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RELEASE – REVISION OF DCMWC PROCEDURE MANUAL CHAPTER 2-501, MEDICAL EVIDENCE

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EXPLANATION OF MATERIAL TRANSMITTED:

This transmittal publishes the updated DCMWC Procedure Manual Chapter 2-501, Medical Evidence. This chapter incorporates regulatory and procedural changes effective following the September 1994 release of the prior chapter. The updated chapter replaces the previous version in full and will be posted on the DCMWC website as well as the Black Lung Library. Accordingly, the prior chapter will be removed from the library and archived for historical purposes.

Changes in this chapter, outlines the type of medical evidence considered in Black Lung claims and identifies the parties who may submit such evidence to the DCMWC.

In addition to updates within this chapter, are the standards for the administration of clinical tests and examinations, contained in subpart B of the 718 portion of the regulations, applicable to all evidence developed by any party after January 19, 2001. This Section also provides the quality requirements subject to substantial compliance, applicable in order to constitute evidence of fact for which they are proffered.

Also, in an effort to streamline and consolidate policy and procedural guidance, as each updated chapter is released, the previous chapter and associated guidance in the Black Lung Library will be removed from the library and archived for historical purposes.

Action: Staff should destroy locally-stored paper copies of the previous version of Procedure Manual Chapter 2-501.

Michael A. Chance
Director, Division of
Coal Mine Workers' Compensation

Distribution: All DCMWC Staff and Regional Directors

CHAPTER 2-501, MEDICAL EVIDENCE

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1. Purpose and Scope.

This Procedure Manual (PM) chapter outlines the types of medical evidence considered in black lung claims and identifies the parties who may submit such evidence to the Division of Coal Mine Workers' Compensation (DCMWC) Program. It also sets forth the criteria for determining if medical evidence complies with the quality guidelines of the regulations. It does not contain the information necessary for determining if a miner is totally disabled by pneumoconiosis arising out of coal mine employment, or if a miner's death was caused or hastened by pneumoconiosis. Those topics are covered in Chapters 2-1001, 2-1002 and 2-1003.

2. Legislative Authority.

Section 402(f) and 426 of the Black Lung Benefits Act, and the attending regulations at the following Sections: 20 CFR 718.101 - 107, 718 Appendix A, 718 Appendix B, 718 Appendix C; 20 CFR 725.404 - .406, and 20 CFR 725.414.

3. Policy.

a. Complete Pulmonary Evaluations. Section 718.101 states that "The Office of Workers' Compensation Programs must develop the medical evidence necessary to determine each claimant's entitlement to benefits. Each miner who files a claim for benefits under the Act must be provided an opportunity to substantiate his/her claim by means of a complete pulmonary evaluation including, but not limited to, a chest radiograph (X-ray), physical examination, pulmonary function tests, and a blood-gas study." See also 30 USC 923(b); 20 CFR 725.406.

b. Administration of Tests and Exams. The standards for the administration of clinical tests and examinations contained in subpart B of the 718 portion of the regulations apply to all evidence developed by any party after January 19, 2001.

c. Compliance with Quality Standards. Section 718.101(b) requires that "Any clinical test or examination subject to these standards shall be in substantial compliance with the applicable standard in order to constitute evidence of the fact for which it is proffered any evidence which is not in substantial compliance with the applicable standard is insufficient to establish the fact for which it is proffered."

d. Parties' Rights When Submitting Evidence. In addition to the Department of Labor (DOL) authorized complete pulmonary evaluation, the miner and a responsible operator (RO) have the right to submit their own medical evidence, in accordance with the limitations prescribed in 20 CFR 725.414. See Chapter 2-502, Limitations on Medical Evidence for a detailed discussion of this topic.

4. References.

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5. Definitions.

What follows is information clarifying commonly used terms in categorizing medical evidence. For a more complete glossary of medical terms used in connection with black lung claims, please see PM Chapter 3-GLO-Medical Glossary.

- a. Arterial Blood Gas Study (ABG). Blood-gas studies are performed to detect an impairment in the process of alveolar gas exchange. This defect will manifest itself primarily as a fall in arterial oxygen tension either at rest or during exercise. It can also manifest as an increase in arterial PCO₂ (partial pressure of carbon dioxide).

In an arterial blood gas study, a sample of blood is drawn via needle from an artery in the patient's wrist. The sample is first drawn while the patient is at rest. If the results of the resting portion of the test do not satisfy the disability requirements of Appendix C, an exercise sample is also drawn, unless medically contraindicated. The sample is analyzed for three results: (1) The PO₂ (partial pressure of oxygen); (2) PCO₂; and (3) pH (symbol for hydrogen ion concentration of arterial blood, the measure of alkalinity versus acidity of blood in the arteries carrying blood from the heart).

All arterial blood gas studies performed in connection with black lung claims must conform to the quality requirements outlined in Section 718.105. The results are evaluated under the criteria outlined in Appendix C to Part 718. Form CM-1159 is used by DCMWC to collect the ABG results from the physician or technician performing the test.

Tests should not be performed during or soon after an acute respiratory or cardiac illness. The ABG can be performed when the miner has returned to his/her baseline function. In making that determination, the examining physician should take into consideration the nature of the miner's illness (i.e. bronchitis vs myocardial infarction) and make a determination on a case-by-case basis.

If one or more blood-gas studies producing results which meet the appropriate table in Appendix C is administered during a hospitalization which ends in the miner's death, then any such study must be accompanied by a physician's report establishing that the test results were produced by a chronic respiratory or pulmonary condition. Failure to produce such a report will prevent reliance on the blood gas study as evidence that the miner was totally disabled at death. See 20 CFR 715.105(d).

In the case of a deceased miner, where no blood gas tests are in substantial compliance with the requirements of 718.105(a)(b) and (c), noncomplying tests may form the basis for a finding if, in the opinion of the claims examiner, the only available tests demonstrate technically valid results. This provision does not excuse compliance with the requirement that any blood gas study administered during a

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hospitalization which ends in the miner's death be accompanied by a physician's report establishing that the test results were produced by a chronic respiratory or pulmonary condition.

Refer to PM Chapter 2-500 for guidance in validating qualifying studies.

b. Chest X-ray (Chest Radiograph). A chest X-ray is a film-based or digital image of the chest. The resulting radiograph can show the presence or absence of "clinical" coal workers' pneumoconiosis (black lung disease).

All chest X-rays performed in connection with black lung claims must conform to the quality requirements outlined in Section 718.102 of the regulations. The regulations were amended in 2014 to include standards for the classification of digital X-ray images, in addition to film-based images.

The standards for X-rays found in the regulations were developed in consultation with the National Institute for Occupational Safety and Health (NIOSH). For many years, the International Labour Office (ILO) has published a series of guidelines on how to classify chest radiographs for indications of pneumoconiosis, the ILO Classification of Radiographs of the Pneumoconiosis. The guide provides for standardized classification methods, and the latest edition includes classification standards for both film and digital images. According to the regulations, and in agreement with NIOSH and ILO standards, a chest X-ray must be classified as Category 1, 2, 3, A, B, or C in order to establish the existence of clinical pneumoconiosis.

Form CM-933 is used by DCMWC to collect the classification from the physician reading the image.

Refer to PM 2-500 for information on quality review of chest films.

c. Pulmonary Function Test (PFT). This test, sometimes called a spirometry or a ventilatory test, measures the amount of breath a patient can exhale. If the amount is reduced to a sufficiently significant degree, that can show pulmonary disability. The patient's capacity to exhale is measured by having him/her forcibly and completely exhale into a spirometer. This test measures: (1) the amount of air exhaled in one second (the FEV₁ --forced expiratory volume in one second); and (2) the total amount of air exhaled (the FVC -- forced vital capacity). The report must also provide the FEV₁/FVC ratio, expressed as a percentage. The MVV (maximum voluntary ventilation) is optional, but if reported, the results of such test must be obtained independently rather than calculated from the results of the FEV₁. The tracings of the MVV must record the individual breath volumes versus time. Form CM-2907 is used by DCMWC to collect the

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results of pulmonary function testing from the physician or technician performing the test.

In most instances, the test is repeated after the miner is administered a bronchodilator (medication intended to open the air passages). If a "post-bronchodilator" test is administered, the physician's report must detail values obtained both before and after administration of the bronchodilator and explain the significance of the results obtained. Both values, the pre and post, should be listed on the Medical Evidence Development Summary, as they are a part of the total record of medical evidence obtained for the claim; however, the pre-bronchodilator results alone will be used in considering whether the miner is disabled.

Tests should not be performed during or soon after an acute respiratory illness. The PFT can be performed when the miner has returned to his/her baseline function. The examining physician should take into consideration the nature of the miner's illness and make a determination on a case-by-case basis.

(1) Documentation. Effective with tests performed after January 19, 2001, any report of pulmonary function tests submitted in connection with a claim for benefits must record the results of flow versus volume (flow-volume loop). All test results must be accompanied by three tracings of the flow versus volume and electronically derived volume versus time tracings. If the MVV is reported, two tracings of the MVV whose values are within 10% of each other are sufficient.

NOTE: The results of a PFT are not valid unless the patient has put forth a genuine full effort, as described in the most recent revision of the ATS Spirometry Standards - 2005 ATS/ERS Task Force Standardization of Lung Function Testing. Where deficiencies in the report are the result of a lack of effort on the part of the miner, the miner will be afforded one additional opportunity to produce a satisfactory result.

All pulmonary function tests performed in connection with black lung claims must comply with the quality criteria outlined in Section 718.103 and Appendix B of the regulations. In the case of a deceased miner, where no pulmonary function tests are in substantial compliance, noncomplying tests may form the basis for a finding if, in the opinion of the claims examiner, the tests demonstrate technically valid results obtained with good cooperation of the miner.

Refer to PM Chapter 2-500 for guidance in validating qualifying studies.

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d. Physical Examination/Medical Report. This is the last of the four components which together comprise the full pulmonary evaluation mentioned in the regulations. The written reports of physical examinations must comply with the requirements outlined in Section 718.104 of the regulations. Form CM-988 may be used by the examining physician as the written report. A narrative report on the physician's letterhead may be used only if all of the questions and information requested on Form CM-988 are addressed.

A report of any physical examination must include the results of a chest X-ray and the results of a pulmonary function test. If the miner is physically unable to perform a pulmonary function test or if the test is medically contraindicated, in the absence of the irrebuttable presumption of total disability or death due to pneumoconiosis, the medical report must be based on other medically acceptable clinical and laboratory diagnostic techniques, such as a blood gas study. (See Section 7 of this Chapter for additional information regarding the physical examination.)

In the case of a deceased miner, where no report is in substantial compliance, a report prepared by a physician who is unavailable (for example, due to his or her retirement or death) may nevertheless form the basis for a finding if, in the opinion of the claims examiner, it is accompanied by sufficient indicia of reliability in light of all relevant evidence. See 20 CFR 718.104(c).

e. Autopsy/Biopsy. The report of an autopsy (a postmortem exam to discover cause of death or extent of disease) or biopsy (tissue sample removed from a living patient) must include a detailed macroscopic and microscopic description of the lungs or visualized portion of the lungs. If a surgical procedure has been performed to obtain a portion of a lung, the evidence must include a copy of the surgical note and the pathology report of the gross microscopic examination of the surgical specimen. If any autopsy has been performed, a complete copy of the autopsy report must be submitted. Any such report must comply with the quality guidelines in Section 718.106 of the regulations.

In the case of a miner who died prior to March 31, 1980, an autopsy or biopsy report must be considered even when the report does not substantially comply with the requirements of 718.106. A noncomplying report concerning a miner who died prior to March 31, 1980, shall be accorded the appropriate weight in light of all relevant evidence.

A negative biopsy is not conclusive evidence that the miner does not have pneumoconiosis. However, where positive findings are obtained on biopsy, the results will constitute evidence of the presence of pneumoconiosis.

Autopsy or biopsy reports prepared in connection with a claim are subject to the limitations on medical evidence as described in 725.414

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(a)(2)(3). The claimant and the RO, or the District Director in a Trust Fund claim, may submit no more than one report of an autopsy and no more than one report of each biopsy as affirmative medical evidence. (See Chapter 2-502, Limitations on Medical Evidence, for additional discussion of autopsy and biopsy reports.) An autopsy or biopsy report that was not prepared in connection with a claim is not subject to the limitations; rather, it is considered to be hospital or medical treatment record evidence under 725.414 (a)(4).

f. Computerized Tomography (CT) Scans. CT scan of the chest are three dimensional images. CT scans are not one of the standard tests of the pulmonary evaluation, but their results are sometimes submitted in connection with black lung claims.

The CT scan cannot be used in place of an X-ray to meet the quality standards for a medical report, but may be submitted in addition to the chest X-ray and must be considered along with all other evidence submitted in connection with the claim. When evaluating CT scan evidence, keep in mind that there are no standards in the regulations for the evaluation and classification of findings from the CT scan. (The CT scan is not interpreted based upon the ILO Classification standards as set forth in the regulations.)

g. Depositions. An attorney for one of the parties in a claim may depose a physician. This could occur when a party deposes its own physician or cross-examines another party's physician (or the Section 413(b) physician). A party's deposition of its physician is considered a medical report for purposes of the evidentiary limitations, assuming that doctor has not previously submitted a medical report. If a party deposes another party's physician for cross-examination, that does not count against either party for evidentiary limitations purposes. (Chapter 2-502, Limitations on Medical Evidence.)

6. Responsibilities.

a. District Director. The District Director is responsible for providing a miner with a complete pulmonary evaluation.

b. Claims Examiner. The claims examiner is responsible for reviewing the complete pulmonary evaluation to ensure that it is in substantial compliance with the regulations and addresses all elements of entitlement.

7. The Complete Pulmonary Evaluation.

Under section 725.406(a), all coal miners who claim benefits must be afforded the opportunity to establish their claims by undergoing complete pulmonary testing paid for by the Black Lung Disability Trust Fund. The miner is not required to undergo the complete pulmonary evaluation, however. (Refer to Chapter 2-1104, Order To Show Cause, for actions to be taken when the miner refuses to undergo the DOL complete pulmonary evaluation.)

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To ensure that the miner is afforded a complete evaluation, each and every test must be offered and the tests must be administered and reported in substantial compliance with the provisions of Part 718. If any test is not in substantial compliance for technical reasons, it must be repeated until results are obtained that are in substantial compliance.

If a test is not in substantial compliance because of a lack of effort or cooperation by the miner, that test will be repeated only once. If a test is contraindicated or the miner refuses the test, a decision must be made based on the evidence that has been obtained. If a miner refuses a test during the initial examination, a statement from the examining physician stating that the test was refused and the reason for refusal will be sufficient. If the miner refuses a repeat a test, the claims staff should request a signed statement from the miner to document the refusal for the file.

Tests not in substantial compliance should be repeated even if the test results would seemingly not affect the outcome of the claim. Providing a complete evaluation initially will preempt any later contention that the claim should be remanded because a complete evaluation was not provided. For example, if the miner underwent all the tests, the X-ray established the presence of the disease, the PFT established total disability, the reasoned medical opinion established causality and supported the presence of the disease and disability, BUT the ABG was found to be invalid, the ABG would have to be repeated unless the miner refused the additional testing or the test was contraindicated. In addition, the physician should be asked to supplement his or her report to address the valid test results.

In some instances, miners have refused to undergo an X-ray in the current claim when the presence of disease was established in a prior filing and DOL has stipulated to presence in that prior filing. This creates a problem because the X-ray report is an integral part of any informed and complete pulmonary examination. The regulations require that each medical opinion developed in connection with a claim be based on specified tests and information including a chest X-ray and pulmonary function test which comply with the applicable quality standards. In view of the fact that presence would be established if DOL had stipulated to the presence of the disease in a prior claim and, because repeated X-rays are not necessarily in the best interest of the claimant's health, do not try to force the miner to take another X-ray in this very specific type of case. Instead, since the medical report may not be in substantial compliance without the X-ray reading, the X-ray reading and X-ray film, if available from the prior filing, will be provided to the doctor performing the current physical examination. The physician should be asked to consider the X-ray evidence along with the current PFT, ABG, and physical examination when making his/her findings. Apply this recommendation only if the miner refuses to submit to an X-ray and there was a stipulation by DOL in a prior claim that presence was found. In cases where there is no stipulation in the prior claim or no prior claim, the claimant should generally be required to submit to an X-ray unless he/she is physically incapable of being transported for such an examination. There may

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be some cases where the claims examiner would conclude that the omission of an X-ray does not undermine the overall credibility of the medical opinion, but this determination must be made on a case-by-case basis.

- a. Non-Miners. Section 725.405(a) recognizes that we do not provide a complete pulmonary evaluation if the CE concludes, based on the initial evidence submitted, that the claimant never worked as a coal miner.

When developing a non-miner claim, fully develop the employment history for any potential coal mine employment. If, when all evidence has been developed, it is determined that the claimant is not a miner, issue an Order to Show Cause (OSC) why the claim should not be denied on that basis. Following the response period, issue a Proposed Decision and Order (PDO) denying the claim on the basis that the claimant was not a miner. (See Chapter 2-1104, Order to Show Cause, for additional information regarding development and adjudication of non-miner cases.)

In non-miner cases, a complete pulmonary evaluation will not be authorized unless and until a hearing is requested. We will always provide the complete pulmonary evaluation before the claim is sent to the OALJ, even if an OALJ, the Benefits Review Board (BRB), or a court previously ruled that the claimant was not a miner and his alleged mining history has not changed since the prior filing(s). The complete pulmonary evaluation must be scheduled as soon as it becomes evident that the claimant will be requesting a hearing. However, if we do not know if the claimant is going to request a hearing until after we have issued the PDO, we will schedule the evaluation as soon as we receive the request for a hearing.

After receiving the medical evidence, issue a Schedule for the Submission of Additional Evidence (SSAE) giving the applicable time for submission of additional evidence followed by a PDO. The issues regarding coal mine employment need to be addressed in both the SSAE and the new PDO with the conclusion that the claimant was not a miner even though those issues were discussed in the Not a Miner - PDO. (See Chapter 2-302, Claimant Master Data Entry, for systems instructions.)

Unless the claimant advises that he/she no longer wants a hearing, the claim should be prepared for referral to the OALJ based on the claimant's prior hearing request.

8. Responsible Operator's Development of Medical Evidence.

The designated responsible operator (RO) is entitled to obtain and submit, in support of its position, medical evidence and the results of medical testing it arranges for the miner (see Section 3d above). (See also Chapter 2-502, Limitations on Medical Evidence.)

- a. Travel for Testing. The regulations provide that the designated RO may schedule the miner for evaluation at the distance the claimant

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travels for the DOL complete pulmonary evaluation or up to 100 miles, whichever is greater. Thus, if the miner chooses a provider 200 miles from his residence, the operator may also schedule the miner for evaluation at a location up to 200 miles from the miner's residence. If the miner chooses a provider 40 miles from his residence, the operator may still schedule the miner for examination at a distance of up to 100 miles from the miner's residence, according to the regulations. Note that the contiguous state rule DOES NOT APPLY to ROs. If the operator does not exceed the mileage limitations it can send the miner to a state that is not contiguous to the state of the miner's residence. Any trip of greater distance for RO testing must be pre-authorized in writing by the district director.

b. Cost of Testing and Travel. The operator is responsible for payment of the provider it selects to perform its evaluation of the miner. The operator is also responsible for payment of the travel expenses associated with its testing. The mileage rate and per diem rate that applies to Federal government travelers also applies to miners traveling for DOL or RO medical examinations and testing, and is published periodically as PM Exhibit 845.

c. Additional Tests. Note that a designated RO has the right to have additional testing completed other than the basic complete pulmonary evaluation. Many physicians require an EKG before doing the complete pulmonary evaluation to ensure the safety of the miner, and RO might also request a CT scan or other tests. If, in such a case, the claimant refuses to have the testing scheduled by the RO, the claims examiner must determine whether a claimant's refusal to undergo testing is reasonable in light of all relevant circumstances in that particular case. If the test is dangerous we would certainly never sanction the miner for refusing to undergo such testing or procedure. On the other hand, it is generally acceptable to require the miner to undergo an EKG.

d. Medical Development Prior to the SSAE. If the RO requests that DOL sanction the claimant (i.e. issue an Order to Show Cause - Abandonment) for failing to attend an RO authorized test AND the SSAE has not yet been issued, the District Director (DD) must deny the request. The RO is specifically given the right to medical testing of the miner only when the SSAE is issued. Although the DD will not prevent a "potentially liable" RO from scheduling the miner for a testing before the RO is formally designated as the liable operator, the miner cannot be required to undergo testing until the SSAE is issued. In the event that two operators are put on notice via the Notice of Claim, both operators should be advised that they are not to initiate medical development until such time as the SSAE is issued designating one as the liable RO. The correspondence system has an attachment to the Notice of Claim addressing the limitation of medical development in such situations.

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e. Medical Development following SSAE. If the SSAE has been issued and the miner **fails** to attend testing or an evaluation authorized by the RO, the DD should informally attempt to determine the reason(s) for non-attendance and resolve it. For example, if the miner was ill or weather was bad on the day of the appointment, advise the RO to reschedule the appointment and notify the miner that the appointment should be kept. All conversations with the miner and RO should be fully documented and bronzed into the claim. An Order to Show Cause may be issued advising all parties that the miner must keep the appointment or inform both the RO and DOL why the appointment cannot be attended as scheduled. A finding that the claim will be abandoned without additional notice if the appointment is not kept or if the miner fails to inform the parties that it needs to be rescheduled is recommended.

If the SSAE has been issued, and the miner **refuses** to attend testing or an evaluation authorized by the RO, the DD should determine the reason(s) and attempt to resolve the issue(s). For example, the miner may not have transportation or a driver that is willing to drive the distance to the appointment. The DD should work with the miner and RO to find suitable transportation or an alternate appointment site. All conversations with the miner and RO should be fully documented and bronzed into the claim. An Order to Show Cause, as mentioned above, is recommended. If the miner simply outright refuses to attend the RO's appointment and has no legitimate issue restricting the miner from going, there is no need to ask the RO to reschedule the appointment. Furthermore, an Order to Show Cause should be issued without a provision regarding keeping a newly scheduled appointment. Again, all conversations with the miner regarding his refusal should be fully documented and bronzed into the claim.

9. Claimant Party's Development of Medical Evidence.

In addition to the complete pulmonary evaluation provided by DOL, the regulations provide that each miner has the right to gather and submit two complete pulmonary evaluations in support of his/her case (see Section 3d above). See also PM Chapter 2-502, Limitations on Medical Evidence.

To aid the miner in developing his/her medical evaluation, the regulations require DOL, at the claimant's request, to provide to the miner's treating physician the results of DOL's pulmonary testing (chest X-ray, ABG, PFT). Share only the objective test results, and NOT the report of the DOL physical. The miner's treating physician can then use the results of the DOL objective testing to prepare a medical report that is in substantial compliance with the quality standards.

The miner's decisions about developing his/her own medical evidence are important. Therefore, the DD advises the claimant in the Guide to Filing, sent when a claim is filed, that he/she may wish to consult with an attorney before deciding what evidence to develop and submit. In fact, the miner is not required to submit additional evidence or to submit a report from his/her

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treating physician. The miner will have to decide if he/she wants to submit additional evidence, how much to submit, and when to submit it. The miner will also have to decide whether to submit evidence from a specialist or from his/her treating physician or from both. The DD is required to explain to the miner the possible consequences of having his/her test results reviewed by his/her treating physician. DOL must provide this opportunity to the miner and inform him/her that any opinion submitted by his/her treating physician will count as one of the two medical reports that the miner can submit.

10. Substantial Compliance.

Section 718.101 states that the standards for the administration of clinical tests and examinations are applicable to all medical evidence developed by any party after January 19, 2001, in connection with a black lung claim. All clinical tests or examinations subject to the 718 standards must be in substantial compliance with the applicable standard in order to constitute evidence of the fact for which they are proffered. This rule includes not only the evidence developed by DOL as part of the miner's complete pulmonary evaluation, but also evidence developed by the claimant and by the RO. However, this rule does not apply to evidence that is not developed "in connection with" a claim for black lung benefits.

a. Non-complying evidence. Since noncomplying evidence generally is not very reliable, it should not be the basis for awarding or denying a claim, except in very limited circumstances. Those limited circumstances are:

- (1) No Evidence in Substantial Compliance. If no evidence exists which does comply with the applicable standards; and
- (2) Unable to Rehabilitate Evidence. The defect(s) cannot be cured by a supplementary opinion or other evidence; and
- (3) Unable to Retest. The death of the miner precludes developing evidence which would be in substantial compliance.

For non-complying evidence to support a decision, the claims examiner must find the evidence sufficiently reliable to establish the fact(s) for which it is offered, despite its failure to meet the threshold "substantial compliance" standard.

A party (absent a timely and approved request for extension of time) cannot cure defects in their evidence once the original time limits for the submission have expired. Prior to the expiration of the time period, a DD can grant an extension for that purpose.

See Chapter 2-1103, Schedule for the Submission of Additional Evidence, for a complete discussion of the time frames for submitting evidence, submitting rebuttal evidence, and submitting evidence to rehabilitate evidence that has been rebutted.

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b. Hospitalization and Treatment Records. The quality standards apply only to evidence *developed in connection with a claim*. Hospitalization and treatment records, therefore, do not fall under 718.101 and need not be in substantial compliance. Chest X-rays, pulmonary function tests and blood gas studies administered in the hospital or as part of the miner's routine care, and not developed for the purpose of establishing or defeating entitlement to black lung benefits, are also exempt from the substantial compliance guidelines. Despite the inapplicability of the quality standards to certain categories of evidence, the claims examiner still must be persuaded that the evidence is reliable in order for it to form the basis for a finding of fact on an entitlement issue.

c. Applying the Substantial Compliance Guidelines. The part 718 quality standards apply to all evidence developed by any party after January 19, 2001, in connection with a claim for benefits. The quality standards apply only prospectively in order to avoid invalidating evidence already submitted in pending claims. It is important that non-complying evidence not be given weight because of the need for technically accurate and reliable evidence for the adjudication of entitlement issues. Noncomplying evidence is generally not considered reliable. Therefore, although noncomplying evidence is admitted into the record and is counted as one of the submitting party's pieces of evidence, such evidence should only form the basis for awarding or denying a claim in limited circumstances. (See Section 10(a) of this Chapter.)

The district director is responsible for ensuring that the complete pulmonary evaluation complies with all applicable quality standards. In addition, if an opposing party challenges evidence as non-complying, the party originally submitting it may rehabilitate the evidence by submitting an additional report from the author of the original report in an attempt to rehabilitate the evidence. Note that the DD, in an RO claim, cannot rebut the evidence of the RO or the claimant. The DD can only note that the evidence is non-complying and then must weigh the evidence accordingly.

The "substantial compliance" standard is a rule of reason. Whether a particular piece of evidence is in substantial compliance with the standards and therefore reliable, is a matter for the claims examiner to determine. In each case in which an issue of noncompliance is raised, the CE must identify any failure to comply strictly with the applicable standard. The CE must then determine whether the test or report is reliable, despite its failure to comply with every criterion in the standard. The finding is necessarily dependent, to an extent, on the element(s) of entitlement for which the test or report may be relevant. The significance of the particular defect must therefore be ascertained by considering whether it is critical to the physician's conclusions.

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As noted above, one important factor is the element of entitlement for which the evidence is offered. For example, a medical opinion diagnosing pneumoconiosis based on a valid PFT and ABG may be submitted, without a chest X-ray. Although an X-ray is an integral part of any examination for pneumoconiosis, the regulations require only that the evidence be in "substantial" compliance with the applicable quality standards. The lack of an X-ray is not necessarily fatal to a report. The report may contain:

- (1) Objective Test Results. Other valid and pertinent tests and information upon which the physician can make a diagnosis;
- (2) Medical History. Accurate medical, smoking and employment histories;
- (3) Physical Findings. Results of a physical examination confirming the presence of pulmonary symptoms or impairment;
- (4) Demonstration of Impairment. Pulmonary function tests and/or arterial blood gas studies demonstrating impairment.

Based on this documentation, the physician may provide a documented and reasoned diagnosis which the claims examiner considers reliable, i.e., in "substantial compliance" with the quality standards.

In another example, presume a "positive" medical opinion based on an invalid pulmonary function test, valid arterial blood gas study, physical examination and other data. The lack of a valid pulmonary function test is not necessarily a reason to reject the entire report. The hypothetical assumes a valid blood gas test, physical examination, etc. As in the first example, this testing and information may support a documented and reasoned diagnosis depending on the purpose for which the report is offered. If the physical examination and clinical tests, other than the pulmonary function test, substantiate the presence of a pulmonary/respiratory impairment, the fact-finder may deem the physician's diagnosis a reliable assessment of the miner's extent of impairment. If, however, the physician clearly relied on the invalid pulmonary function test (or other inaccurate data or information), the claims examiner may find the opinion unreliable in one or more respects.

Keep in mind that DOL's complete pulmonary evaluation must include a valid X-ray, PFT, ABG and physical examination. The guidelines above, therefore, relate to the weighing of medical evidence and are not to be interpreted to mean that the claims examiner can make a decision on a claim if one or more of DOL's tests or examinations are found to be invalid or noncomplying. Any such tests would need to be repeated until valid tests are obtained in order to insure that the miner is offered a complete pulmonary evaluation. Only if the miner declines to

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be retested, if the testing is contraindicated, or if the reason for non-compliance was failure on the part of the miner to cooperate and the miner had been given one additional opportunity to cooperate, would the claim be moved forward for adjudication without valid testing.

A CLAIMS EXAMINER MUST REVIEW AND EVALUATE ALL MEDICAL EVIDENCE THAT IS RECEIVED IN THE DISTRICT OFFICE. This function cannot be delegated to a Workers' Compensation Assistant, Claims Assistant or any other claims staff.

d. Chest X-rays. A chest radiograph (X-ray) must be of suitable quality for proper classification of pneumoconiosis and must conform to the standards for administration and interpretation of chest X-rays as set forth in 20 CFR 718.102 and Appendix A. A CE must review the X-ray report itself to determine whether the X-ray meets these requirements, or is in "technical compliance."

Technical compliance means strict adherence to each applicable quality standard. An X-ray report may be in "substantial compliance" even if it does not meet each and every quality standard. The CE must determine whether the X-ray reading is, or is not, in substantial compliance if one or more items of required information have been omitted, including classification of X-ray findings according to 20 CFR 718.102(e). In some circumstances, the CE may determine that these X-ray interpretations provide sufficient information to make a factual finding on the presence or absence of pneumoconiosis.

For example, a physician may describe the film findings in terms of "no pneumoconiosis", and be in "substantial compliance" without classifying the film as "0/-, 0/0 or 0/1." Conversely, a physician's interpretation or report of X-ray findings may indicate that he/she read the film for reasons unrelated to diagnosing pneumoconiosis, such as lung cancer or cardiac surgery. This reading is likely related to the miner's treatment and therefore is not subject to the "substantial compliance" standard. The CE will consider this report at face value in conjunction with the other evidence in the record. The absence of a finding of clinical pneumoconiosis on a treatment record does not necessarily negate another finding of pneumoconiosis.

An unclassified X-ray, which yields positive indications of lung disease, cannot establish the presence of pneumoconiosis under 718.202(a)(1), which is intended as a means of proving only the existence of clinical pneumoconiosis. On the other hand, 718.202(a)(4) provides that a determination of pneumoconiosis may be made if a physician, exercising sound medical judgement and notwithstanding a negative X-ray, bases the finding on other objective medical evidence (such as ABGs, PFTs, etc.), i.e., "legal" pneumoconiosis (defined as "any chronic lung disease or impairment and its sequelae arising out of coal mine employment", including, but not limited to "any chronic restrictive or obstructive pulmonary disease arising out of coal mine

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employment"). Even an unclassified X-ray may therefore provide some clinical basis for a diagnosis of a respiratory disease rising out of coal mine employment.

Section 718.102(f) requires that the original film for film X-rays or a copy of the original digital object (DVD or other media) for digital X-rays be supplied to the district office, unless prohibited by law. Therefore, X-ray reports from the RO or claimant must include the X-ray film/DVD/other media, as applicable.

The regulations do not require that an X-ray reading be submitted on Form CM-933. However, providers on the listing of approved providers should use the approved CM-933 form. The regulations require the physician reading the film to state his/her qualifications, and to indicate specifically whether he/she is a Board-Certified or Board-Eligible radiologist or a certified "B" reader; they do not require the reading physician to possess those or any other specific qualifications, however. In short, the doctor's qualifications are a factor to be considered when weighing the credibility of the reading, but are not a factor when determining if the X-ray reading is in substantial compliance.

In the case of a deceased miner, an X-ray that is not in substantial compliance with the quality standard may still establish the presence or absence of pneumoconiosis if the film is of sufficient quality and was interpreted by a board-eligible radiologist, board-certified radiologist, or a B-reader. The non-complying X-ray will be considered and will be accorded appropriate weight in light of all relevant evidence. In cases where the chest X-ray of a deceased miner has been lost, destroyed or is otherwise unavailable, a report of a chest X-ray from any party will be considered in connection with the claim.

e. Pulmonary Function Tests (PFT). The results of a PFT will not constitute evidence of the presence or absence of a respiratory or pulmonary impairment, unless the test is conducted and reported in accordance with 20 CFR 718.103 and Appendix B. A CE must review the PFT report itself to determine whether the PFT meets these requirements, or is in "technical compliance."

The regulations require flow-volume loops for every pulmonary function test developed after January 19, 2001. If a DOL-authorized PFT is performed without a flow-volume loop, it must be repeated at the expense of the provider; the miner should be re-tested at the same facility if it has the ability to do the test with flow-volume loop. If the original facility cannot, the miner should be rescheduled at another facility.

The validity of the MVV and the FEV1/FVC values must be assessed independently, and the MVV maneuver is optional for compliance

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purposes. If the MVV is reported, the results must be obtained independently rather than calculated from the results of the FEV1.

Substantial compliance allows a party to establish the credibility of the study, even if one or more of the 718.103 requirements is absent.

NOTE - A medical report cannot be rejected for lack of a PFT, if the test was medically contraindicated.

A non-complying PFT involving a deceased miner may be used to establish the presence or absence of a respiratory impairment, if no complying test is in the record and, in the CE's opinion, the non-complying test yielded technically valid results and the miner provided good cooperation.

As previously noted, if a bronchodilator is administered, the physician's report must provide both pre and post results and explain the significance of the results obtained. Both values, the pre and post, should be listed on the Medical Evidence Development Summary, but only the pre-bronchodilator results will be used in determining whether the miner suffers from a disabling impairment.

f. Report of Physical Examination (PE). Physical examinations must conform to the standards set forth in 20 CFR 718.104. A CE must review the report to determine if the exam includes all of the necessary information and test results to determine whether it meets these requirements:

(1) Based on Specified Tests/Information. A medical opinion developed in connection with the claim must be based on objective tests and information, including a chest X-ray and PFT which comply with the applicable quality standards, unless the PFT is medically contraindicated and the physician conducted other types of medically accepted diagnostic tests. A report of a PE may be based on any other procedures such as an electrocardiogram (EKG), ABG studies conducted and reported as required in 718.105, and other blood analyses which, in the physician's opinion, aid his/her evaluation of the miner.

Example: The physician diagnoses pneumoconiosis based on valid PFT results, etc., but does not obtain an X-ray. X-rays are a general requirement and are an integral part of any informed and complete pulmonary evaluation of a miner. However, the quality standards require only "substantial compliance" with the various criteria, not technical compliance with every criterion in every quality standard in every case. A CE may conclude that the omission of an X-ray does not undermine the overall credibility of the opinion, but this conclusion must be made on a case-by-case basis.

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Example: The physician conducts an examination. The physician finds simple pneumoconiosis on an X-ray, but does not conduct a PFT. The PE report does not satisfy the "substantial compliance" standard because of the absence of the PFT. Medical opinions in a claim must be based on specific tests and information, including chest X-ray and PFT results which comply with the applicable quality standards. The lack of a PFT does not affect the probative value of the X-ray reading(s) as evidence of pneumoconiosis, but to determine the degree of any impairment a PFT is necessary. The physician's report may address the source of any impairment, and may provide additional valuable insight into his/her reasons for interpreting the X-ray as positive for pneumoconiosis rather than some other condition detectable by X-ray. Thus, the report may be relevant in weighing the credibility of the X-ray evidence, but cannot be used to determine the degree of impairment, without other objective testing.

Example: A physician relies, in part, on a noncomplying PFT, but his/her report also cites another, complying test, yielding comparable results. If the report otherwise complies with 718.104, the invalid PFT may be mitigated by the presence of a complying PFT which supports the physician's interpretation of the invalid test. The CE must evaluate all relevant circumstances and determine whether the specific omission undermines the credibility of the evidence. In this example, the CE must consider not only the defects in the physician's PFT, but also the remaining documentation in the report (other clinical studies, the miner's employment, smoking and personal information, etc.).

(2) Treating Physician Opinions. The regulations codify the longstanding judicial recognition of the treating physician's special status. In order to ensure a critical analysis of the physician-patient relationship, the regulations provide four basic factors that the CE MUST consider when weighing medical evidence submitted by the treating physician.

The four factors include: Whether the physician provided pulmonary or non-pulmonary treatment; how long the physician treated the miner; how often the physician treated the miner; and what types of tests and examinations the physician conducted. These factors are expanded upon in the following text.

The CE must consider not only the quality of the physician's relationship with the miner, but also the reasoning and documentation in the opinion itself, and in the context of the remainder of the record, before crediting that opinion.

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Although a treating physician's opinion could be used to establish all elements of a miner's entitlement, Section 718.104(d) does not preclude considering other relevant evidence of record. Rather, it provides criteria for evaluating the quality of the doctor-patient relationship. The purpose of this regulation is to recognize that a physician's professional relationship with the miner may enhance his/her insight into the miner's pulmonary condition. If the CE concludes that the treating physician has a special understanding of the miner's pulmonary health, that opinion may receive "controlling weight" over contrary opinions. That determination may be made, however, only after the CE has considered the credibility of the physician's opinion, in light of its documentation and reasoning and the relevant medical evidence. The CE may, on the other hand, conclude that no additional weight is due the physician's opinion because one or more of the criteria establish facts which make such weight inappropriate.

The guidelines prescribe four basic factors a CE must consider to ensure critical analysis of the doctor-patient relationship:

- (a) Nature of the Relationship. The opinion of a physician who treated the miner for respiratory or pulmonary conditions is entitled to more weight than a physician who has treated him/her for non-respiratory conditions.
- (b) Duration of the Relationship. The length of the treatment relationship demonstrates whether the physician has observed the miner long enough to have a superior understanding of his/her condition.
- (c) Frequency of Treatment. The frequency of the doctor-patient visits demonstrates whether the physician has observed the miner often enough to obtain a superior understanding of his/her condition.
- (d) Extent of Treatment. The types of tests and/or examinations which the physician conducted during the treatment demonstrate whether he/she has gained superior and relevant information about the miner's pulmonary condition.

When the CE weighs evidence, he/she must consider the above-mentioned factors. If a party raises the issue of the qualifications of the doctor, the CE will need to consider the information presented about the doctor's qualifications. The CE may ask the miner to provide information about his/her doctor or the CE may contact the doctor if additional information is needed regarding qualifications. The CE makes the ultimate decision

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regarding the weight to be granted the attending physician's evidence.

In the absence of contrary probative evidence, the CE must accept the statement of a physician with regard to the factors listed above. In appropriate cases, the relationship between the miner and his/her treating physician may constitute substantial evidence to support the giving of that physician's opinion controlling weight over contrary opinions. The weight given to the opinion of the miner's treating physician must, however, be based on the credibility of that physician's opinion in light of its reasoning and documentation, other relevant evidence, and the record as a whole. Section 718.104(d) requires the claims examiner to consider the possible enhanced value of a treating physician's opinion, but it does not require an automatic acceptance of that opinion.

(3) Noncomplying Physical Examination. If there is no complying evidence, 718.104(c) permits non-complying evidence to be considered only in cases of deceased miners.

The regulations allow us to consider reports of physical examinations not in substantial compliance when the miner is deceased, the physician is unavailable to cure the defects of the report and there are no complying reports in the record. In order for a non-complying report of physical examination to provide evidence to support an element of entitlement, it must be prepared by a physician who is "unavailable" (deceased, whereabouts unknown, etc.). The report also must be found sufficiently reliable so that the CE may reasonably depend on it for factual findings.

In deceased miner cases, the physician who is available to review and further comment on his/her own report may cure the defect in the noncomplying report and bring it into substantial compliance.

g. Arterial Blood Gas (ABG) Studies. ABGs should be conducted and reported in accordance with 20 CFR 718.105 and Appendix C. A CE must review the ABG report itself to determine whether the ABG meets these requirements, or is in "technical compliance."

Section 718.105(d) requires that, if one or more ABG results which meet the appropriate table in Appendix C, was administered during a hospitalization which ended in the miner's death, any such study must be accompanied by a physician's report establishing that the test results were produced by a chronic respiratory or pulmonary condition. Failure to produce such a report will prevent reliance on the ABG as evidence that the miner was totally disabled at death.

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This regulation addresses the concern that "deathbed" ABGs may produce qualifying values for reasons unrelated to chronic pulmonary disease. Therefore, a claimant must submit a physician's report linking the ABG results to a *chronic* pulmonary condition in order to rely on the qualifying results as evidence of total disability.

As with other tests, ABGs must be in substantial compliance with their prescribed quality standards, which are set forth in 718.105. In the case of a deceased miner, where no ABG tests are in substantial compliance, noncomplying tests may form the basis for a finding if, in the opinion of the CE, the only available tests demonstrate valid results. This provision does NOT release parties from the requirement to provide a physician's report when qualifying deathbed ABGs are submitted.

If a statement is not included with a qualifying deathbed ABG, the CE must contact the physician and request his opinion regarding whether the ABG reflects the miner's chronic pulmonary condition. The question should be posed in terms of "please explain" rather than "was this or was this not." NOTE: If the claim is a survivor RO claim, the DD cannot develop this evidence, but can assist the claimant in obtaining the necessary statement.

Note: There may be instances where a physician attempts to invalidate a qualifying ABG on the basis of a normal A-a Gradient. The A-a Gradient, or Alveolar-arterial Gradient, is a measure of the difference between the alveolar concentration of oxygen and the arterial concentration of oxygen. It is used in diagnosing the source of hypoxemia, not determining hypoxemia itself. It gives an idea of how well oxygen is moving from the alveoli in the lung to the arterial blood. PO2 measures the actual content of the blood, that which is available for organ and tissue use. The A-a Gradient may not be reliable because it can be affected by many factors.

h. Evaluation of A-a Gradient. Current policy is that the A-a Gradient is not used as a standard measure of disability for the following reasons:

- (1) Relevant Factors. It is dependent on many factors (i.e. age, obesity, heavy exercise, etc.);
- (2) Hypoxemia. Hypoxemia, or low blood arterial oxygen content, is a direct indication of what is provided to body tissues in order for proper functioning to occur;
- (3) Not Indicative of Work Capacity. The A-a Gradient, while it may be normal, would not be an indication of what task a miner can or cannot perform (disability).

Evidence that is not in substantial compliance will *not* be returned to the submitting party and *will* count against the evidentiary limits imposed by the

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regulations. In most cases, the evidence will carry no weight since it was determined not to be in substantial compliance. The evidence should be listed on the Medical Summary which accompanies the SSAE and PDO. Include a full explanation of the basis of this decision and the weight given the evidence in the narrative portion of the SSAE or PDO.

- i. Disclosure of Medical Information. 725.413 requires all parties to exchange any medical information about the miner that they developed in connection with a claim, even if the party does not intend to submit the information into evidence. The developing party must send a complete copy of the medical information to all other parties in the claim within 30 days after receipt. If the information is received after the claim is already scheduled for hearing before an administrative law judge, the disclosure must be made at least 20 days before the scheduled hearing is held (see §725.456(b)).

Medical information disclosed under this section must not be considered in adjudicating any claim unless a party designates the information as evidence in the claim.

At the request of any party or on his/her own motion, a district director may impose sanctions on any party or his/her representative who fails to timely disclose medical information in compliance with this section.

Sanctions must be appropriate to the circumstances and may only be imposed after giving the party an opportunity to demonstrate good cause why disclosure was not made and sanctions are not warranted.