



DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 37

[Docket No. CDC-2019-0088; NIOSH-330]

RIN 0920-AA68

Coal Workers' Health Surveillance Program: Autopsy Payment

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Final rule.

SUMMARY: With this final rule, HHS amends existing regulatory text to allow compensation for pathologists who perform autopsies on coal miners at a market rate, on a discretionary basis as needed for public health purposes. HHS has determined that the agency needs additional time to consider the public comments received on the addition of procedures for suspending or revoking B Reader certification, as proposed in the notice of proposed rulemaking preceding this final rule; those procedures will be finalized at a later date.

DATES: This rule is effective on [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Comments on the information collection approval request sought under the Paperwork Reduction Act must be received by [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit comments on the Paperwork Reduction Act information collection to CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT: Rachel Weiss, Program Analyst; 1090 Tusculum Ave., MS: C-48, Cincinnati, OH 45226; telephone (855) 818-1629 (this is a toll-free number); email NIOSHregs@cdc.gov.

SUPPLEMENTARY INFORMATION:

I. Public Participation

HHS invited interested parties to participate in a proposed rulemaking published on February 14, 2020 (85 FR 8521) by submitting written views, opinions, recommendations, and data. HHS received 12 submissions from 11 commenters, including unaffiliated individuals, professional societies, trade associations, a labor union, and a law firm. No submissions were received regarding the proposed Paperwork Reduction Act information collection.

Within the February 14, 2020 rulemaking, HHS published a “Proposed Data Collection Submitted for Public Comment and Recommendations” to obtain comments from the public and affected agencies. HHS did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, email omb@cdc.gov. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

II. Statutory Authority

The Federal Mine Safety and Health Act of 1977 (Pub. L. 91-173, 30 U.S.C. 801 *et seq.*) (Mine Act), authorizes the HHS Secretary (Secretary) to work with coal mine operators to make available to coal miners the opportunity to have regular and routine chest radiographs (X-rays) in order to detect coal workers’ pneumoconiosis (*i.e.*, black lung) and prevent its progression in individual miners. The Mine Act grants the Secretary general authority to issue regulations as is deemed appropriate to carry out provisions of the Act and authorizes the Coal Workers’ Health

Surveillance Program (Program), within the NIOSH Respiratory Health Division, to detect pneumoconiosis and prevent its progression in individual miners and to provide information to NIOSH for the evaluation of temporal and geographic trends in pneumoconiosis. The Mine Act also authorizes the Secretary to establish specifications for the reading of radiographs and to pay for autopsies submitted to the Program.

III. Background and Need for Rulemaking

The NIOSH Respiratory Health Division uses coal miner autopsies to study important issues affecting coal miners, such as evaluating the cause of rapidly progressive and severe pneumoconiosis by assessing its pathology and determining the lung content of mineral particles relative to what was seen in the past. Also, autopsies are sometimes requested after mine disasters. With this final rule, regulatory language promulgated over 45 years ago is updated to reflect the contemporary costs associated with autopsies. HHS anticipates that increasing the compensation rate will make it economically feasible for pathologists to conduct autopsies of coal miners, thereby allowing the NIOSH Respiratory Health Division to better study pneumoconiosis in contemporary coal miners and to perform public health investigations more thoroughly, especially in the aftermath of mine disasters.

IV. Summary of Final Rule

Of the 12 submissions to the docket for this activity, only one addressed the autopsy payment provisions. The commenter agreed that the proposed increase in payment for pathologists who provide autopsies to the NIOSH Coal Workers' Health Surveillance Program is "essential to assure that autopsies can and will be conducted when indicated," and should be incorporated.

To promote administrative efficiency and ensure program integrity, HHS amends 42 CFR part 37 by updating existing regulatory text in §§ 37.202 through 37.204 to allow NIOSH, on a discretionary basis as needed for public health purposes, to better compensate pathologists who perform autopsies on coal miners. Existing text in § 37.202(a) is revised to clarify that

pathologists must secure prior authorization for payment from NIOSH and provide proof that legal consent to conduct an autopsy on a coal miner was either obtained or not required, as in the case of a forensic autopsy. New language in § 37.202(a)(2)(i) and (ii) clarifies the types of chest radiographic images accepted by the Program.

New language in § 37.202(b) specifies that pathologists will be compensated in accordance with their ordinary, usual, or customary fees or at amounts agreed upon through negotiation with NIOSH. NIOSH may survey other board-certified pathologists who provide the same services in the same geographic area to inform payment amounts. Existing language in paragraph (b) is revised to clarify that NIOSH will provide additional payment for the submission of chest radiographs of the autopsy subject made within 5 years of the miner's death. Compensation for chest radiographs is offered to the pathologist because NIOSH has found that asking families or estates to provide radiographs is often cumbersome, difficult, and emotionally painful.

Language in § 37.202(c) states that NIOSH will not pay a pathologist for their services if that pathologist has already received payment from another party. The text is revised to clarify that the prohibition on double payment is extended to the pathologist's employer, the organization in which the pathologist practices, or another entity receiving payment on behalf of or for services provided by the pathologist.

Section 37.203 is revised to update the reference for standard autopsy procedures. Although no public comments addressed § 37.203, NIOSH has added language to paragraph (b)(7) to clarify that the three microscopic slides required for each autopsy must be accompanied by three blocks of tissue that correspond to those slides. The slides and tissue blocks must correspond so that NIOSH can make additional slides if needed.

Finally, new language in § 37.204(a) details the new requirement that the pathologist obtain written authorization from the NIOSH Respiratory Health Division prior to completion of the autopsy. Language specifying how claims for payment should be submitted to NIOSH is

reorganized. New language is added to § 37.204(b)(1) to clarify that the claim for payment must include a statement that the pathologist or the pathologist's employer, the organization in which the pathologist practices, or another entity receiving payment on behalf of or for services provided by the pathologist has not been paid for performing the specific autopsy by another party.

In § 37.201(b), the definition of *Miner* is revised to remove the word “underground,” to clarify that the autopsy provisions pertain to all coal miners. Section 37.201(d) is also revised to update the definition of *NIOSH*, clarifying that the name of the NIOSH division responsible for administering the Coal Workers' Health Surveillance Program is now the Respiratory Health Division.

V. Regulatory Assessment Requirements

A. Executive Order 12866 (Regulatory Planning and Review) and Executive Order 13563 (Improving Regulation and Regulatory Review)

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This final rule has been determined not to be a “significant regulatory action” under section 3(f) of E.O. 12866. The revisions finalized in this notice allow NIOSH to compensate pathologists at a contemporary rate for autopsies submitted to the Coal Workers' Health Surveillance Program.

The revisions to Part 37 do not impose significant costs on the public and will benefit coal miners and coal mine operators. Allowing the NIOSH Respiratory Health Division to better compensate pathologists for autopsies submitted to the Program would also enhance NIOSH's

ability to study pneumoconiosis in coal miners.

The costs to the Federal government of administering these revisions would be minor and infrequent. In addition to the administrative costs, NIOSH estimates that over a 5-year period, it might fund up to 20 autopsies, costing NIOSH approximately \$60,000.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, requires each agency to consider the potential impact of its regulations on small entities including small businesses, small governmental units, and small not-for-profit organizations. HHS certifies that this final rule has “no significant economic impact upon a substantial number of small entities” within the meaning of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

C. Paperwork Reduction Act

The Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, requires an agency to invite public comment on, and to obtain Office of Management and Budget (OMB) approval of, any regulation that requires 10 or more people to report information to the agency or to keep certain records. In accordance with section 3507(d) of the PRA, HHS has determined that the PRA does apply to information collection and recordkeeping requirements included in this rule. OMB has already approved the information collection and recordkeeping requirements under OMB Control Number 0920-0020, *National Coal Workers’ Health Surveillance Program (CWHSP)* (expiration date 9/30/2021). HHS has determined that the amendments in this final rulemaking will not impact the existing collection of data but would add one new item to the approval: the pathologist prior authorization request. To request more information or to obtain a copy of the data collection plan and instrument send an email to omb@cdc.gov.

Comments are invited on the following: (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; (d) ways to minimize the burden of the collection of information on respondents; and (e) information collection costs. Written comments must be received within 30 days of the publication of this notice. The addition of additional paperwork requirements resulting from this final rule will increase the burden associated with the following provision:

Section 37.204 Procedure for obtaining payment. This section establishes that a pathologist who wants to submit an autopsy to the Coal Workers' Health Surveillance Program must first obtain written authorization from the NIOSH Respiratory Health Division. HHS expects an average of about four requests for prior authorization annually. HHS estimates that each request for prior authorization will take no more than 15 minutes to complete, averaging about one hour annually over a period of years.

Section	Title	Number of respondents	Responses per respondent	Average burden per response (min)	Total burden (hr)
37.204	Authorization for Payment of Autopsy	4	1	15/60	1

D. Small Business Regulatory Enforcement Fairness Act

As required by Congress under the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), HHS will report the promulgation of this rule to Congress prior to its effective date.

E. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531 *et seq.*) directs agencies to assess the effects of Federal regulatory actions on State, local, and Tribal

governments, and the private sector “other than to the extent that such regulations incorporate requirements specifically set forth in law.” For purposes of the Unfunded Mandates Reform Act, this final rule does not include any Federal mandate that may result in increased annual expenditures in excess of \$100 million by State, local, or Tribal governments in the aggregate, or by the private sector.

F. Executive Order 12988 (Civil Justice Reform)

This final rule has been drafted and reviewed in accordance with Executive Order 12988 and will not unduly burden the Federal court system. This rule has been reviewed carefully to eliminate drafting errors and ambiguities.

G. Executive Order 13132 (Federalism)

HHS has reviewed this final rule in accordance with Executive Order 13132 regarding federalism and has determined that it does not have “federalism implications.” The rule does not “have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.”

H. Executive Order 13045 (Protection of Children from Environmental Health Risks and Safety Risks)

In accordance with Executive Order 13045, HHS has evaluated the environmental health and safety effects of this final rule on children. HHS has determined that the rule will have no environmental health and safety effect on children.

I. Executive Order 13211 (Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use)

In accordance with Executive Order 13211, HHS has evaluated the effects of this final rule on energy supply, distribution, or use, and has determined that the rule will not have a significant adverse effect.

J. Plain Writing Act of 2010

Under Public Law 111-274 (October 13, 2010), executive Departments and Agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal government administers or enforces. HHS has attempted to use plain language in promulgating the final rule consistent with the Federal Plain Writing Act guidelines.

List of Subjects in 42 CFR Part 37

Autopsy, Chronic Obstructive Pulmonary Disease, Coal Workers' Pneumoconiosis, Incorporation by reference, Lung diseases, Mine safety and health, Occupational safety and health, Part 90 miner, Part 90 transfer rights, Pneumoconiosis, Respiratory and pulmonary diseases, Silicosis, Spirometry, Surface coal mining, Underground coal mining, X-rays.

Final Rule

For the reasons discussed in the preamble, the Department of Health and Human Services amends 42 CFR part 37 as follows:

PART 37—SPECIFICATIONS FOR MEDICAL EXAMINATIONS OF COAL MINERS

1. The authority citation for part 37 continues to read as follows:

Authority: Sec. 203, 83 Stat. 763, 30 U.S.C. 843, unless otherwise noted.

2. Revise § 37.201 to read as follows:

§ 37.201 Definitions.

As used in this subpart:

(a) *Secretary* means the Secretary of Health and Human Services.

(b) *Miner* means any individual who during their life was employed in any coal mine.

(c) *Pathologist* means:

(1) A physician certified in anatomic pathology or pathology by the American Board of Pathology or the American Osteopathic Board of Pathology,

(2) A physician who possesses qualifications which are considered board-eligible by the American Board of Pathology or American Osteopathic Board of Pathology, or

(3) An intern, resident, or other physician in a training program in pathology who

performs the autopsy under the supervision of a pathologist as defined in paragraph (c) (1) or (2) of this section.

(d) *NIOSH* means the National Institute for Occupational Safety and Health, located within the Centers for Disease Control and Prevention (CDC). Within NIOSH, the Respiratory Health Division (formerly called the Division of Respiratory Disease Studies and the Appalachian Laboratory for Occupational Safety and Health) is the organizational unit that has programmatic responsibility for the medical examination and surveillance program.

3. Revise § 37.202 to read as follows:

§ 37.202 Payment for autopsy.

(a) NIOSH may, at its discretion, pay any pathologist who has received prior authorization for payment from NIOSH pursuant to § 37.204(a). Payment will only be provided with proof that legal consent for an autopsy as required by applicable law from the next of kin or other authorized person has been obtained, or that consent is not required, such as for a forensic autopsy. Payment may be provided to a pathologist who:

(1) Performs an autopsy on a miner in accordance with this subpart; and

(2) Submits the findings and other materials to NIOSH in accordance with this subpart within 180 calendar days after having performed the autopsy.

(i) Types of chest radiographic images accepted for submission include a digital chest image (posteroanterior view) provided in an electronic format consistent with the DICOM standards described in § 37.42(c)(5), a chest computed tomography provided in an electronic format consistent with DICOM standards, or a good-quality copy or original of a film chest radiograph (posteroanterior view).

(ii) More than one type of chest radiographic image may be submitted.

(b) If payments are available, pathologists will be compensated in accordance with their ordinary, usual, or customary fees or at amounts determined through negotiation with NIOSH. To inform payment amounts, NIOSH may collect information about the fees charged by other

pathologists with the same board certifications for the same services, in the same geographic area. NIOSH will additionally compensate a pathologist for the submission of chest radiographic images made of the subject of the autopsy within 5 years prior to their death together with copies of any interpretations made.

(c) A pathologist (or the pathologist's employer, the organization in which the pathologist practices, or another entity receiving payment on behalf of or for services provided by the pathologist) who receives any other specific payment, fee, or reimbursement in connection with the autopsy from the miner's surviving spouse, family, estate, or any other Federal agency will not receive payment from NIOSH.

4. Revise § 37.203 to read as follows:

§ 37.203 Autopsy specifications.

(a) Each autopsy for which a claim for payment is submitted pursuant to this subpart must be performed in a manner consistent with standard autopsy procedures such as those, for example, set forth in *Autopsy Performance & Reporting, third edition* (Kim A. Collins, ed., College of American Pathologists, 2017). Copies of this document may be borrowed from NIOSH.

(b) Each autopsy must include:

(1) Gross and microscopic examination of the lungs, pulmonary pleura, and tracheobronchial lymph nodes;

(2) Weights of the heart and each lung (these and all other measurements required under this subparagraph must be in the metric system);

(3) Circumference of each cardiac valve when opened;

(4) Thickness of right and left ventricles; these measurements must be made perpendicular to the ventricular surface and must not include trabeculations or pericardial fat. The right ventricle must be measured at a point midway between the tricuspid valve and the apex, and the left ventricle must be measured directly above the insertion of the anterior papillary

muscle;

(5) Size, number, consistency, location, description and other relevant details of all lesions of the lungs;

(6) Level of the diaphragm;

(7) From each type of suspected pneumoconiotic lesion, representative microscopic slides stained with hematoxylin eosin or other appropriate stain, and one formalin fixed, paraffin-impregnated block of tissue; a minimum of three stained slides and three blocks of tissue corresponding to the three stained slides must be submitted. When no such lesion is recognized, similar material must be submitted from three separate areas of the lungs selected at random; a minimum of three stained slides and three formalin fixed, paraffin-impregnated blocks of tissue corresponding to the three stained slides must be submitted.

(c) Needle biopsy techniques will not be accepted.

5. Revise § 37.204 to read as follows:

§ 37.204 Procedure for obtaining payment.

(a) Prior to performing an autopsy, the pathologist must obtain written authorization from NIOSH and agreement regarding payment amount for services specified in § 37.202(a) by submitting an Authorization for Payment of Autopsy (form CDC 2.19).

(1) NIOSH will maintain up-to-date information about the availability of payments on its website.

(2) After receiving a completed authorization request form, NIOSH will reply in writing with an authorization determination within 3 working days.

(b) After performance of an autopsy, each claim for payment under this subpart must be submitted to NIOSH and must include:

(1) An invoice (in duplicate) on the pathologist's letterhead or billhead indicating the date of autopsy, the amount of the claim, and a signed statement that the pathologist (or the pathologist's employer, the organization in which the pathologist practices, or another entity

receiving compensation on behalf of or for services provided by the pathologist) is not receiving any other specific compensation for the autopsy from the miner's surviving spouse or next-of-kin, the estate of the miner, or any other source.

(2) Completed Consent, Release and History Form for Autopsy (CDC/NIOSH (M)2.6).

This form may be completed with the assistance of the pathologist, attending physician, family physician, or any other responsible person who can provide reliable information.

(3) Report of autopsy:

(i) The information, slides, and blocks of tissue required by this subpart.

(ii) Clinical abstract of terminal illness and other data that the pathologist determines is relevant.

(iii) Final summary, including final anatomical diagnoses, indicating presence or absence of simple and complicated pneumoconiosis, and correlation with clinical history if indicated.

Xavier Becerra

Secretary,

Department of Health and Human Services

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