DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

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

The meeting 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 the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications. The disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: National Biomedical NMR Resource. 

Date: April 13–15, 2015.

Time: 7:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda. (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Michael Eissenstat, Ph.D., Scientific Review Officer, BCMR IRC, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4166, Bethesda, MD 20892, 301–435–1722, eissenstatma@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS and AIDS Related Research.

Date: April 13, 2015.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Eduardo A Montalvo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7852, Bethesda, MD 20892, (301) 435–1168, montalve@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program: PAR–14–1085: Metabolic Reprogramming in Immunotherapy.

Date: March 17, 2015.

Time: 1:30 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Denise R Shaw, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6158, MSC 7804, Bethesda, MD 20892, 301–435–0198, shawden@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.


Dated: March 12, 2015.

Carolyn A. Baum, Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–06121 Filed 3–17–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Proposed Collection

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to ombr@cdc.gov. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Coal Workers’ Health Surveillance Program (CWSP)—(0920–0020).

Reinstatement with Change—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

NIOSH would like to submit an Information Collection Request (ICR) to revise the data collection instruments being utilized within the Coal Workers’ Health Surveillance Program (CWSP). On May 1, 2014, the Mine Safety and Health Administration (MSHA) published final rule 30 CFR 70, 71, 72, 75, and 90. The new MSHA rule added surface coal miners, a respiratory health assessment, and spirometry testing for chronic obstructive pulmonary disease (COPD) to the previously mandated chest x-ray examination program. These additions are being referred to as the Expanded CWSP (an additional component under the current CWSP). This request incorporates all components that now fall under the CWSP. Those components include: Coal Workers’ X-ray Surveillance Program (CWXSP), B Reader Program, Enhanced Coal Workers’ Health Surveillance Program (ECWHP), Expanded Coal Workers’ Health Surveillance Program, and National Coal Workers’ Autopsy Study (NCWAS).

The CWSP is a congressionally-mandated medical examination program for monitoring the health of coal miners. The Program was originally authorized under the 1969 Federal Coal Mine Health and Safety Act and is currently authorized under the 1977 Federal Mine Safety and Health Act and subsequent amendments (the Act). The Act provides the regulatory authority for
the administration of the CWHSP. This Program, which operates in accordance with 42 CFR part 37, is useful in providing information for protecting the health of miners (whose participation is entirely voluntary), and also in documenting trends and patterns in the prevalence of coal workers’ pneumoconiosis (‘black lung’ disease) among miners employed in U.S. coal mines.

The total estimated annualized burden hours of 20,282 is based on the following collection instruments:

- Coal Mine Operator Plan (2.10) and Coal Contractor Plan (2.18)—Under 42 CFR part 37, every coal operator and coal contractor in the U.S. must submit a plan approximately every 4 years, providing information on how they plan to notify their miners of the opportunity to obtain the medical examination. Completion of this form with all requested information (including a roster of current employees) takes approximately 30 minutes.
- Radiographic Facility Certification Document (2.11)—X-ray facilities seeking NIOSH approval to provide miner radiographs under the CWHSP must complete an approval packet including this form which requires approximately 30 minutes for completion.
- Miner Identification Document (2.9)—Miners who elect to participate in the CWHSP must fill out this document which requires approximately 20 minutes. This document records demographic and occupational history, as well as information required under the regulations in relation to the examinations. In addition to completing this form, acquiring the chest image from the miner takes approximately 15 minutes.
- Chest Radiograph Classification Form (2.8)—NIOSH utilizes a radiographic classification system developed by the International Labour Office (ILO) in the determination of pneumoconiosis among coal miners. Physicians (B Readers) fill out this form regarding their interpretations of the radiographs (each image has two separate interpretations, and approximately 7% of the images require additional interpretations). Based on prior practice it takes the physician approximately 3 minutes per form.
- Physician Application for Certification (2.12)—Physicians taking the B Reader examination are asked to complete this registration form which provides demographic information as well as information regarding their medical practices. It typically takes the physician about 10 minutes to complete this form.
- Spirometry Facility Certification Document (2.14)—This new form is analogous to the Radiographic Facility Certification Document (2.11) and records the spirometry facility equipment/staffing information. Spirometry facilities seeking NIOSH approval to provide miner spirometry testing under the CWHSP must complete an approval packet which includes this form. It is estimated that it will take approximately 30 minutes for this form to be completed at the facility.
- Respiratory Assessment Form (2.13)—This new form is designed to assess respiratory symptoms and certain medical conditions and risk factors. It is estimated that it will take approximately five minutes for administration of this form to the miner by an employee at the facility.
- Spirometry Results Notification Form (2.15)—This new form replaces previous forms 2.15, 2.16 and 2.17. It is used to: collect information that will allow NIOSH to identify the miner in order to provide notification of the spirometry test results; assure that the test can be done safely; record certain factors that can affect test results; provide documentation that the required components of the spirometry examination have been transmitted to NIOSH for processing; and conduct quality assurance audits and interpretation of results. It is estimated that it will take the facility approximately 20 minutes to complete this form. In addition to completing this form, acquiring an acceptable spirometry test from the miner takes approximately 15 minutes.
- Pathologist Invoice—Under the NCWAS, the invoice submitted by the pathologist must contain a statement that the pathologist is not receiving any other compensation for the autopsy. Each participating pathologist may use their individual invoice as long as this statement is added. It is estimated that only five minutes is required for the pathologist to add this statement to the standard invoice that they routinely use.
- Pathologist Report—Under the NCWAS the pathologist must submit information found at autopsy, slides, blocks of tissue, and a final diagnosis indicating presence or absence of pneumoconiosis. The format of the autopsy report is variable depending on the pathologist conducting the autopsy. Since an autopsy report is routinely completed by a pathologist, only additional burden is the specific request for a clinical abstract of terminal illness and final diagnosis relating to pneumoconiosis. Therefore, only 5 minutes of additional burden is estimated for the pathologist’s report.
- Consent, Release and History Form (2.6)—This form documents written authorization from the next-of-kin to perform an autopsy on the deceased miner. A minimum of essential information is collected regarding the deceased miner including an occupational history and a smoking history. From past experience, it is estimated that 15 minutes is required for the next-of-kin to complete this form.

There are no costs to respondents other than their time.

**Estimated Annualized Burden Hours**

<table>
<thead>
<tr>
<th>Type of respondent</th>
<th>Form name</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden per response (in hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coal Mine Operator</td>
<td>2.10</td>
<td>388</td>
<td>1</td>
<td>30/60</td>
</tr>
<tr>
<td>Coal Mine Contractor</td>
<td>2.18</td>
<td>575</td>
<td>1</td>
<td>30/60</td>
</tr>
<tr>
<td>Radiograph Facility Supervisor</td>
<td>2.11</td>
<td>40</td>
<td>1</td>
<td>30/60</td>
</tr>
<tr>
<td>Coal Miner</td>
<td>2.9</td>
<td>14,560</td>
<td>1</td>
<td>15/60</td>
</tr>
<tr>
<td>Coal Miner—Radiograph</td>
<td>2.8</td>
<td>No form required</td>
<td>10</td>
<td>30/60</td>
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<tr>
<td>B Reader Physician</td>
<td>2.12</td>
<td>50</td>
<td>1</td>
<td>30/60</td>
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<tr>
<td>Physicians taking the B Reader Examination</td>
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<td>100</td>
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<td>10/60</td>
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<tr>
<td>Spirometry Facility Supervisor</td>
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<tr>
<td>Spirometry Technician</td>
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<td>14,560</td>
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<td>Pathologist</td>
<td>Invoice—No standard form</td>
<td>5</td>
<td>1</td>
<td>5/60</td>
</tr>
</tbody>
</table>
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Notice of Hearing: Reconsideration of Disapproval Louisiana Medicaid State Plan Amendment (SPA) 12–66–B

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

ACTION: Notice of hearing: Reconsideration of disapproval.

SUMMARY: This notice announces an administrative hearing to be held on April 30, 2015, at the Department of Health and Human Services, Centers for Medicare and Medicaid Services, Division of Medicaid & Children’s Health, Dallas Regional Office, 1301 Young Street, Room 730, Dallas, TX 75202, to reconsider CMS’ decision to disapprove Louisiana’s Medicaid SPA 12–66–B.

Closing Date: Requests to participate in the hearing as a party must be received by the presiding officer by April 2, 2015.

FOR FURTHER INFORMATION CONTACT: Benjamin R. Cohen, Presiding Officer, CMS, 2520 Lord Baltimore Drive, Suite L, Baltimore, Maryland 21244, Telephone: (410) 786–3169.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider CMS’ decision to disapprove Louisiana’s Medicaid SPA 12–66B which was submitted to the Centers for Medicare and Medicaid Services (CMS) on December 20, 2012 and disapproved on December 11, 2014. In part, this SPA requested CMS approval to revise the current pharmacy reimbursement methodology for estimated acquisition cost (EAC) which is currently calculated as average acquisition cost (AAC) of the drug dispensed to a new calculation of AAC adjusted by a multiplier of 1.1 for multiple source drugs and 1.01 for single source drugs. In addition, propose a reimbursement methodology of wholesale acquisition cost (WAC) adjusted by a multiplier of 1.05 for state-defined specialty therapeutic classes of drugs.

The issues to be considered at the hearing are:

- Whether the state’s proposed increased payment methodology under Louisiana Medicaid SPA 12–66–B complies with the requirements of section 1902(a)(30)(A) of the Act which requires, in part, that states have methods and procedures to assure that payment rates are consistent with efficiency, economy, and quality of care.
- Whether the state demonstrated that the proposed payment increases are consistent with the aggregate upper payment limits set in implementing regulations at 42 CFR 447.512 which provide that payments for drugs are to be based on the lower of: (1) The ingredient EAC of the drug and a reasonable dispensing fee; or (2) the provider’s usual and customary charges to the general public.
- Whether the proposed calculation of EAC used in calculating upper payment limits (based on a multiple of the AAC) is consistent with the definition of EAC in 42 CFR 447.502, which defines EAC as “the agency’s best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers.”

Section 1116 of the 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 Louisiana announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

J. Ruth Kennedy
State Medicaid Director
Louisiana Department of Health and Hospitals
628 N. 4th Street
P.O. Box 91030
Baton Rouge, LA 70821

Dear Ms. Kennedy:

I am responding to your request for reconsideration of the decision to disapprove Louisiana’s Medicaid state plan amendment (SPA) 12–66B, which was submitted to the Centers for Medicare and Medicaid Services (CMS) on December 20, 2012, and disapproved on December 11, 2014. I am scheduling a hearing on your request for reconsideration to be held on April 30, 2015, at the Department of Health and Human Services, Centers for Medicare and Medicaid Services, Division of Medicaid & Children’s Health, Dallas Regional Office, 1301 Young Street, Room 730, Dallas, TX 75202.

I am designating Mr. Benjamin R. Cohen as the presiding officer. If these arrangements present any problems, please contact Mr. Cohen at (410) 786–3169. In order to facilitate any communication that may be necessary between the parties prior to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the state at the hearing. If the hearing date is not acceptable, Mr. Cohen can set another date mutually agreeable to the parties. The hearing will be governed by the procedures prescribed by federal regulations at 42 CFR part 430.

In part, this SPA would revise the current pharmacy reimbursement methodology for estimated acquisition cost (EAC) which is currently calculated as average acquisition cost (AAC) of the drug dispensed to a new...