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1. Purpose and Scope

This chapter outlines the limitations on the submission of medical evidence in claims for black lung benefits filed after January 19, 2001. It describes the three basic categories of evidence governed by the limitations - affirmative evidence, rebuttal evidence and rehabilitative evidence. The chapter explains the specific types of evidence that are included in each category, the limits imposed on the submission of that evidence, and the exceptions to the evidentiary limitations.

2. Authority

20 CFR 718.1 - 718.306, Appendix A, Appendix B, Appendix C, 20 CFR 725.406, 20 CFR 725.414, 20 CFR 725.456 - 725.459, 20 CFR 725.310.

3. Background and General Limitations

The regulations that apply to claims filed after January 19, 2001 limit the quantity of medical evidence that parties to a claim can submit.

a. As a general rule, the claimant and the party opposing the claimant's entitlement (the responsible operator or the Trust Fund, as appropriate) are each allowed to submit the results of no more than two complete pulmonary evaluations as affirmative evidence. Consequently, each party is limited to no more than two chest X-ray interpretations, the results of no more than two pulmonary function tests and two arterial blood gas studies, and no more than two medical reports. Additionally, the claimant and the party opposing entitlement may submit no more than one report of an autopsy and no more than one report of any biopsy conducted on the miner. The results of other medical tests or procedures, such as CT scans, may be submitted as well, and are also subject to limitations. The regulations also limit the evidence that may be submitted to rebut the opposing party's medical evidence and to rehabilitate medical evidence that has been the subject of rebuttal.

b. Some categories of evidence are not subject to the limitations. In the case of a subsequent claim, medical

evidence that is in prior claim files is not counted against the limitations for the subsequent claim. Hospital or medical treatment records are also not subject to the limitations. For example, if the miner's attending physician sends him for a consultative evaluation as part of treatment, the resulting report is not subject to the limitations.

4. Responsibilities of the District Director

The District Director (DD) is responsible for ensuring that all parties comply with the evidentiary limitations. The DD must evaluate each piece of medical evidence submitted in conjunction with a claim and determine whether it exceeds the regulatory limitations. Evidence that exceeds the limitations must be excluded from the record.

The DD must also ensure that the miner has received a complete pulmonary evaluation and that every component of that evaluation is in substantial compliance with the regulatory quality standards. The DD may delegate these duties to the claims examiner.

5. Affirmative Medical Evidence

As part of its affirmative case, each party may submit two chest x-ray readings, the results of two pulmonary function studies and two arterial blood gas tests, and two medical reports. Each party may also submit one autopsy report, one report of each biopsy conducted on the miner, and the results of any other medical test or procedure. In a Trust Fund case, the Department may submit affirmative case evidence, except that the examination report and test results obtained pursuant to 725.406 count as affirmative case evidence.

a. Definition of Medical Report

(1) A medical report is defined as a physician's written assessment of the miner's respiratory or pulmonary condition. A medical report may be prepared by a physician who examined the miner or by a physician who reviewed the available admissible evidence. A medical report need not be contained in a single written document; a physician may

supplement his or her initial report in order to review additional evidence submitted after the initial report is prepared. The report of physical examination which is part of the complete pulmonary evaluation required by 20 CFR 725.406 is a medical report. This report does not count against the claimant; it does count as one of the two affirmative reports allowed the Fund in a Trust Fund case. If the objective test results from the Department's complete pulmonary evaluation are forwarded to the claimant's treating physician, and the treating physician prepares a report based upon his/her own records and the objective tests from the Department's examination, the treating physician's report is a claimant's medical report for purposes of the evidentiary limitations.

(2) A physician's written assessment of a single objective test (for example, a physician's reading of a chest x-ray) is not a medical report for the purposes of the evidentiary limitations.

(3) The DD must review each piece of evidence to determine if it constitutes a medical report as contemplated in the evidence limiting rules. If a physician prepares a report for the current claim and assesses the miner's respiratory or pulmonary condition based on a review of multiple pieces of medical evidence, such as current examinations and test results, old evidence in prior claims, and/or old or current treatment records, the resulting report is a medical report under the limitations.

(4) Medical reports that were submitted in a prior federal black lung claim (assuming the claim was not withdrawn) or medical evaluations contained in hospital and/or treatment records do not count against the limitations.

b. Depositions

(1) General. Depositions of medical experts are subject to the evidentiary limitations. They may either take the place of, or supplement, a written medical report. Thus, a party may submit a physician's deposition as one of its two medical reports even if the physician has not prepared a written report. A party may also depose the physician who

prepared one of its two written reports. That deposition would be considered part of the original written medical report and would not count as a separate medical report. During a deposition, the doctor may consider any medical evidence that is in the record; the doctor is not limited to discussing only that evidence previously considered in a written opinion.

(2) RO or Claimant Depositions of 725.406 Physician. The Department's 725.406 physician may be deposed by an RO or the claimant. The deposition in that situation is considered to be "cross-examination" of a witness and does not count as affirmative, rebuttal or rehabilitative evidence for the purposes of the evidentiary limitations. The same rule applies if a party deposes the witness of another party. The RO deposition of the 725.406 physician or the claimant's physician will be listed as medical evidence on the Medical Summary, but will not count against the RO for purposes of the limitations.

(3) Recording on the Medical Summary. The deposition will be recorded on the Medical Summary and will include the name of the individual deposed, the date of the deposition and a summary of the findings as they relate to entitlement issues. If the physician changes his opinion on any issue while being deposed, the change should be discussed in the narrative portion of the SSAE. The DD must evaluate the reasons for the change in order to determine if the physician's revised opinion is credible.

(4) Reviewing and Categorizing the Deposition. The DD must consider carefully the contents of the deposition when determining whether the evidence is one of the two affirmative case medical reports by a party or is cross-examination of another party's physician. The deposition transcript will ordinarily indicate which party requested the deposition.

(5) Content of the Deposition. The regulations prohibit a physician from offering testimony based on evidence relevant to the miner's medical condition that is not admissible under the limitations. Consequently, the DD must carefully examine the deposition transcript to ensure

that the testifying physician relies only on evidence that is in conformance with the evidentiary limitations.

(6) SOL Participation In Depositions. The Office of the Regional Solicitor must be notified as soon as the DD receives notice of a deposition or interrogatory, so that they can participate, if warranted.

(7) Paying for Interrogatories, Depositions and Testimony. 725.459(b) and (c) outline the requirements for payment of fees for interrogatories, depositions and testimony. The proponent of the witness shall bear the cost of cross-examination in all cases. The fund remains liable for any costs associated with the cross-examination of the physician who performed the complete pulmonary evaluation pursuant to 725.406, since DOL is the proponent of the witness.

In order for reimbursement to be made for services rendered by the DOL physician, the provider should complete the OWCP-1500. Enter the correct Procedure Code - 99371 for Interrogatories, 99372 for Depositions, and 99075 for Testimony at Litigation. The provider must enter the unit/quantity code which is the number of hours or fractions thereof expended completing the interrogatories, attending the deposition, or testifying at litigation.

Payment for court reporter fees and reimbursements to attorneys who have paid DOL physicians will be made by special check. The DD should prepare a brief memorandum to the Branch of Standards, Regulations and Procedures and attach copies of the itemized bills. The DD should pay such fees only when he/she has received a copy of the transcript, whether or not the deposition has been submitted by the deposing party. This does not apply to DOL physicians, whose deposition fees should be paid by the Trust Fund in all cases. Process the completed OWCP-1500 as you would any other diagnostic medical bill.

c. Autopsy/Biopsy

(1) Each party is limited to one report of an autopsy as part of its affirmative case. The original report of autopsy prepared by the prosector may be submitted as affirmative evidence by any party, although it will typically be submitted by the claimant. If the report has been obtained by the DD in an RO case, the DD should give the parties the opportunity to adopt the report as affirmative case evidence. If both parties decline, the report should be removed from the record. In place of the original autopsy report, any party may obtain the autopsy slides and may submit as part of its affirmative case a report consisting of a consultant's review of the autopsy protocol and tissue slides.

Autopsy and biopsy reports must be in substantial compliance with the regulatory quality standards to constitute probative evidence. If the report submitted is from the autopsy prosector, it must include a detailed gross macroscopic and microscopic description of the lungs or visualized portion of a lung. If the report is from the physician who performed or supervised a biopsy, the evidence must include a copy of the surgical note and the pathology report of the gross and microscopic tissue examination of the surgical specimen. In the case of a miner who died prior to March 31, 1980, an autopsy or biopsy report will be considered, even if the report does not substantially comply with the requirements of 718.106.

(2) The report of a consulting physician who merely reviews the pathology slides is considered to be in substantial compliance with the quality standards.

(3) Each affirmative case autopsy or biopsy report submitted by a party can be the subject of rebuttal. If an autopsy or biopsy report has been the subject of rebuttal, the party that submitted the original report may submit an additional statement from the physician who authored that report as "rehabilitative" evidence.

d. Other Medical Evidence

The results of any medically acceptable tests or procedures that are relevant to demonstrating the presence or absence of pneumoconiosis or a pulmonary impairment may be submitted in connection with a claim (20 CFR 718.107). The party submitting the test or procedure bears the burden of demonstrating that the test or procedure is medically acceptable and relevant to establishing or refuting a claimant's entitlement to benefits. If evidence in the form of other tests and procedures is admitted into the record, that evidence must be included in the medical summary and must be weighed along with the other evidence in the file when the claim is adjudicated.

(i) A computer-assisted tomography (CT or CAT scan) is an example of other medical evidence. It is not part of the complete pulmonary evaluation required by 725.406, but it can be a useful diagnostic tool for a physician.

(ii) Readings of digital x-rays are also "other evidence" because they do not meet the requirements of 20 CFR 718.102.

(iii) Section 725.414 does not strictly limit the number of other medical evidence, such as CT scans, that can be submitted in a claim. Thus, a party could submit the results of multiple individual tests as its affirmative case evidence. Each party may submit only one interpretation of each test, however.

e. Evidence Exempt from the Limitations

(1) Hospital and Medical Treatment Records. The claimant or the RO may submit any record of a miner's hospitalization or treatment for a respiratory, pulmonary, or related disease. Such evidence is not limited by 725.414.

However, the party submitting the evidence has the burden of establishing that the evidence is related to the miner's pulmonary condition.

(i). The Department may obtain hospital and treatment records in RO and Trust Fund claims. In developing RO survivor claims, the DD should take action to assist the survivor in developing the necessary evidence. 718.205(d) states, "The initial burden is upon the claimant, with the assistance of the district director, to develop evidence which meets the requirements of" entitlement to benefits under the Act. The Department should assist the claimant in obtaining existing hospital or treatment records. It cannot develop new evidence for purposes of the claim, however.

In a Trust Fund survivor's claim, the Department may obtain any available hospital and medical treatment records and may request a consulting physician to review the treatment records or ask the miner's treating physician for an opinion. The Department may also have up to two x-rays taken as part of the miner's treatment re-read and submit the readings as affirmative evidence. Because the DD is relying on the complete pulmonary evaluation to make a decision in a miner's claim, there is usually no need to obtain these types of records in an LM claim.

(ii) The party submitting the treatment or hospital records bears the burden of demonstrating that the records are relevant to the miner's pulmonary condition. Thus the RO is responsible for demonstrating the relevance of any hospital or medical treatment records it has submitted. The DD can include all evidence in the record or ask the RO for a statement as to its relevance. After evaluation of that response, the DD may include or exclude the evidence from consideration.

In most cases the DD will evaluate and include the evidence. If the evidence relating to non-respiratory or pulmonary conditions is excluded from consideration at the DD level, it must be returned to the operator under a cover letter that advises that the DD has determined that the evidence submitted is not relevant. In addition, the letter will advise that the RO may still seek the admission of the evidence at the ALJ level, subject to the objection of any party, if such evidence is sent to all other parties

at least 20 days before a hearing is held in connection with the claim.

(iii) Records of a miner's treatment for respiratory, pulmonary, or related conditions are not subject to limitations, but evaluations of that evidence are limited. For example, if a party obtains an x-ray film from a hospital after learning of it through a review of treatment records and has the film re-read, that reading will be treated as one of the party's two affirmative case X-ray submissions. If any party requests a treating physician to generate an entirely new report for purposes of the claim, that report will constitute a medical report and not a treatment record, and will be subject to the limitations.

Medical evidence that was developed in connection with a state workers' compensation claim is not considered a hospitalization or treatment record and is thus subject to the limitations.

(2) Evidence from a Prior Claim

In the case of a subsequent claim filed by a miner, any medical evidence that was included in the record of a prior claim will be included in the record regardless of the limitations pursuant to 725.309(d)(1). In the case of a survivor's claim, evidence from any prior miner's claim will be admitted into the record only if a party so requests and the evidence is consistent with the limitations.

6. Rebuttal Evidence

After the affirmative medical evidence has been submitted and exchanged, each party has the right to rebut the evidence submitted by the opposing parties and by the DD.

a. Rebuttal evidence is limited to one piece of evidence analyzing each piece of objective evidence submitted by the opposing side. Parties may also rebut the results of the Department's complete pulmonary evaluation by submitting one piece of evidence analyzing each objective test performed during the Department's complete pulmonary evaluation. For example, an operator could have each of the claimant's chest X-rays re-read once, and could submit

one report challenging the validity of, or otherwise analyzing, each pulmonary function test and each ABG submitted by the claimant. The operator could also submit one report analyzing each component of the Department's complete pulmonary evaluation. The claimant has the same right to challenge each component of the Department's complete pulmonary evaluation and each X-ray, PFS, and ABG submitted by the RO. Each party may also submit one autopsy report and one report of each biopsy to rebut an autopsy or biopsy report submitted by the opposing party. The regulations do not specifically allow a party to "rebut" the medical reports of the opposing party. A party may instead have one or both of the physicians who prepared its affirmative case medical reports review the opposing party's medical report in the context of its affirmative medical report. If a party attempts to rebut the medical opinion of the opposing party by submitting a report from a third physician who has analyzed the medical report of the opposing party, that report must be considered a third affirmative case medical report, and should not be admitted.

b. The claimant and the operator may present rebuttal evidence. 20 CFR 725.414(a)(2)(ii) outlines the claimant's rights to submit rebuttal evidence, and 725.414(a)(3)(ii) outlines the RO's rights. The Department may submit rebuttal evidence only in Trust Fund cases. In those cases, the Department will validate all qualifying PFS and ABG results submitted by the claimant, and the resulting report will be submitted as rebuttal evidence.

c. Novel situations may arise in determining what evidence is rebuttal evidence and what evidence is affirmative evidence. Some examples may help in making this determination:

Example 1: The doctor for the RO performs his own examination and reports on it. This is one affirmative medical report for the purposes of the limitations. He then submits another report regarding his own exam and the DOL exam. The second submission is not considered rebuttal evidence because the regulations specifically allow for rebuttal only of objective evidence. The second submission is

considered as a supplement to the original medical report.

Example 2: The RO obtains the DOL X-ray film and three films from the prior filing. RO doctors read all four of the films and submit their readings. The re-reading of the DOL X-ray film is rebuttal evidence. The re-readings of the three films from the prior filing are new affirmative case evidence and only two can be submitted.

7. Rehabilitation of Evidence

The claimant, the RO and the Department in Trust Fund cases, may rehabilitate evidence they have submitted in connection with their affirmative case that has been the subject of rebuttal. The physician who rehabilitates evidence must be the physician who originally prepared the report. A second physician cannot be called upon to rehabilitate evidence that has been the subject of rebuttal. A rehabilitative report by a second physician would be considered another medical report for the submitting party and would be admissible only if that party had not already submitted the two reports it is allowed under the limitations.

a. The party submitting a report of an x-ray or objective test that has been the subject of rebuttal is entitled to submit an additional statement from the physician who originally interpreted the x-ray or objective test, explaining his conclusion in light of the rebuttal evidence. For example, where a party submits a physician's interpretation in rebuttal of a chest X-ray interpretation or objective test, the party that originally submitted the chest X-ray or test into evidence may introduce a contrary statement from the physician who originally interpreted it. Similarly, if a party submits a physician's opinion stating that the results of a pulmonary function study are invalid because the miner expended less than maximal effort in performing the test, the party who originally submitted the test would be able to introduce a contrary statement from the administering physician.

b. If rebuttal evidence tends to undermine the conclusion of a physician who prepared a medical report, the claimant

or the RO, or the Department in a Trust Fund case, is entitled to submit an additional statement from the physician who prepared the medical report explaining his conclusion in light of the rebuttal evidence. 20 CFR 725.414(a)(2)(ii) and (a)(3)(ii).

8. The Department's Development of Medical Evidence

(a) The Department's Obligation to Provide the Miner With a Complete Pulmonary Evaluation

The Black Lung Benefits Act requires the Department to provide a miner who applies for benefits with "an opportunity to substantiate his or her claim by means of a complete pulmonary evaluation." In order to comply with this provision, the Department will schedule the miner for a complete pulmonary evaluation with a physician chosen by the miner from a list maintained by the Department.

DOL must ensure that its own evidence is in substantial compliance with the quality standards. As outlined at 725.406(c), if any medical examination or test conducted as part of the Department's complete pulmonary evaluation is not administered or reported in substantial compliance with the quality standards or does not provide sufficient information to allow the DD to make a decision, the DD shall schedule the miner for further examination and testing. If evidence submitted by the RO or the claimant undermines DOL's complete pulmonary evaluation, the DD can ask the 725.406 physician for clarifying information in order to ensure substantial compliance.

(b) The Department's Development of Medical Evidence in Trust Fund Cases

In a Trust Fund claim the Department exercises the rights of an RO. Thus, the Department can submit the results of up to two complete pulmonary evaluations, except that the pulmonary evaluation provided to the claimant pursuant to 725.406 will count as one of the Department's evaluations. In a Trust Fund case, the Department can also submit one report of an autopsy and one report of each biopsy and can rebut evidence submitted by the claimant and rehabilitate evidence rebutted by the claimant. If the Department chooses to have a second evaluation

in a Trust Fund claim, the second set of tests can be scheduled with a provider selected by DOL.

(c) The Department's Development of Medical Evidence in RO Cases

In an RO miner's case, the Department has no authority to develop medical evidence, apart from the section 725.406 evaluation. When an RO is designated in a survivor's case, the Department's role is limited to assisting the survivor in obtaining existing evidence, such as hospital records.

9. Other Parties' Submission of Medical Evidence in Trust Fund and RO Cases

a. The claimant may obtain medical evidence from any physicians he or she chooses and may submit the results of up to two complete pulmonary evaluations as his or her affirmative evidence. The examination provided pursuant to 725.406 does not count as one of the two complete pulmonary evaluations the claimant is entitled to submit.

b. The RO also has the right to require the claimant to undergo two complete pulmonary evaluations and to submit the resulting evidence, in support of its position. Thus, in an RO case, the claimant may undergo up to five complete pulmonary evaluations while the claim is pending a Proposed Decision and Order (four in a case in which the Black Lung Disability Trust Fund is liable for the payment of any benefits).

10. The Claimant's Rights

a. The claimant may submit two X-ray reports, two pulmonary functions studies, two arterial blood gas tests, one report of an autopsy, one report of each biopsy and two medical reports. The claimant may also submit one piece of rebuttal evidence for each piece of objective evidence proffered by the RO or the Department, and may rehabilitate

any of its own evidence that has been rebutted by evidence submitted by the RO.

b. All parties are required to serve all other parties with copies of evidence submitted to DOL. However, if a claimant is not represented by an attorney, the Department will make copies of the claimant's evidence and forward them to the other parties. NOTE: If an unrepresented claimant requests withdrawal of his or her claim, immediately share the request with the operator and carrier so that it may suspend development of evidence pending resolution of the claimant's request.

c. The claimant may ask his attending physician to provide a report in connection with the claim. The resulting report would count as one of his two affirmative medical reports. The claimant could ask someone other than his attending physician, a pulmonary specialist, for instance, to review all of the medical evidence of record and supply a report, or to perform a complete medical evaluation. Any resulting report would also count as an affirmative medical report for the claimant.

d. The district office should fully advise the miner that medical reports, including reports from a treating physician, must be reasoned and documented to establish entitlement. The miner should understand the consequences of the decision he is making regarding submitting reports. The miner should also be advised to seek counsel when making these decisions.

e. After the section 725.406 physician completes the report for DOL's complete pulmonary evaluation, the DD must inform the miner that he may elect to have the results of the objective testing (but not the doctor's narrative report) sent to his treating physician for use in preparing a medical opinion. The claimant must make a specific request in order for the test results to be sent to his physician. The DD must also inform the claimant that any medical opinion submitted by his treating physician based on these results will count as one of the two affirmative case medical opinions that the miner may submit under 725.414. This procedure is meant to ensure that the claimant can obtain a report from his treating physician

utilizing test results that are in substantial compliance with the quality standards. The required notice to the miner is included in the Guide for Submitting Additional Medical Evidence, which is attached to the SSAE. No additional notice is needed.

f. The miner must specifically request DOL to share the objective tests with the treating physician. After DOL receives such a request, the DD will send the objective tests to the treating physician for his use in preparing a report. The treating physician should not be provided with a copy of the physical examination report.

11. The Responsible Operator's Rights

The Responsible Operator may submit two X-ray reports, two pulmonary functions studies, two arterial blood gas tests, one report of an autopsy, one report of each biopsy and two medical reports, subject to additional limitations concerning multiple operators. (See Section 13, Limitations with Multiple Operators, below.) The RO may also submit one piece of rebuttal evidence for each piece of objective evidence proffered by the claimant or the Department, and may rehabilitate any of its own evidence that has been rebutted by evidence submitted by the claimant.

a. An operator may begin development of medical evidence immediately following the issuance of the Notice of Claim if it is clear that there is only one potentially liable operator. If two operators are named with the Notice of Claim, advise both operators that they are precluded from initiating medical development until such time as one operator is designated. Operators can be informed of the preclusion by attaching the standard CORS note to the Notice of Claim form. When the SSAE is issued, one operator is designated and that operator can then initiate medical development.

b. An operator that has been named as potentially liable has the right to ask that the claim be deemed abandoned if it believes that the claimant has not cooperated with the operator in the development of its evidence. The DD will evaluate the basis for the RO request. If the claimant has not cooperated with the RO in having a medical examination

in a claim in which the operator has not yet been designated in the SSAE, the DD will inform the RO that the claimant cannot be compelled to undergo a medical examination until an operator is named on the SSAE as being the designated liable operator. Similarly, if the claimant has failed to complete interrogatories prior to issuance of the SSAE, the DD should only compel the claimant to respond to liability issues. The claimant need not respond to questions regarding his medical history until an operator is designated in the SSAE.

c. If the DD determines that the claimant has unreasonably refused to cooperate with the RO by refusing to undergo examination or testing, refusing to allow the RO access to his/her cardiopulmonary treatment records, or by failure to cooperate in any other way that the DD determines to be unreasonable, the DD may issue an Order To Show Cause Why The Claim Should Not Be Abandoned under 20 CFR 725.310. The RO has the right to have its physician perform testing other than the specific tests listed in section 725.414 (i.e., analogue chest x-ray, pulmonary function test, arterial blood gas study). The DD should not compel the miner to undergo unnecessary and possibly dangerous medical procedures, however. The adjudicating official determines whether a claimant's refusal to undergo testing is reasonable.

12. The Department's Rights

In miners' claims involving a Responsible Operator, the Department is limited to ensuring that a complete pulmonary evaluation has been performed in substantial compliance with the quality standards. DOL will reread its own field X-ray for quality only, and will validate qualifying PFS and ABG results from the DOL testing.

a. The RO or the claimant may attempt to rebut the medical evidence of the opposing party or of the 725.406 evaluation and to document that the opposing party's evidence is not in substantial compliance. In an RO case, the Department cannot develop such evidence and, therefore, cannot validate or invalidate the evidence of the RO or the

claimant. If, however, evidence submitted in rebuttal of the Department's evidence tends to undermine the 725.406 evaluation, the DOL can further develop that evidence to ensure that it is in substantial compliance with the quality standards.

b. In Trust Fund cases, the Department has the same right with regard to rebuttal and rehabilitation as a responsible operator. In a claim where no RO has been identified, the Department may submit one piece of evidence in rebuttal of each piece of evidence submitted by the claimant. For example, we will send a qualifying PFS submitted by the claimant to our consultant for validation. If our doctor invalidates the PFS, that test would be given little or no weight. The evidence would remain in the record and still would be counted as one of the claimant's submissions. The claimant could, of course, rehabilitate that evidence, in which case the Department would evaluate the rehabilitation evidence and determine if the evidence could be given weight. In a Trust Fund case, the Department may rehabilitate evidence that was rebutted by the claimant by having the examining physician respond to the rebuttal report.

13. Claims with Multiple Operators

In cases in which the Department names more than one potentially liable operator as a party to the claim, medical evidence should not be developed until after the SSAE is issued. Only the operator that is identified as potentially liable in the SSAE may develop medical evidence. If, upon review of all evidence submitted after the SSAE is issued, the DD identifies a different RO as the designated operator liable for payment of benefits, that operator must be given the opportunity to submit medical evidence pursuant to 725.410. The DD will allow the newly designated RO and the claimant not less than 60 days within which to submit evidence relevant to the claimant's eligibility for benefits and the RO liability issues. The newly designated operator may elect to adopt any medical evidence previously submitted by another operator as its own evidence, subject to the limitations of 725.414. If the second RO chooses

to develop its own evidence, the medical evidence submitted by the first RO will not be considered and will be returned to the first RO.

For example, ABC Coal Company is named the designated RO. ABC Coal Company schedules the miner for a pulmonary evaluation. Following development of the liability issue, it is determined that XYZ Mining Company is actually the responsible RO. ABC Coal Company is notified that it is no longer the designated RO. XYZ Mining Company is notified that it is the designated RO and is given at least 60 days to develop eligibility and liability issues. XYZ Mining Company has the right to accept and use the evidence developed by ABC Coal Company or to reject that evidence and develop its own. Thus, XYZ Mining Company could, if it desired, schedule the miner for two complete pulmonary evaluations in addition to the one evaluation already completed on behalf of ABC Coal Company. The medical evidence submitted by ABC Coal Company would, in that case, be excluded from consideration and would be returned to ABC Coal Company.

Evidence that is excluded and returned to an RO should be accompanied by a letter that states: "The newly designated responsible operator has exercised its rights under 20 CFR 725.415(b), which gives the operator the right to adopt any medical evidence previously submitted by another operator as its own evidence, subject to the limitations of 725.414, or to reject the previously submitted medical evidence and obtain its own evidence. The newly designated operator has elected not to adopt the medical evidence of another operator. That evidence is, therefore, being returned to you." A copy of the notice letter will be retained in the file and a copy of the letter will be provided to all parties. No copy of the returned medical evidence will be retained.

14. Exceeding the Limitations

The DD does not have authority to accept excess medical evidence for good cause. That authority lies only with an ALJ. Thus, the DD must strictly apply the limitations without exception and return evidence submitted that exceeds the limitations.

Evidence that exceeds the limitations will be returned to the submitting party with a letter explaining the reason for the

return. A copy must be sent to all parties to the claim. The letter should state that the submitting party may request that the excluded evidence may be resubmitted with a request that it be substituted for previously submitted evidence of the same type. The submitter should also be advised that if the case goes to a hearing, the excluded evidence may be submitted to the OALJ. A copy of the letter returning the excluded evidence to the submitter, but not the evidence, must be included as evidence in the file.

15. Substantial Compliance

Under 725.406 the Department is required to provide reports that are in substantial compliance with the quality standards. Therefore, the Department must obtain a B-reading of the original X-ray to verify its quality, and must validate any PFS or ABG that meets the regulatory standards for disability.

a. X-ray readings. The X-ray re-reading from the Department's examination must be recorded on a blank CM-933 with a reading for quality only. (See Procedure Manual Resource Book - Exhibit 622.) If the Department were to re-read its own X-ray and submit a reading for presence of the disease, the Department would have submitted two X-ray reports. In a Trust Fund case the Department can submit two complete pulmonary evaluations. The DD should use his/her discretion in obtaining a second X-ray reading before issuing the PDO. If the field-reading is positive for presence of disease and the Department concedes pneumoconiosis on the PDO, we cannot contest that issue later, even if we obtain a new X-ray with a negative reading. If the DD feels that the field-reading is questionable or believes that a B-reading is required for a decision, the B-reading for quality and presence of the disease may be obtained. If the field-reader has no qualifications or is not a B-reader, but has diagnosed pneumoconiosis, the DD should consider getting a second reading. However, in an RO case, the DD cannot get a second reading for any reason other than because the first reading was not in substantial compliance.

b. Arterial Blood Gas and Pulmonary Function Studies. Section 718.105 states: "A blood gas study shall initially

be administered at rest and in a sitting position. If the results of the blood gas test at rest do not satisfy the requirements of Appendix C to this part, an exercise blood gas test shall be offered to the miner, unless medically contraindicated." For purposes of the evidentiary limitations, the resting blood gas study and the exercise blood gas study are considered one complete arterial blood gas study, rather than two separate tests.

The regulations also require that the PFS report state whether a bronchodilator was administered. If a bronchodilator was administered, the physician's report must detail values obtained both before and after administration of the bronchodilator. The pre- and post-bronchodilator test results are considered one piece of evidence for purposes of the limitations.

c. In RO cases the DD cannot obtain a consultant's report in order to clarify issues from the complete pulmonary examination. Instead, the DD must ask for clarification from the physician who originally completed the testing or the medical report.

d. Evidence Not in Substantial Compliance. In the event that the Department's X-ray is re-read with a finding that the film is unreadable or if the PFS or ABG is invalid, the Department must have the miner re-tested by the same provider who performed the original testing. The testing should be scheduled with another provider only if the original provider is unable to perform the test in substantial compliance with the quality standards. Since the Department must provide a complete pulmonary evaluation to the miner, if any of the DOL tests are invalid, the Department has not met that requirement. The miner must be offered the opportunity to repeat the test in order to obtain a valid test.

If an initial test of the claimant does not conform to the quality standards due to the claimant's lack of effort, the claimant will be provided an opportunity to re-take the test. If the resulting test again does not comply due to lack of effort, the claimant need not be provided another opportunity to re-take the test.

e. If clarification of unresolved medical issues is needed following receipt of the results from the Department's complete pulmonary evaluation, the original physician may be asked to clarify and/or supplement his or her initial report. In an RO case, the DD cannot obtain a consulting physician's report because evidentiary limitations allow only the RO and claimant to submit medical evidence. Although the Department could obtain a consulting report in a Trust Fund case, the Department would then be precluded from obtaining another physical exam or medical report in subsequent proceedings, except in the case of modification when one additional report would be permitted.

f. If the DD needs additional information and contacts the original doctor for a reasoned medical opinion, we are clarifying an existing report, and the new report will not count against the limitation. In Trust Fund cases the CE should get clarification from DOL's approved provider before considering obtaining a second evaluation. In Trust Fund claims the Department may use its consulting physicians to validate qualifying PFS and ABG results submitted by the claimant in addition to the results obtained in the 725.406 examination.

16. DOL Response to Operator and Claimant Evidence

a. Substantial Compliance. Any clinical tests or exams that were performed after January 19, 2001, must be in substantial compliance with the Part 718 quality standards (718.101(b)). The responsibility for submitting complying evidence rests with the party submitting it. It is the DD's responsibility to review all medical evidence submitted to determine if it is in substantial compliance. (See PM Chapter 2-XXX Medical Evidence for complete discussions regarding substantial compliance.) If the DD determines that evidence submitted by the claimant or the RO is not in substantial compliance, that evidence will still count toward the number of reports or tests permitted under 725.414. The evidence, however, will be given no weight, unless the exceptions for deceased miners are found to exist. The Medical Summary on the SSAE and/or PDO will

list the non-complying evidence, and the narratives will clearly state that the evidence is non-complying, the reason why the evidence is non-complying and the weight, if any, given to the evidence by the adjudicator.

b. Categorizing Evidence Submitted. The Department's response to evidence submitted by other parties will differ, depending on whether or not a Responsible Operator has been designated. In RO cases, the Department cannot rebut the evidence of the operator or the claimant. The Department must review the evidence to determine if it is in substantial compliance, but it cannot develop evidence to determine whether other parties' evidence is in substantial compliance or to bring flawed evidence into substantial compliance. Those functions are reserved to the RO and the claimant. The DD must evaluate the tests as submitted and weigh those tests along with the DOL evidence.

c. Trust Fund Claims. When no RO has been designated, 725.414(a)(3)(iii) entitles the DD to exercise the rights of a responsible operator. That is, in a Trust Fund case, we will request the X-ray films for any X-ray report submitted as affirmative evidence by the claimant and have the film read for quality and presence of disease. The resulting report would constitute rebuttal evidence. If the claimant submits hospital or treatment records containing x-ray readings into the record the Department may have the films re-read. Because the regulations do not specifically allow for rebuttal of hospital or treatment records, any re-reading would constitute affirmative case evidence and would count as one of the Department's two X-ray reports.

In the event that the claimant's X-ray film is found by the Department's B-reader to be unreadable, the claimant will have the right to rehabilitate his evidence but, as with other evidence that is not in substantial compliance, the DD need take no action regarding the claimant's decision to rehabilitate his own evidence.

d. Multiple X-rays. In any case in which a party submits multiple X-ray readings, the DD must categorize the

readings as affirmative or rebuttal evidence in order to determine if the evidence is in conformance with the evidentiary limitations. The DD must determine whether the evidence is one of the two affirmative case X-ray interpretations, whether it is evidence in rebuttal of the claimant's X-ray readings, whether it is rebuttal of the Department's 725.406 x-ray reading or whether it is rehabilitation of evidence that has been rebutted by the claimant. Each party is entitled to submit one rebuttal reading of each X-ray submitted by the opposing party and one rebuttal reading of the one X-ray obtained during the Department's examination.

A party's two affirmative case x-ray readings could come from a number of sources. The party may submit two X-ray reports obtained during its physical examinations; it may have another party's x-ray read two times and submit one reading as rebuttal and the second as affirmative evidence; a party may have an x-ray film that was taken for treatment purposes re-read and submit the reading as affirmative evidence; or a party could have a x-ray that was taken as part of a prior, withdrawn claim re-read. Some x-ray readings would not count against the limitations, however. For example, a party may submit original readings that appear in the miner's hospital or treatment records.

After classifying each x-ray reading, the DD must include in the record those readings that do not exceed the limitations, list them on the Medical Summary form, and consider them along with all other evidence in the narrative portion of the SSAE and/or PDO.

e. Counting Evidence. It is up to the submitting party to decide what pieces of medical evidence it wants the DD to consider. Evidence is admitted into the record as it is received. When the limitations are met, additional evidence is returned to the party that sent it. That evidence should not be considered in the adjudication decision unless the party resubmits the evidence with a request that it be substituted for previously submitted evidence. If a party submits multiple pieces of evidence at one time, and exceeds the allowable amount of that type of evidence, the adjudicator should return the original documents to the

submitting party, and ask the party to select the evidence it wishes to be considered. If the party refuses to select the evidence it wants submitted and resubmits all returned evidence, the DD should not admit any of that evidence.

f. Time limitations. The RO and claimant both must submit their evidence within the time frames given by the SSAE, unless an extension of time has been asked for within those time frames and has been granted. Once the time periods for submission of evidence before the DD have expired, evidence received cannot be considered by the DD. Evidence received after the time periods have expired will be returned to the submitting party and will not be considered by the DD.

17. Returning Evidence to Parties

Evidence that is in excess of the limitations will be returned to the submitting party. A letter describing the evidence, including the date, the type and the source, will accompany the return of the evidence. The letter will state the reason for the return of the evidence. Evidence that is not submitted timely will also be returned with a letter listing the evidence and explaining why the evidence is being returned. Letters returning evidence will themselves become evidence in the file. No record of the returned evidence should be made on the Medical Summary portion of the SSAE and/or PDO and no discussion of the evidence should be in the narrative portion.

Evidence that is not in substantial compliance will not be returned to the submitting party for that reason only. It will count against the limitations on evidence permitted by the regulations. The evidence will be listed on the Medical Summary portion of the SSAE and/or PDO and will be discussed in the narrative portion. That evidence will be considered but, in most cases, will carry little weight, unless the exceptions for deceased miners apply, since it was determined not to be in substantial compliance.

18. Additional Testing after Modification Request

If a miner requests modification of a PDO, the regulations at 725.310(b) permit the claimant and the operator to submit no more than one additional x-ray interpretation, arterial blood gas study, pulmonary functions test, and medical report. Each party is also entitled to such rebuttal evidence and rehabilitation evidence as are authorized by 725.414(a)(2)(ii) and (a)(3)(ii).

The limitations contained in 725.310(b) supplement, rather than supplant, the 725.414 limitations. Consequently, if a party has not already submitted its full complement of tests and reports, it may do so at this time. For example, if a party submitted no pulmonary function tests prior to the PDO, it may submit up to three such tests following the modification request.