

Dated: March 30, 2007.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day-07-06AP]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-4766 and send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information

on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Aerosol Generation by Cough—NEW—The National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Federal Occupational Safety and Health Act of 1970, section 501, enables NIOSH to carry out research relevant to the health and safety of workers. NIOSH is conducting a two-year study of airborne clouds of particles or droplets called "aerosols". Some diseases like influenza and Severe Acute Respiratory Syndrome (SARS) can be spread when people produce infectious aerosols by coughing or sneezing. Aerosol transmission of infectious diseases is especially important to health-care workers and emergency responders, who face a much greater risk of exposure to these hazards than does the general public. Cough-generated aerosols are of particular concern because coughing is one of the most common symptoms of respiratory infections. However, substantial gaps exist in our understanding about the generation of aerosols during coughing. This lack of information hampers the ability of health scientists to model and predict the generation of infectious aerosols by coughing and to understand whether or not cough-generated aerosols are likely to be an important means of transmission of particular diseases.

The purpose of this study is to gain a better understanding of the production of aerosols by coughing. The results of

this research will give scientists and health professionals greater insight into the airborne transmission of disease and allow them to better assess the potential effectiveness of preventive measures.

The first part of this study will measure the quantity and size distribution of aerosol produced during human coughs. To accomplish this, volunteers will cough into a spirometer, which is a commonly used piston-like medical device that measures the volume of air exhaled by a patient. After the volunteer coughs into the spirometer, the air in the spirometer will be drawn into a commercial aerosol measurement device. These experiments will also provide information on how much cough aerosols vary over time for individuals and how much aerosol generation varies between individuals.

The second part of this study will determine how effectively surgical masks and N95 respirators block cough-generated aerosols. N95 respirators are dust masks that are certified to filter out at least 95% of airborne material during normal breathing. N95 respirators are known to be more effective than surgical masks at filtering out airborne particles during inhalation, but it is not known whether masks or respirators are more effective at blocking cough-generated aerosols. For this work, masks and respirators will be placed in a special holder with a disposable mouthpiece, and human subjects will cough into the mouthpiece and through the mask. The aerosol produced by each subject will be analyzed before and after flowing through the mask. These experiments will determine how effective each mask or respirator is at preventing the release of cough-generated aerosols.

Volunteers from part 1 may also participate in part 2 if they wish. There will be no costs to study participants other than their time.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Part 1 participants	20	5	1.5	150
Part 2 participants	120	1	1.5	180
Total	330

Dated: March 29, 2007.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Notice of Hearing: Reconsideration of Disapproval of Minnesota State Plan Amendment 05-10

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of hearing.

SUMMARY: This notice announces an administrative hearing to be held on May 30, 2007, at 233 N. Michigan Avenue, Suite 600, the Indiana Room, Chicago, IL 60601, to reconsider CMS' decision to disapprove Minnesota State plan amendment 05-10.

CLOSING DATE: Requests to participate in the hearing as a party must be received by the presiding officer by (15 days after publication).

FOR FURTHER INFORMATION CONTACT: Kathleen Scully-Hayes, Presiding Officer, CMS, Lord Baltimore Drive, Mail Stop LB-23-20, Baltimore, Maryland 21244. Telephone: (410) 786-2055.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider CMS' decision to disapprove Minnesota State plan amendment (SPA) 05-10 which was submitted on September 21, 2005. This SPA was disapproved on December 29, 2006.

Under this SPA, the State proposed to revise coverage and reimbursement methodology for Early and Periodic Screening, Diagnosis, and Treatment services related to children's mental health rehabilitative services and rehabilitative services pursuant to an Individualized Education Plan or Individual Family Service Plan.

The amendment was disapproved because CMS found that the amendment violated the statute for reasons set forth in the disapproval letter.

The issues to be decided at the hearing are:

- Whether the per diem (bundled) payment methodologies for mental health rehabilitative services described in Minnesota's SPA 05-10 accurately reflect true costs or reasonable fees for the services included in the bundles;

- Whether the amount or scope of services reimbursed through the bundled rate is sufficiently constant so that the proposed methodologies would be an economic and efficient method of payment;

- Whether all of the component parts of the service are delivered as recommended within the scope of practice of the physician or licensed practitioner of the healing arts;

- Whether the actual practitioners who will be furnishing services can be readily identified; and

- Whether the bundled rates provide for direct payment to the actual practitioners who provide the service.

Section 1116 of the Social Security Act and Federal regulations at 42 CFR part 430, establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a State plan or plan amendment. 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 days 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 curiae* 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 Notice to Minnesota Announcing an Administrative Hearing To Reconsider the Disapproval of Its SPA Reads as Follows

Ms. Christine Bronson,
Medicaid Director,
Minnesota Department of Human Services,
P.O. Box 64998,
St. Paul, MN 55164-0998

Dear Ms. Bronson: I am responding to your request for reconsideration of the decision to disapprove the Minnesota State plan amendment (SPA) 05-10, which was submitted on September 21, 2005, and disapproved on December 29, 2006.

Under this SPA, the State proposed to revise coverage and reimbursement methodology for Early and Periodic Screening, Diagnosis, and Treatment services related to children's mental health rehabilitative services and rehabilitative services pursuant to an Individualized

Education Plan or Individual Family Service Plan. The Centers for Medicare & Medicaid Services (CMS) disapproved the SPA because the State did not document that its proposed reimbursement methodology meets the conditions specified in sections 1902(a)(10), 1902(a)(30), and 1902(a)(32) of the Social Security Act (the Act).

At issue in this reconsideration is whether Minnesota has demonstrated that the bundled rate methodology proposed in SPA 05-10 is consistent with the requirements of section 1902(a)(30)(A) of the Act, which requires that States have methods and procedures to assure that payments to providers are consistent with efficiency, economy, and quality of care. A second issue is whether the State has shown that the payment methodology is for care and services that are within the scope, and meet the requirements, of section 1902(a)(10)(A) to make available "medical assistance," which is defined at section 1905(a) and implementing requirements. Also at issue is whether the proposed payment methodology complies with the direct payment requirements of section 1902(a)(32) of the Act, which precludes payment to anyone other than the individual, person, or institution providing the care and service (with specified exceptions). We discuss each of these issues in more detail below in relation to SPA 05-10.

Section 1902(a)(30)(A) of the Act requires that States have methods and procedures to assure that payments to providers are consistent with efficiency, economy, and quality of care. The per diem payment methodologies for mental health rehabilitative services described in SPA 05-10 represent bundled payment methodologies under which the State pays a single rate for one or more of a group of different services furnished to an eligible individual during a fixed period of time. The State has failed to demonstrate that its methodologies are in compliance with section 1902(a)(30)(A), in that it has not shown: that these methodologies accurately reflect true costs or reasonable fees for the services included in the bundles; and that the amount or scope of services reimbursed through the bundled rate is sufficiently constant so that the proposed methodologies would be an economic and efficient method of payment.

Section 1902(a)(10)(A) requires that State plans make available medical assistance, which is defined at section 1905(a) and in implementing regulations. For a number of categories of medical assistance, there are provider standards applicable to different types of care and services, and for rehabilitative services there is a requirement that rehabilitative services must be recommended by a physician or other licensed practitioner of the healing arts. Minnesota did not provide evidence of a method to identify that providers of the component parts of the care and services would meet all applicable provider requirements. Nor did Minnesota demonstrate a method to ensure that all of the component parts of the care and services furnished under the bundled payment methodology proposed in SPA 05-10, would