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**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: B Reader Decertification and Autopsy Payment

**AGENCY:** Centers for Disease Control and Prevention, HHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** HHS proposes to revise the National Institute for Occupational Safety and Health (NIOSH), Coal Workers' Health Surveillance Program (Program) regulations by adding a provision to allow NIOSH to suspend or revoke B Reader certification. Certification may be revoked for any B Reader found by NIOSH to have engaged in a pattern of providing unreasonably inaccurate chest radiograph classifications in practice – those that are found by the Program to diverge substantially from a competent interpretation of the radiographs, as determined by a panel of practicing, certified B Readers selected by NIOSH. In addition to the B Reader provisions, HHS would also amend 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.

**DATES:** Comments must be received by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Comments on the information collection approval request sought under the Paperwork Reduction Act must be received

by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** *Written comments*: Comments may be submitted by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments to the docket.
- Mail: NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 1090 Tusculum Avenue, Cincinnati, OH 45226.

*Instructions*: All submissions received must include the agency name (Centers for Disease Control and Prevention, HHS) and docket number (CDC-2019-0088; NIOSH-330) or Regulation Identifier Number (0920-AA68) for this rulemaking. All relevant comments, including any personal information provided, will be posted without change to *http://www.regulations.gov*. For detailed instructions on submitting public comments, see the "Public Participation" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

**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**

Interested parties may participate in this rulemaking by submitting written views, opinions, recommendations, and data. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure.

Do not include any information in your comment or supporting materials that you do not wish to be disclosed. You may submit comments on any topic related to this notice of proposed rulemaking.

**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 specifically directs that medical examination of coal miners shall be given in accordance with specifications prescribed by the Secretary (30 U.S.C. 843(a), 957). 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**

All mining work generates fine particles of dust in the air. Coal miners who inhale excessive dust are known to develop a group of diseases of the lungs and airways, including dust-induced fibrotic lung disease (pneumoconiosis) and chronic obstructive pulmonary disease, including chronic bronchitis and emphysema. To address such threats to the U.S. coal mining workforce, the Mine Act was enacted in 1969 and amended in 1977, authorizing the NIOSH Coal Workers' Health Surveillance Program, within the Respiratory Health Division, to detect pneumoconiosis and prevent its progression in individual miners, while at the same time providing information for evaluation of

temporal and geographic trends in pneumoconiosis.

To inform each miner of his or her health status, the Act requires that coal mine operators provide each miner who begins work at a coal mine for the first time a chest radiograph (X-ray) through an approved facility as soon as possible after employment starts. Three years later a miner must be offered a second chest radiograph. If this second examination reveals evidence of pneumoconiosis, the miner is entitled to a third chest radiograph 2 years after the second. Further, all miners working in a coal mine must be offered a chest radiograph approximately every 5 years.

Under NIOSH supervision, chest radiographs are assessed and a summary report based on at least two independent classifications (readings) of each periodic chest radiograph is sent to each participating coal miner, who then has the opportunity to take action to reduce further dust exposure if early dust-induced lung disease is detected. The combined results of these radiographic examinations of miners also enable NIOSH to track rates and patterns of pneumoconiosis among the participating miners.

**B Readers**

Pursuant to NIOSH Coal Workers' Health Surveillance Program regulations in 42 CFR 37.51 and 37.52, chest radiographs taken for the Program are assessed by qualified licensed physician B Readers. B Readers are physicians who have demonstrated proficiency in the use of the International Labour Office (ILO) Classification of Radiographs of Pneumoconioses[1] by taking and passing a specially-designed proficiency examination offered by NIOSH, as specified in 42 CFR 37.52. The goal of the NIOSH B Reader Program is to ensure competency in the detection of pneumoconiosis by

[1] International Labour Office [2011], *Guidelines for the use of ILO International Classification of Pneumoconiosis*, revised edition 2011, Geneva, Switzerland: International Labour Office. Occupational Safety and Health Series No. 22 (Rev. 2011).

evaluating the ability of readers to classify a test set of radiographs, thereby creating and maintaining a pool of qualified readers having the skills and ability to provide accurate and precise classifications in accordance with ILO standards. The B Reader examination currently offered by NIOSH consists of the classification of 125 chest radiographs over the course of 6 hours; the test addresses proficiency in classification of small opacities, large opacities, pleural abnormalities, and certain other abnormalities that may appear in the lung radiographs. In order to maintain B Reader status, B Readers must take and pass the B Reader recertification exam every 5 years.

B Readers participate in the NIOSH Coal Workers' Health Surveillance Program, as well as other national and state programs addressing dust-related illnesses,[2] and are also involved with epidemiologic evaluations, surveillance, and worker monitoring programs involving many types of pneumoconioses. In applying the ILO Classification, B Readers compare sets of standard images, which represent different types of abnormalities and levels of disease severity, with images of the individual being evaluated to identify parenchymal abnormalities (small and large opacities), pleural changes, and other features that can occur in chest radiographs of individuals with pneumoconiosis. In the current ILO Classification, the B Reader is first asked to grade film quality and then to categorize small opacities according to their presence, shape and size, location, and profusion. Large opacities are classified according to their presence and size. The B Reader also assesses the presence, location, width, extent, and degree of calcification of pleural abnormalities as well as provides a description of additional

[2] Other examples of national compensation programs that use B Readers include the Department of Labor, Office of Workers' Compensation Programs (OWCP), Division of Coal Mine Workers' Compensation, Black Lung Program; and the Asbestos Medical Surveillance Program, administered by the Navy and Marine Corps Public Health Center.

features related to dust exposure and other etiologies visible on the chest radiograph.[3]

The classification of chest radiographs is semi-quantitative and relies on the B Reader's professional judgment, comparing case radiographs to the ILO standard classification radiographs. Skilled B Readers can disagree about the presence of disease, particularly in a radiograph with borderline findings, or differ somewhat in classifying the severity of disease. However, since the beginning of the Program in the 1970s, the NIOSH Respiratory Health Division has occasionally learned of B Readers found to provide unreasonably inaccurate radiograph classifications in formal litigation and compensation proceedings relative to the actual features of the chest radiographs in question. "Unreasonably inaccurate" classifications are those that diverge substantially from a competent interpretation of the radiographs and are unsupported by the chest radiographs in question, as determined by a panel of practicing, certified B Readers selected by NIOSH. For example, one B Reader was accused of "under-reading" chest radiographs, frequently not identifying severe cases of pneumoconiosis that may have been indicated by the radiographs;[4] another was accused of "over-reading," frequently identifying asbestosis where the radiographs were subsequently found not to support that determination.[5] The Program regulations in 42 CFR part 37 do not currently provide a mechanism for NIOSH to take remedial action addressing such B Readers.

**Autopsies**

The Mine Act also authorizes HHS to provide for coal miner autopsies and to pay for their submission to NIOSH. Autopsies can be used for public health purposes such as

[3] NIOSH [2015], *Chest Radiograph Classification*, CDC/NIOSH form (M) 2.8, http://www.cdc.gov/niosh/topics/surveillance/ords/pdfs/CWHSP-ReadingForm-2.8.pdf.
[4] The Center for Public Integrity [2013], *Johns Hopkins Medical Unit Rarely Finds Black Lung, Helping Coal Industry Defeat Miners' Claims*, https://publicintegrity.org/environment/johns-hopkins-medical-unit-rarely-finds-black-lung-helping-coal-industry-defeat-miners-claims/.
[5] Fisher D [2012], *Law Firm Hit with $429,000 Verdict over Faked Asbestos Suits*, Forbes, https://www.forbes.com/sites/danielfisher/2012/12/21/law-firm-hit-with-429000-verdict-over-faked-asbestos-suits/#14f1d2f92325.

studying the emerging issue of rapidly progressive and severe pneumoconiosis in coal miners by assessing its pathology and lung content of mineral particles relative to what was seen in the past. Also, autopsies are sometimes requested after mine disasters. The current regulatory language, promulgated over 45 years ago, provides for payments to pathologists up to $200; today, autopsies generally cost between $2000 and $3000. As a result, very few autopsies of coal miners are provided to the Coal Workers' Health Surveillance Program and the Autopsy Program is rarely used. Increasing the compensation rate would make it possible 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 more thoroughly perform public health investigations, especially in the aftermath of mine disasters.

**IV. Summary of Proposed Rule**

To promote administrative efficiency and ensure program integrity, HHS proposes to amend 42 CFR part 37 by adding a new paragraph (d) to § 37.52, to allow NIOSH to take remedial action for any B Reader found by NIOSH to have engaged in a pattern of providing chest radiograph classifications in practice that are found by the Program to be unreasonably inaccurate, as determined by a panel of practicing, certified B Readers selected by NIOSH.

Remedial actions may be taken at NIOSH's discretion or in response to a complaint from any interested party or at the discretion of the Coal Workers' Health Surveillance Program. To ensure that NIOSH can identify those B Readers who provide unreasonably inaccurate classifications to compensation programs, a valid complaint from any interested party must provide the chest radiograph(s) and ILO classification(s)

being contested, as well as a letter from a medical professional supporting the complaint that the classification was unreasonable. A new § 37.52(d)(1) would describe the complaint process. Paragraph (d)(1)(i) would define "unreasonably inaccurate" classifications as those that a panel of B Readers would unanimously determine are substantially divergent from a competent interpretation of the radiographs and are unsupported by the radiographs in question. Paragraph (d)(1)(ii) would describe the elements of a valid complaint; paragraph (d)(1)(iii) would describe an invalid complaint.

A new § 37.52(d)(2) would describe the procedures that would be used by NIOSH to determine whether an individual B Reader has engaged in a pattern of providing unreasonably inaccurate chest radiographs in practice. Complaint investigations would involve a panel of at least four B Readers who would independently review the information provided in each complaint. If at least one B Reader on the panel finds that the contested classification is reasonable, no further review will be conducted. If the B Readers on the panel independently and unanimously conclude that the classification is not reasonable, the actions described in paragraphs (d)(2)(ii)-(v) will be taken.

In accordance with the new provisions in § 37.52(d)(2), the certification of a B Reader who is under investigation will remain in good standing until the Program issues its final decision regarding remedial actions. If three independent complaint investigations conclude that an individual B Reader has engaged in a pattern of providing unreasonably inaccurate chest radiographs in practice, the B Reader's certification will be permanently revoked.

A new paragraph (d)(3) would establish an appeal process for those B Readers whose certifications have been revoked by the Coal Workers' Health Surveillance

Program.

HHS is also considering permitting the revocation or suspension of B Reader certifications for demonstrated patterns of violating the B Reader's Code of Ethics. The Code of Ethics is available on the NIOSH website at *https://www.cdc.gov/niosh/topics/chestradiography/breader-ethics.html*, and would be included in part 37 as an appendix should this option be adopted. HHS encourages comments on this matter.

In addition to the proposed regulatory language on remediating inaccurate B Readers, HHS would also amend 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) would be revised to clarify that pathologists must secure prior authorization from NIOSH and have legal consent to conduct an autopsy on a coal miner. New language in § 37.202(a)(2)(i) and (ii) would clarify the types of chest radiographs accepted by the Program, and new language in § 37.202(b) would specify that pathologists would be compensated in accordance with the ordinary, usual, or customary fee charged by other pathologists for the same services. Section 37.203 would be revised to update the reference for standard autopsy procedures. Finally, new language in § 37.204(a) would detail the new requirement that the pathologist obtain written authorization from the NIOSH Respiratory Health Division prior to completion of the autopsy. Existing language specifying how claims for payment should be submitted to NIOSH would be reorganized.

In existing § 37.201(b), the definition of *Miner* would be revised to remove the

word “underground,” to clarify that the autopsy provisions pertain to all coal miners. Section 37.201(d) would also be 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 proposed rule has been determined not to be a “significant regulatory action” under section 3(f) of E.O. 12866. The revisions proposed in this notice would allow NIOSH to take remedial action addressing any B Readers who frequently provide chest radiograph classifications in practice that are determined by the Program to be unreasonably inaccurate. Part 37 would also be revised to allow NIOSH to compensate pathologists at a contemporary rate for autopsies submitted to the Coal Workers’ Health Surveillance Program.

The proposed revisions to Part 37 would not impose significant costs on the public and would benefit coal miners and coal mine operators. Depending on the types of unreasonably inaccurate classifications they provide, B Readers can compromise the

health of and benefits owed to coal miners who have pneumoconiosis by under-reading or cause unnecessary emotional distress to miners and unnecessary costs for mine operators by over-reading. Allowing the NIOSH Respiratory Health Division to take remedial actions addressing these B Readers through suspension or revocation of their B Reader certifications would ensure that these adverse outcomes were minimized or avoided. Allowing the NIOSH Respiratory Health Division to better compensate pathologists for autopsies submitted to the Program would also ensure that NIOSH is able to study pneumoconiosis in coal miners.

The costs to the Federal government of administering these revisions would be minor and infrequent. NIOSH estimates that over a 5-year period, it might conduct two evaluations of B Readers, costing NIOSH approximately $3000. Over the same period, NIOSH estimates it might fund up to 20 autopsies, costing NIOSH approximately $60,000.

The only costs potentially imposed on the public would be borne by B Readers whose certifications are suspended or revoked. NIOSH estimates that over a 5-year period it might suspend or revoke certifications for one B Reader. However, conducting B Reader medical examinations is generally infrequent within a physician's medical practice, and moreover, other medical procedures similarly compensated would likely substitute for conducting B Reader examinations. It is not possible to reasonably estimate whether such costs would arise and, if so, their level and frequency.

B. Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs)

Executive Order 13771 requires executive departments and agencies to eliminate at least two existing regulations for every new significant regulation that imposes costs.

HHS has determined that this rulemaking is cost-neutral because it does not require any new action by stakeholders. The rulemaking ensures that coal miners properly receive compensation for their occupational illness and that NIOSH can more thoroughly study the development of pneumoconiosis. Because OMB has determined that this rulemaking is not significant, pursuant to E.O. 12866, and because it does not impose costs, OMB has determined that this rulemaking is exempt from the requirements of E.O. 13771. Thus it has not been reviewed by OMB.

C. 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 proposed 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*.).

D. 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 proposed amendments in this rulemaking would not impact the existing collection of data but would add two new items to the approval: B Reader challenge and appeal, and the pathologist prior authorization request. To request more information or to obtain a copy of the data collection plans and instruments, you may call 404-639-5960; send comments to Kimberly S. Lane, 1600 Clifton Road, MS-D74, Atlanta, GA 30333; or 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; and (d) ways to minimize the burden of the collection of information on respondents. Written comments should be received within 60 days of the publication of this notice. The addition of additional paperwork requirements resulting from this proposed rule will increase the burden associated with the following provisions:

*Section 37.52 Proficiency in the use of systems for classifying the pneumoconioses*. This section establishes the process for certifying B Readers. Of the 167 B Readers currently certified and the approximately additional 200 who will be certified over the next 10 years, HHS anticipates that no more than three B Readers may be disciplined over time. Of those, HHS expects two B Readers to challenge or appeal the decision to take disciplinary action; if all decisions are challenged and the final decision to revoke certification is appealed, NIOSH would receive up to eight letters (for each of the four final disciplinary decisions). HHS estimates that the challenge or appeal letter

will take no more than 30 minutes to complete, totaling 4 hours annually. There will be no form associated with this collection.

*Section 37.204 Procedure for obtaining payment*. This section would establish 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 that the number of requests will vary substantially from year-to-year. For example, more requests might be granted following a mine disaster. Over a period of years, 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 1 hour annually over a period of years.

| Section | Title | Number of respondents | Responses per respondent | Average burden per response (min) | Total burden (hr) |
|---|---|---|---|---|---|
| 37.52 | Challenge to disciplinary action and appeal of decertification decision | 2 | 4 | 30/60 | 4 |
| 37.204 | Autopsy prior authorization | 4 | 1 | 15/60 | 1 |
| Total | | | | | 5 |

E. 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.

F. 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 proposed 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.

G. Executive Order 12988 (Civil Justice Reform)

This proposed 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.

H. Executive Order 13132 (Federalism)

HHS has reviewed this proposed 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."

I. 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 proposed rule on children. HHS has determined that the rule would have no environmental health and safety effect on children.

J. 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 proposed rule on energy supply, distribution or use, and has determined that the rule will not have a significant adverse effect.

K. 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 proposed rule consistent with the Federal Plain Writing Act guidelines.

**List of Subjects in 42 CFR Part 37**

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.

**Proposed Rule**

For the reasons discussed in the preamble, the Department of Health and Human Services proposes to amend 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 § 37.52 by adding paragraph (d) to read as follows:

**§ 37.52 Proficiency in the use of systems for classifying the pneumoconioses.**

* * * * *

(d) *Remedial Actions.* (1) Any interested party may make a complaint to the NIOSH Coal Workers' Health Surveillance Program against any B Reader who routinely provides chest radiograph classifications in practice that are believed to be unreasonably inaccurate.

(i) Inaccurate classifications are those that fail to identify small or large opacities in lung fields, pleural changes, and other features indicating the presence of lung disease where they exist, or those that identify small or large opacities, pleural changes, and other features where they do not exist. Unreasonably inaccurate classifications are those that a panel of B Readers would unanimously determine are substantially divergent from a competent interpretation of the radiographs and are unsupported by the chest radiographs in question.

(ii) A valid complaint must be submitted to the NIOSH Coal Workers' Health Surveillance Program, Respiratory Health Division, and include the chest radiographs and ILO classifications being contested as well as a letter of support from a medical professional. A complaint that demonstrates more than a reasonable difference of opinion will be considered valid.

(iii) A complaint that fails to include any required element will be considered

invalid, and the NIOSH Respiratory Health Division will notify the complainant that no further investigation will occur.

(2) Investigations may be initiated at NIOSH's discretion or in response to a valid complaint, pursuant to paragraph (d)(1) of this section, to determine whether a B Reader has provided chest radiograph classifications in practice that are unreasonably inaccurate.

(i) Investigations will include the following:

(A) The NIOSH Respiratory Health Division will choose a panel of at least four B Readers who will independently review the information provided in each valid complaint.

(B) If one or more of the B Readers on the panel independently determines that the classification being contested is reasonable, the NIOSH Respiratory Health Division will conclude that the classification being contested is reasonable. The complainant will be notified of the finding and no further action will be conducted.

(C) If the B Readers on the panel independently and unanimously concur that the classification being contested is unreasonable, remedial actions will be taken by the NIOSH Respiratory Health Division pursuant to paragraphs (d)(2)(ii) through (v) of this section, accordingly.

(ii) If, after an investigation, a panel of B Readers unanimously finds that the classification contested in a complaint is unreasonably inaccurate, the Program will issue an initial report to the B Reader under review. If the B Reader chooses not to challenge the initial report within 30 days, the initial report becomes a final determination. If the B Reader chooses to challenge the initial report, the Coal Workers' Health Surveillance Program will respond within 90 days; the Program's decision is final. The first final report may be considered a warning that further misclassification of small or large

opacities or other types of pleural abnormalities will result in suspension or revocation of the B Reader's certification.

(iii) If, after an investigation, a panel of B Readers unanimously finds that the classification contested in a second complaint is unreasonably inaccurate, the Program will issue an initial report to the B Reader under review. If the B Reader chooses not to challenge the initial report within 30 days, the initial report becomes a final determination. If the B Reader chooses to challenge the initial report, the Coal Workers' Health Surveillance Program will respond within 90 days, during which time the B Reader's certification will remain in good standing; the Program's decision is final and may result in the 1-year suspension of the B Reader's certification with the 1-year period beginning on the date the Program issues the final decision letter. The suspended B Reader must take and pass the certification examination at the conclusion of the suspension period in order to be reinstated.

(iv) If, after an investigation, a panel of B Readers unanimously finds that the classification contested in a third complaint is unreasonably inaccurate, the Program will issue an initial report to the B Reader under review. If the B Reader chooses not to challenge the initial report within 30 days, the initial report becomes a final determination. If the B Reader chooses to challenge the initial report, the Coal Workers' Health Surveillance Program will respond within 90 days, during which time the B Reader's certification will remain in good standing; the Program's decision is final, unless the B Reader successfully appeals the decision pursuant to § 37.52(d)(3), and will result in permanent revocation of the B Reader's certification beginning on the date the Program issues the final decision letter.

(v) If the first complaint is found to be valid and to demonstrate a pattern of inaccurate chest radiograph classifications, the Program will issue an initial report to the B Reader under review and immediately apply the procedures in paragraph (d)(2)(iv) of this section. To demonstrate a pattern of inaccurate classifications, the valid complaint must provide radiographs from three or more patients conducted within a one-year period that are determined by the Program to be inaccurate.

(3) A B Reader whose certification is revoked after three final adverse determinations is no longer a certified B Reader. Such B Reader may appeal the Coal Workers' Health Surveillance Program's decision to revoke the B Reader's certification.

(i) An appeal request must be submitted in writing to the NIOSH Respiratory Health Division Director, signed and postmarked within 30 calendar days of the date of the letter notifying the B Reader of the decertification decision. Electronic versions of the signed appeal request letter will also be accepted.

(ii) The appeal request must state the reason(s) the B Reader believes the decertification decision is incorrect and should be reversed. The appeal request may include scientific or medical information correcting factual errors, any information demonstrating that the decertification decision was not reasonable, and/or relevant new information not previously considered by the Coal Workers' Health Surveillance Program.

(iii) The appeal request must be sent to the NIOSH Respiratory Health Division Director at the address specified in the decertification letter.

(iv) The NIOSH Respiratory Health Division Director will review the Coal Workers' Health Surveillance Program decision and any relevant information provided

by the B Reader and make a final decision on the appeal. The Director will notify the B Reader of the following in writing:

(A) The Director's final decision on the appeal;

(B) An explanation of the reason(s) for the Director's final decision on the appeal; and

(C) Any administrative actions taken by the Coal Workers' Health Surveillance Program.

3. 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 his/her 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.

4. 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 from NIOSH pursuant to § 37.204(a), and with legal consent:

(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) Pathologists will be compensated in accordance with the ordinary, usual, or customary fee charged by other pathologists for the same services, at the discretion of NIOSH. 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 his/her death together with copies of any interpretations made.

(c) A pathologist who receives any other specific payment, fee, or reimbursement

in connection with the autopsy from the miner's widow/widower, his/her family, his/her estate, or any other Federal agency will not receive compensation from NIOSH.

5. 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 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 must be submitted.

(c) Needle biopsy techniques will not be accepted.

6. 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 #0.1585).

(1) NIOSH will maintain up-to-date information about the availability of payments on its website. If payments are not available, the online Authorization of Payment for Autopsy form will not be active and available for completion on the NIOSH 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 is not receiving any other specific compensation for the autopsy from the miner's widow/widower, his/her surviving 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.

Dated: January 10, 2020.

**Alex M. Azar II**
*Secretary,*
*Department of Health and Human Services*
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