244–2670, Telephone: (410)–786–2055.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider CMS’s decision to disapprove Ohio SPA 98–020.

Section 1116 of the Social Security Act (the Act) and 42 CFR, part 430 establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a state plan or plan amendment. The Centers for Medicare & Medicaid Services (CMS) is required to publish a copy of the notice to a state Medicaid agency that informs the agency of the time and place of the hearing and the issues to be considered. If we subsequently notify the agency of additional issues that will be considered at the hearing, we will also publish that notice. Any individual or group that wants to participate in the hearing as a party must petition the presiding officer within 15 day after publication of this notice, in accordance with the requirements contained at 42 CFR 430.76(b)(2). Any interested person or organization that wants to participate as *amicus curia* must petition the presiding officer before the hearing begins in accordance with the requirements contained at 42 CFR 430.76(c). If the hearing is later rescheduled, the presiding officer will notify all participants.

The issue is whether the claiming methodology Ohio proposed for determining allowable administrative costs is consistent with the requirements of the Social Security Act (the Act) and implementing regulations, including the issue of whether the methodology would adequately

document such claims. As discussed below in more detail, the disapproval was based on findings that the proposed claiming methodology would permit the development of unallowable claims for Federal financial participation (FFP) primarily because it was based on time study that did not reflect Medicaid requirements.

Ohio submitted SPA 98–020 on December 24, 1998. This amendment contains an interagency agreement between the Ohio Department of Job and Family Services and the Ohio Department of Education through which the State would claim FFP under the Medicaid program for the costs of administrative activities performed by local education agencies in the State of Ohio. The CMS was unable to approve Ohio Medicaid SPA 98–020 because the methodology that would serve as the basis for the development of Medicaid administrative claims is flawed.

After review of the information and materials in the December 24, 1998, SPA submission and the June 25, 2001, response to our request for additional information, CMS determined that the requirements for administrative claiming in schools were not met. The primary basis for this conclusion is that the administrative claiming methodology was based on a time study that would permit development of unallowable Medicaid claims. The time study developed as part of this methodology includes: (1) Education-related activities that are not allowed under Medicaid; (2) activities at the enhanced FFP rate, which do not meet the requirements for Skilled

Professional Medical Personnel claiming; and (3) an activity code structure that does not meet the requirement to account for all the activities performed by time study participants. As a result, CMS found that SPA 98-020 did not comply with applicable Medicaid requirements, including those related to methods of administration under section 1902(a)(4) of the Act and implementing CMS regulations.

The CMS found that the flawed methodology means that the claim which would be authorized by SPA 98-020 are not reasonable and necessary for the proper and efficient administration of the State plan. This conclusion is based on the CMS review of the proposed activity code definitions, sampling methodology, documentation requirements, interagency agreement, and indirect cost rate. Therefore, after consulting with the Secretary as required by Federal regulation, CMS informed Ohio of its decision to disapprove this amendment.

The notice to Ohio announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

Section 1116 of the Social Security Act (42 U.S.C. section 1316); 42 CFR section 430.18 (Catalog of Federal Domestic Assistance Program No. 13.714, Medicaid Assistance Program)

Dated: December 11, 2001.

Thomas A. Scully,

Administrator, Center for Medicare & Medicaid Services.

[FR Doc. 01-32110 Filed 12-28-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0580]

Preparation for ICH Meetings in Brussels, Belgium, Including Progress on Implementation of the Common Technical Document; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration is announcing a public meeting entitled "Preparation for ICH Meetings in Brussels, Belgium, Including Progress on Implementation of the Common Technical Document (CTD)" to solicit information and receive comments on the International

Conference on Harmonisation (ICH) as well as the upcoming meetings in Brussels, Belgium. The purpose of the public meeting is to solicit public input prior to the next Steering Committee and Expert Working Group meetings in Brussels, Belgium, February 4 through 7, 2002, at which discussion of the implementation of the CTD and the future of ICH will continue.

Date and Time: The public meeting will be held on January 17, 2002, from 10:30 a.m. to 2 p.m.

Location: The public meeting will be held in the Center for Drug Evaluation and Research, Advisory Committee Conference Room, at 5630 Fishers Lane, rm. 1066, Rockville, MD 20857.

Contact: Kimberly Topper, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, FAX 301-827-6801, e-mail: Topperk@cder.fda.gov.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), and written material and requests to make oral presentations, to the contact person by January 10, 2002.

If you need special accommodations due to a disability, please contact Kimberly Topper (address above) at least 7 days in advance.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

SUPPLEMENTARY INFORMATION: The ICH of Technical Requirements for the Registration of Pharmaceuticals for Human Use was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

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 medical product

development among regulatory agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization among three regions: The European Union, Japan, the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health, Labor 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. The ICH Steering Committee includes representatives from each of the ICH sponsors and Canadian Therapeutics Programme, and the European Free Trade Area. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions. The current ICH process and structure can be found on the Internet at <http://www.ifpma.org/ich1.html>.

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Oral presentations from the public meeting will be scheduled between approximately 11:30 a.m. and 1 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by January 10, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses, phone number, fax, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.

The agenda for the public meeting will be made available on January 10, 2002, under Docket Number 01N-0580 at the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 26, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01-32123 Filed 12-26-01; 3:36 pm]

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