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20 CFR Part 718 et al.

Regulations Implementing the Federal Coal Mine Health and Safety Act of 1969, as Amended; Final Rule

DEPARTMENT OF LABOR

Employment Standards Administration

20 CFR Parts 718, 722, 725, 726, 727

RIN 1215–AA99

Regulations Implementing the Federal Coal Mine Health and Safety Act of 1969, as Amended

AGENCY: Employment Standards Administration, Labor.

ACTION: Final rule.

SUMMARY: On January 22, 1997, the Department issued a proposed rule to amend the regulations implementing the Black Lung Benefits Act. 62 FR 3338–3435 (Jan. 22, 1997). When the comment period closed on August 21, 1997, the Department had received written submissions from almost 200 interested persons, including coal miners, coal mine operators, insurers, physicians, and attorneys. The Department also held hearings in Charleston, West Virginia, and Washington, D.C. at which over 50 people testified. The Department carefully reviewed the testimony and the comments and, on October 8, 1999, issued a second notice of proposed rulemaking. 64 FR 54966–55072 (Oct. 8, 1999). In its second notice, the Department proposed changing several of the most important provisions in its initial proposal. The Department also explained its decision not to alter the original proposal with respect to other key regulations based on the comments received to date. Finally, the Department prepared an initial regulatory flexibility analysis. In order to ensure that small businesses that could be affected by the Department's proposal received appropriate notice of the Department's proposed changes, the Department mailed a copy of the second notice of proposed rulemaking to all coal mine operators contained in the databases maintained by the Mine Safety and Health Administration.

The Department initially allowed interested parties until December 7, 1999 to file comments to its second proposal, but extended that period until January 6, 2000. The Department received 37 written submissions before the close of the comment period, from groups representing both coal miners and coal mine operators. The Department also received comments from individual miners, various coal mining and insurance companies, as well as from claims processing organizations, attorneys, and various professional organizations. The Department has carefully reviewed all of the comments, and is issuing its final rule. The rule contains a final regulatory flexibility analysis as required by the Regulatory Flexibility Act.

EFFECTIVE DATE: January 19, 2001.

FOR FURTHER INFORMATION CONTACT: James L. DeMarce, (202) 693–0046.

SUPPLEMENTARY INFORMATION: The Department's final rule reprints 20 CFR Parts 718 (except Tables B1 through B6 in Appendix B), 722, 725, and 726 in their entirety. The Department has not revised all of the regulations in these parts. A detailed list of the regulations to which the Department has made substantive revisions follows the Summary of Noteworthy Regulations below, accompanied by a list of regulations to which the Department has made technical revisions, a list of regulations that the Department has deleted, and a list of regulations that the Department has not changed in any manner.

Summary of Noteworthy Provisions

District Director Claims Processing

These final regulations implementing the Black Lung Benefits Act provide simplified administrative procedures for the adjudication of claims pending before the Office of Workers' Compensation Programs (OWCP). The new streamlined procedures are less formal and should be easier for claims participants to understand. They require the district director to issue fewer documents and therefore involve fewer procedural steps and deadlines. They also require fewer responses from the parties. These changes are in response to the many comments the Department has received asking that OWCP's procedures be simplified and made less formal and adversarial.

In its initial notice of proposed rulemaking, the Department announced its intent to amend these regulations with the goal of helping to improve services, streamline the adjudication process and simplify the regulations' language. The Department noted OWCP's many years of experience administering the program and the variety of ideas for change which had resulted from it. 62 FR 3338 (Jan. 22, 1997). In the second notice of proposed rulemaking, the Department emphasized its commitment to improve the quality of the information it provides the parties to a black lung claim. As part of this commitment, the Department noted its intent to substantially rewrite the documents used by district directors to notify parties of the ''initial findings'' on their claims. The Department stated its goal was to help make claim processing by district offices easier to understand and to give claimants a clear picture of the medical evidence developed in connection with their claims so that they were able to make more informed decisions as to how to proceed. The Department also noted that it had attempted to ''eliminat[e] the hierarchy of response times'' at the district director level. 64 FR 54992 (Oct. 8, 1999). After the receipt of many comments addressing its proposals, the Department has determined that a more comprehensive streamlining of district director procedures is warranted.

The Department has therefore eliminated the use of initial findings and the required responses to them, as well as the district director's initial adjudication as proposed in §§ 725.410–725.413. Similarly, the Department has altered the rules governing informal conferences, § 725.416. If a conference is held, no memorandum of conference will result, § 725.417(c). Instead, OWCP will issue only one decisional document at the conclusion of the district director's processing of a claim: in most cases a proposed decision and order, § 725.418. The proposed decision and order will give rise to the thirty-day period for requesting a hearing before the Office of Administrative Law Judges and, if no such hearing is requested, to the one-year period for filing a request for modification, § 725.419. The proposed decision and order will also contain the district director's final designation of the responsible operator liable for the payment of benefits, and the dismissal of all other potentially liable operators that had previously received notice of the claim.

The Department hopes that the absence of documents with titles such as ''initial findings'' and ''memorandum of conference'' will encourage a less adversarial and less formal development of the necessary evidence and will promote more timely evidentiary development. As previously proposed, the district director will engage in a preliminary gathering of the relevant evidence. He will develop medical evidence, including the complete pulmonary evaluation, §§ 725.405–725.406. He will identify and notify those coal mine operators among the claimant's former employers which he deems to be potentially liable operators, § 725.407, and gather evidence from them regarding their employment of the miner and their status as operators, § 725.408. At the conclusion of this evidence-gathering, however, rather than issue an initial finding (a document with the appearance of a preliminary adjudication of the claim), the district director will issue a schedule for the submission of additional evidence, § 725.410. This

document will contain a summary of the results of the complete pulmonary evaluation and the district director's preliminary analysis of that evidence. The analysis will include a discussion of any of the elements of entitlement that appear not to have been established and why. The schedule will also contain the district director's designation of a responsible operator liable for the payment of claimant's benefits. If the designated responsible operator is not the miner's last employer, the district director will include with the schedule the statements necessary to comply with § 725.495(d).

The schedule will allow the claimant and the designated responsible operator not less than 60 days to submit additional evidence, including evidence relevant to the claimant's entitlement to benefits and the employer's liability for them. The schedule will also allow at least an additional 30 days within which to respond to evidence the other party submits, § 725.410(b). These time periods may be extended for good cause shown, § 725.423. The district director will serve the schedule by certified mail on all parties and will include with it copies of all relevant evidence, § 725.410(c). The schedule will also inform the claimant and the designated responsible operator of their rights, including the right to submit additional evidence and the right to further adjudication of the claim, § 725.410(a)(4). Finally, the schedule will notify the claimant that he has the right to obtain representation and that, if the designated responsible operator fails to accept the claimant's entitlement within the specified time and the claimant establishes his entitlement to benefits payable by that operator, the responsible operator will be liable for a reasonable attorney's fee.

The new procedure requires a responsible operator to respond within 30 days as to the liability designation in the schedule, § 725.412(a)(1). Silence on the responsible operator's part will be deemed an acceptance of the district director's designation as to its liability. Silence on the operator's part with respect to claimant's entitlement, however, will be deemed a controversion. If the operator wishes to accept a claimant's entitlement to benefits, it must file a statement indicating this intent within 30 days of issuance of the district director's schedule, § 725.412(b). Thus, this schedule requires a less comprehensive operator response than the initial findings would have. The responsible operator must file a response only to contest its liability and/or to accept a claimant's entitlement to benefits. In addition, fewer parties are required to respond to the schedule since the claimant need not respond at all.

By contrast, if the district director concludes that there is no operator responsible for the payment of benefits and that the results of the complete pulmonary evaluation support a finding of eligibility, the district director shall issue a proposed decision and order awarding the claimant benefits, § 725.411. In such a case, no schedule for the submission of additional evidence is necessary, and no claimant response to the proposed decision and order is required.

At the conclusion of the time scheduled for the submission of additional evidence, § 725.415(b), the district director may either notify additional operators of their potential liability for benefits under § 725.407, issue another schedule for the submission of additional evidence identifying another potentially liable operator as the responsible operator liable for the payment of benefits, § 725.410, schedule a case for an informal conference, § 725.416, or issue a proposed decision and order, § 725.418. In the event the district director issues another schedule for the submission of additional evidence pursuant to § 725.410, the district director shall not permit the development or submission of any additional medical evidence until after he has determined the responsible operator liable for the payment of benefits. If the operator determined to be the responsible operator has not had the opportunity to submit medical evidence, the district director shall afford that operator the opportunity outlined in § 725.410. The designated responsible operator may elect to adopt any medical evidence previously submitted by another operator as its own, subject to the § 725.414 limitations.

The regulations also contain significant modifications to the informal conference procedure in order to reduce delay and to ensure that conferences are held only in appropriate cases. Thus, if an informal conference is scheduled, it must be held within 90 days of the conclusion of the evidentiary development period unless a party requests that it be postponed for good cause, § 725.416(a). A district director may schedule a conference only if all the parties to a claim are represented or deemed represented, although lay representation is sufficient, § 725.416(b). If all the pertinent requirements are met, however, and an informal conference is scheduled, the unexcused failure of a party to appear constitutes grounds for the imposition of sanctions, § 725.416(c). These sanctions may include denial of the claim by reason of abandonment, § 725.409(a)(4). In the event an ALJ ultimately reviews the denial by reason of abandonment and concludes that it was improper, he may proceed to address the merits of the claim, but only with the written agreement of the Director, § 725.409(c).

In most cases, however, at the conclusion of either the evidentiary development period or informal conference proceedings, the district director will issue a proposed decision and order setting forth his findings and conclusions with respect to the claim. In order to reduce the delay caused by informal conferences, the regulations require issuance of a proposed decision and order within 20 days after the conclusion of all informal conference proceedings, § 725.418(a). The proposed decision and order will contain the district director's final designation of the responsible operator liable for the payment of benefits, and will dismiss, as parties to the claim, all other potentially liable operators that received notification pursuant to § 725.407. Any party may request a hearing within 30 days of issuance of the decision and order, § 725.419(a). If no party responds to the proposed decision, it shall become final and effective upon the expiration of the 30-day period and no further proceedings with respect to the claim shall be possible, except for the filing of a request for modification, § 725.419(d).

The Department hopes that this simplified procedure will reduce, if not eliminate, hearing requests filed before the conclusion of a district director's claims processing. In the event a hearing request is filed before a district director has concluded his adjudication of the claim, however, OWCP will honor the request at the conclusion of processing in the absence of a party's affirmative statement that it no longer desires a hearing. Thus, if a claimant has previously requested a hearing and has been denied benefits in a proposed decision and order, the case will be forwarded to the Office of Administrative Law Judges for hearing in the absence of a statement that a hearing is no longer desired. Similarly, if an operator has previously requested a hearing, and the proposed decision and order awards the claimant benefits, OWCP will forward the claim for hearing absent a statement from the operator that it no longer desires a hearing, § 725.418(c).

Evidentiary Development

Documentary Evidence

With one substantive addition and several deletions, these final rules implement the Department's second proposal with respect to the development of both documentary medical evidence and evidence pertaining to operator liability. The designated responsible operator may submit documentary medical evidence either to the district director or to the administrative law judge (ALJ) up to 20 days before an ALJ hearing, or even thereafter, if good cause is shown. Documentary medical evidence may only be submitted up to the numerical limitations outlined in §§ 725.414(a), however, absent a showing of good cause, § 725.456(b). Thus, each side in a claim may submit two chest x-ray interpretations, the results of two pulmonary function tests, two arterial blood gas studies and two medical reports as its affirmative case. In addition, each party may submit one piece of evidence in rebuttal of each piece of evidence submitted by the opposing party. Finally, in a case in which rebuttal evidence has been submitted, the party that originally proferred the evidence which has been the subject of rebuttal may submit one additional statement to rehabilitate its evidence.

By contrast, documentary evidence as to operator liability must be submitted to the district director, absent a showing of exceptional circumstances, §§ 725.408(b)(2), 725.414(d), 725.456(b). There is no limit on the amount of such evidence that may be submitted, however.

At the urging of commenters representing both industry and claimants, the Department has made one addition to § 725.414(a). The Department has added a specific limitation on the amount of autopsy and biopsy evidence which may be submitted in a claim. Each side may submit one autopsy report and one report of each biopsy as part of an affirmative case. Each side may submit one autopsy report and one report of each biopsy in rebuttal of the opponent's case. Finally, where the original autopsy or biopsy evidence 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.

The Department has deleted language throughout § 725.414 referring to potentially liable operators since only the designated responsible operator and/or the Trust Fund will have the authority to develop documentary medical evidence in a claim. The Department has also deleted one provision of proposed § 725.414, § 725.414(e), as well as the comparable provision proposed as § 725.456(c). These subsections would have provided that any evidence obtained by a party while a claim was pending before a district director but withheld from the district director or any other party shall not be admitted into the record in any later proceedings in the absence of extraordinary circumstances unless its admission is requested by another party. Commenters opposed these provisions, and the Department has agreed to delete them. The Department believes they are no longer necessary, given the significant alteration in the district director's methods for gathering evidence under the new regulations, *see* preamble to § 725.456. In addition, these rules would have posed a danger to parties who are unrepresented before the district director and might have run afoul of the rules unintentionally.

Complete Pulmonary Evaluation

With one exception, these final rules implement the Department's second proposal with respect to the administration of the complete pulmonary evaluation required by 30 U.S.C. 923(b). The Department will allow each claimant to select the physician or facility to perform his evaluation from a list of authorized providers maintained by the Department. The list in each case will include all authorized physicians and facilities in the state of the miner's residence and contiguous states, § 725.406(b). The Department will also make available to the claimant's treating physician, at the claimant's request, the results of the objective testing administered as part of the complete pulmonary evaluation and will inform the claimant that any opinion submitted by his treating physician will count as one of the two medical reports that the miner may submit, § 725.406(d).

The Department has not included in the final regulation at § 725.406, however, the provision proposed as subsection (e) which would have allowed the district director to require the claimant to be reexamined after the completion of the complete pulmonary evaluation if the district director believed that unresolved medical questions remained. Commenters from both industry and claimants' groups opposed this provision, and the Department has concluded it is no longer necessary. The complete pulmonary evaluation will now be performed by a highly qualified physician who may be asked by the district director to clarify and/or supplement an initial report if unresolved medical questions remain. In addition, the components of the complete pulmonary evaluation are to be in substantial compliance with the applicable quality standards and the district director retains authority elsewhere in § 725.406 to schedule the miner for further examination or testing to ensure compliance with these standards.

In the second notice of proposed rulemaking, the Department also announced its intent to perform the best possible respiratory and pulmonary evaluation of miners applying for benefits. The Department promised a thorough examination, performed in compliance with the quality standards, in order to provide each claimant with a realistic appraisal of his condition and the district director with a sound evidentiary basis for a preliminary evaluation of the claim. The Department also announced its intent to develop more rigorous standards for physicians who perform complete pulmonary evaluations. The Department invited the interested public to comment on the possible standards that might be used to select physicians and facilities, 64 FR 54988–54989 (Oct. 8, 1999).

The comments the Department received are discussed in detail in the preamble to § 725.406. It is the Department's intent, however, to include in its Black Lung Program Manual the requirements for a physician's or medical facility's inclusion on the list. The Manual is available to the public in every district office of OWCP. Thus, the requirements for participation in OWCP's program and the manner in which the Department has used those requirements to select physicians for inclusion on the approved list will be public information. The Department does not intend to screen the contents of physicians' prior reports and testimony before including them on the list. The Department intends only to ascertain that the required professional credentials are present.

Witnesses

These final rules adopt the provisions governing witness testimony proposed in the Department's second notice of proposed rulemaking. No person shall be permitted to testify as a witness at a hearing, pursuant to deposition or by interrogatory unless that person meets the requirements of § 725.414(c). Thus, in the case of a witness offering testimony relevant to the liability of a potentially liable operator or the identification of a responsible operator,

the witness must have been identified while the claim was pending before the district director in the absence of extraordinary circumstances, § 725.457(c)(1). In the case of a physician offering testimony relevant to the physical condition of the miner, the physician must have prepared a medical report submitted into evidence. Alternatively, the party offering the physician's testimony must have submitted fewer than two medical reports into evidence in which case the physician's testimony shall be considered a medical report for the purpose of the evidentiary limitations in § 725.414(c). A party may offer the testimony of more than two physicians only upon a finding of good cause, § 725.457(c)(2).

Treating Physicians' Opinions

The Department has adopted a rule governing the weighing of treating physicians' opinions similar to the one proposed in its second notice of proposed rulemaking, § 718.104(d). The rule is discussed in detail in the preamble to § 718.104. The language of § 718.104(d) has been altered to provide that, in appropriate cases, the relationship between the miner and his treating physician may constitute substantial evidence in support of the adjudication officer's decision to give that physician's opinion controlling weight. *See* § 718.104(d)(5). The rule's purpose is to recognize that a physician's professional relationship with the miner may enhance his insight into the miner's pulmonary condition. A treating physician may develop a more in-depth knowledge and understanding of the miner's respiratory and pulmonary condition than a physician who examines the miner only once or who reviews others' examination reports. Section 718.104(d) is not an outcome-determinative evidentiary rule, however. It does not preclude consideration of other relevant evidence of record. Rather, it provides criteria for evaluating the quality of the doctor-patient relationship. The criteria at § 718.104(d)(1)–(4) are indicia of the potential insight the physician may have gained from on-going treatment of the miner. The rule is designed to force a careful and thorough assessment of the treatment relationship. If the adjudicator concludes 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 adjudicator considers the credibility of the physician's opinion in light of its documentation and reasoning and the relative merits of the other relevant medical evidence of record.

Definition of Pneumoconiosis and Establishing Total Disability Due to Pneumoconiosis

The Department has adopted the proposed definition of pneumoconiosis without alteration. In the preamble to § 718.201, the Department explains that the term ''legal pneumoconiosis'' does not create a new medical diagnosis, but rather reflects the statute's definition of the disease as ''a chronic dust disease of the lung and its sequelae, including respiratory and pulmonary impairments, arising out of coal mine employment.'' 30 U.S.C. 902(b). The preamble also explains in detail the Department's decision to include chronic obstructive pulmonary disease in the definition of pneumoconiosis to the extent it is shown to have arisen from coal mine employment. The Department attempts to clarify that not all obstructive lung disease is pneumoconiosis. It remains the claimant's burden of persuasion to demonstrate that his obstructive lung disease arose out of his coal mine employment and therefore falls within the statutory definition of pneumoconiosis. The Department has concluded, however, that the prevailing view of the medical community and the substantial weight of the medical and scientific literature supports the conclusion that exposure to coal mine dust may cause chronic obstructive pulmonary disease. Each miner must therefore be given the opportunity to prove that his obstructive lung disease arose out of his coal mine employment and constitutes ''legal'' pneumoconiosis.

The Department has also adopted the proposed regulation defining total disability and disability due to pneumoconiosis with one alteration, § 718.204. To clarify its original intent concerning the extent to which pneumoconiosis must contribute to a miner's total disability, the Department has amended the language of §§ 718.204(c)(1)(i) and 718.204(c)(1)(ii) by adding the words ''material'' and ''materially.'' Thus, a miner has established that his pneumoconiosis is a substantially contributing cause of his disability if it either has a material adverse effect on his respiratory or pulmonary condition or materially worsens a totally disabling respiratory or pulmonary impairment caused by a disease or exposure unrelated to coal mine dust. Evidence that pneumoconiosis made only a negligible, inconsequential or insignificant contribution to the miner's disability is insufficient to establish total disability due to pneumoconiosis. This change is discussed in detail in the preamble at § 718.204. The Department has also adopted one important proposed change with respect to the clinical evidence which may be used to establish total disability, *see* preamble to § 718.103. The Department has concluded that the claims adjudication process would benefit by making mandatory the use of the flow-volume loop in pulmonary function testing (spirometry testing). The Department has previously noted that the test, conducted in this manner, provides a ''more reliable method of ensuring valid, verifiable results * * *.'' 64 FR 54975 (Oct. 8, 1999). In the second notice of proposed rulemaking, the Department announced its intent to conduct a survey of physicians, clinics and facilities which perform pulmonary function testing to evaluate the prevalence of spirometers capable of producing a flow-volume loop. The Department has now evaluated the results of its survey and has concluded that the prevalence of the necessary equipment and the willingness of those physicians who do not currently have it to buy it, warrant the mandatory usage of such equipment.

Subsequent Claims

These final rules adopt the regulation governing subsequent claims that was proposed in the Department's second notice of proposed rulemaking. A subsequent claim is an application for benefits filed more than one year after the denial of a previous claim. It may be adjudicated on its merits only if the claimant demonstrates that an applicable condition of entitlement has changed in the interim. In the second proposal, the Department justified the rule by noting that ''allowing the filing of a subsequent claim for benefits which alleges a worsening of the miner's condition, * * * merely recognizes the progressive nature of pneumoconiosis.'' 64 FR 54968 (Oct. 8, 1999). In the preamble to § 725.309, the Department responds in detail to those commenters who oppose the regulation. They argue, in part, that the Department's recognition of pneumoconiosis as a latent and progressive disease is scientifically unsound. The Department has summarized the scientific and medical evidence supporting its view that pneumoconiosis is both latent and progressive and has responded to the criticism leveled at that evidence. It is the Department's conclusion that the record contains abundant evidence to justify the regulation governing subsequent claims.

Attorneys' Fees

With minor changes, these final rules promulgate the regulation governing the payment of a claimant's attorney's fee as it was proposed in the Department's second notice of proposed rulemaking, § 725.367. The Department wishes to encourage attorneys to represent claimants early in the administrative process, given the important decisions which may be made by a claimant while a claim is pending before the district director. For example, the rules now limit the quantity of medical evidence that a claimant may submit in support of his entitlement. A claimant may request that the Department send the objective test results from his complete pulmonary evaluation to his treating physician. Any treating physician's opinion which is submitted to the district director, however, may become one of the claimant's two medical reports. The Department's rule governing attorney's fees, therefore, seeks to encourage early attorney involvement by providing a different starting point for employer and Fund attorney fee liability. Although the creation of an adversarial relationship and the ultimately successful prosecution of a claim are still necessary to trigger employer or Fund liability, once that liability is triggered, a reasonable fee will be awarded for all necessary work performed, even if it was performed before the creation of the adversarial relationship.

The text of the regulation has been altered in minor ways. The language describing the fee to which an attorney is entitled has been amended to conform with § 725.366. Section 725.367 therefore provides for the payment of a ''reasonable fee[] for necessary services performed. * * *'' In addition, the regulation has been amended to conform with the revised district director claims procedure. Thus, § 725.367(a)(1) now provides that if the responsible operator designated by the district director pursuant to § 725.410(a)(3) fails to accept the claimant's entitlement to benefits within the 30 day period provided by § 725.412(b) and is ultimately determined to be liable for benefits, the operator shall also be liable for a reasonable attorney's fee. Similarly, if there is no operator that may be held liable for the payment of benefits, the district director issues a schedule for the submission of additional evidence under § 725.410, and the claimant successfully prosecutes his application for benefits, the Fund will be liable for a reasonable attorney's fee, § 725.367(a)(2). Finally, if the district director issues more than one schedule for the submission of additional evidence in order to designate a different operator as the responsible operator, and that operator is ultimately determined to be liable for the payment of benefits, that operator will be liable for the payment of claimant's attorney's fee if it fails to accept the claimant's entitlement within 30 days of the date upon which it is notified of its designation as responsible operator.

True Doubt

The Department has not adopted a ''true doubt'' rule in these regulations. The ''true doubt'' rule was an evidentiary weighing principle under which an issue was resolved in favor of the claimant if the probative evidence for and against the claimant was in equipoise. The Department believes that evaluation of conflicting medical evidence requires careful consideration of a wide variety of disparate factors affecting the credibility of that evidence. The presence of these factors makes it unlikely that a factfinder will be able to conclude that conflicting evidence is truly in equipoise. *See* preamble to § 718.3.

Criteria for Determining a Responsible Operator

The Department has made two changes to the regulation governing the identification of a responsible operator, § 725.495. That regulation now provides that if the miner's most recent employer was a self-insured operator which no longer possesses sufficient assets to secure the payment of benefits when the miner files his claim, the Department will not name a previous employer as responsible operator. Rather, the claim will be the responsibility of the Black Lung Disability Trust Fund. The Department has made this change in response to a comment that stated that it is unfair to name a prior employer as liable for a claim when the financial inability of the later employer to pay the claim is the fault of the Department. Because the Department has the authority to accept or reject applications for self-insurance and to set minimum standards for qualifying as a self-insurer, the Department agrees with the commenter. Thus, to the extent the security deposited by a self-insured coal mine operator pursuant to § 726.104 proves insufficient to pay individual claims, liability will not be placed on previous employers, but rather on the Trust Fund. The Department has also altered the language of § 725.495(d) to reflect the changes made in the regulations governing district director claims processing, §§ 725.410–725.413. The district director will no longer issue an initial finding naming a responsible operator but rather will finally designate in a proposed decision and order one operator as the responsible operator liable for a claim, § 725.418(d).

Insurance Endorsement

In the second notice of proposed rulemaking, the Department opened § 726.203 for comment, noting that representatives of the insurance industry had told the Department that a different version of the insurance endorsement than the one contained in § 726.203(a) had been in use since 1984 with the Department's consent. The Department invited the submission of any document the insurance industry might possess from the Department authorizing use of the different endorsement. 64 FR 54969–70, 55005–06 (Oct. 8, 1999). The Department has carefully considered the comments submitted in response to the second notice of proposed rulemaking and declines to amend § 726.203. The revised black lung endorsement offered by the commenters would materially alter the obligations and coverage provided by the insurance industry, thereby increasing the potential exposure of coal mine operators and the Black Lung Disability Trust Fund, *see* preamble to § 726.203.

Explanation of Changes

Complete List of Substantive Revisions

The Department has made substantive revisions to the following regulations: § 718.3, § 718.101, § 718.102, § 718.103, § 718.104, § 718.105, § 718.106, § 718.107, § 718.201, § 718.202, § 718.204, § 718.205, § 718.301, Appendix B to part 718, Appendix C to Part 718, part 722 (entire), § 725.1, § 725.2, § 725.4, § 725.101, § 725.103, § 725.202, § 725.203, § 725.204, § 725.209, § 725.212, § 725.213, § 725.214, § 725.215, § 725.219, § 725.221, § 725.222, § 725.223, § 725.306, § 725.309, § 725.310, § 725.311, § 725.351, § 725.362, § 725.367, § 725.403, § 725.405, § 725.406, § 725.407, § 725.408, § 725.409, § 725.410, § 725.411, § 725.412, § 725.413, § 725.414, § 725.415, § 725.416, § 725.417, § 725.418, § 725.421, § 725.423, § 725.452, § 725.454, § 725.456, § 725.457, § 725.458, § 725.459, § 725.465, § 725.478, § 725.479, § 725.490, § 725.491, § 725.492, § 725.493, § 725.494, § 725.495, § 725.502, § 725.503, § 725.515, § 725.522, § 725.530, § 725.533, § 725.537, § 725.543, § 725.544, § 725.547, § 725.548, § 725.606,

§ 725.608, § 725.609, § 725.620, § 725.621, § 725.701, § 725.706, § 726.2, § 726.3, § 726.8, § 726.101, § 726.104, § 726.105, § 726.106, § 726.109, § 726.110, § 726.111, § 726.114, § 726.300, § 726.301, § 726.302, § 726.303, § 726.304, § 726.305, § 726.306, § 726.307, § 726.308, § 726.309, § 726.310, § 726.311, § 726.312, § 726.313, § 726.314, § 726.315, § 726.316, § 726.317, § 726.318, § 726.319, and § 726.320. Detailed explanations of the reasons for the Department's revisions may be found in the discussion of individual regulations below.

Complete List of Technical Revisions

The Department has made only technical changes to the following regulations: § 718.1, § 718.2, § 718.4, 718.303, Appendix A to Part 718, § 725.3, § 725.102, § 725.201, § 725.206, § 725.207, § 725.216, § 725.217, § 725.218, § 725.220, § 725.301, § 725.302, § 725.350, § 725.360, § 725.366, § 725.401, § 725.402, § 725.404, § 725.419, § 725.420, § 725.450, § 725.451, § 725.455, § 725.462, § 725.463, § 725.466, § 725.480, § 725.496, § 725.497, § 725.501, § 725.504, § 725.505, § 725.506, § 725.507, § 725.510, § 725.513, § 725.514, § 725.521, § 725.531, § 725.532, § 725.536, § 725.540, § 725.601, § 725.603, § 725.604, § 725.605, § 725.607, § 725.702, § 725.703, § 725.704, § 725.705, § 725.707, § 725.708, § 725.711, § 726.1, § 726.4, § 726.103, § 726.203, § 726.207, § 726.208, § 726.209, § 726.210, § 726.211, § 726.212, and § 726.213. In its first notice of proposed rulemaking, the Department revised § 725.3 to create a new subpart E in part 725, and to recognize the relabeling of the remaining subparts. The Department inadvertently omitted the regulation from the list of technical revisions, however. Accordingly, § 725.3 now appears in the complete list of technical revisions. The Department also inadvertently omitted §§ 725.206 and 725.540 from the list of technical revisions. The Department added a reference to § 725.4(d) to each regulation, *see* 62 FR 3340–41 (Jan. 22, 1997). The Department also inadvertently omitted § 725.207 from the list of technical revisions. The Department replaced commas in subsections (b) and (c) with the word ''and.'' The Department also inadvertently omitted § 725.497 from the list of technical revisions. The Department replaced references to the ''Trust Fund'' with references to the ''fund,'' the term defined in § 725.101(a)(8), and capitalized the word ''section'' in subsections (a) and (b). Finally, the Department inadvertently omitted § 725.601 from the list of technical revisions. The Department replaced references to ''deputy commissioner'' with references to ''district director,'' *see* 62 FR 3340 (Jan. 22, 1997), and replaced a reference to the ''Trust Fund'' with a reference to the ''fund.'' The Department explained the other technical changes that it was making to the regulations in its first and second notices of proposed rulemaking. *See* 62 FR 3340–41 (Jan. 22, 1997); 64 FR 54970 (Oct. 8, 1999). With the exception of § 726.203, none of the regulations listed above were open for comment. The Department's decision not to revise § 726.203, other than the technical revisions discussed in the Department's first notice of proposed rulemaking, is explained in the preamble to § 726.203.

Complete List of Deleted Regulations

The following regulations have been deleted: § 718.307, § 718.401, § 718.402, § 718.403, § 718.404, § 725.453A, § 725.459A, § 725.503A, § 725.701A, and part 727 (entire). The Department explained its decision to incorporate the text of sections 725.453A, 725.459A, 725.503A, and 725.701A into other regulations in its first notice of proposed rulemaking. *See* list of Technical revisions, 62 FR 3341 (Jan. 22, 1997). Detailed explanations of the Department's decision to delete the remaining regulations in this list may be found in the discussion of individual regulations below.

Complete List of Unchanged Regulations

The following regulations have not been revised: § 718.203, § 718.206, § 718.302, § 718.304, § 718.305, § 718.306, § 725.205, § 725.208, § 725.210, § 725.211, § 725.224, § 725.225, § 725.226, § 725.227, § 725.228, § 725.229, § 725.230, § 725.231, § 725.232, § 725.233, § 725.303, § 725.304, § 725.305, § 725.307, § 725.308, § 725.352, § 725.361, § 725.363, § 725.364, § 725.365, § 725.422, § 725.453, § 725.460, § 725.461, § 725.464, § 725.475, § 725.476, § 725.477, § 725.481, § 725.482, § 725.483, § 725.511, § 725.512, § 725.520, § 725.534, § 725.535, § 725.538, § 725.539, § 725.541, § 725.542, § 725.545, § 725.546, § 725.602, § 725.710, § 726.5, § 726.6, § 726.7, § 726.102, § 726.107, § 726.108, § 726.112, § 726.113, § 726.115, § 726.201, § 726.202, § 726.204, § 726.205, and § 726.206. The Department did not accept comments on these regulations, and is re-promulgating the regulations for the convenience of readers.

For purposes of this preamble, ''he'', ''his'', and ''him'' shall include ''she'', ''hers'', and ''her''.

20 CFR Part 718—Standards for Determining Coal Miners' Total Disability or Death Due to Pneumoconiosis

Subpart A—General

20 CFR 718.3

(a)(i) In the initial notice of proposed rulemaking, the Department invited public comment on the continued use of the ''true doubt'' rule, and specifically on the language contained in § 718.3(c), which had been cited to the Supreme Court in support of the rule. 62 FR 3341 (Jan. 22, 1997). The ''true doubt'' rule is an evidentiary principle which requires the adjudicator to find in favor of the claimant on a factual issue if the evidence for and against the claimant is evenly balanced. The Supreme Court invalidated the ''true doubt'' rule in *Director, OWCP* v. *Greenwich Collieries,* 512 U.S. 267 (1994). The Court held § 718.3(c) failed to define the rule effectively, and that the rule, as applied by the Benefits Review Board, violated the Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.*, by relieving the claimant of the burden of proving his or her claim by a preponderance of the evidence (the ''burden of persuasion''). The Department therefore proposed deleting § 718.3(c) and moving the existing 20 CFR 718.403 (1999) (''Burden of proof'') to proposed § 725.103. (ii) In the second notice of proposed rulemaking, the Department addressed the comments responding to the proposed deletion of paragraph (c). 64 FR 54974 (Oct. 8, 1999). Some comments urged the Department to promulgate a version of the ''true doubt'' rule which would comply with *Greenwich Collieries.* Other comments suggested retaining paragraph (c) as a statement of general principle and a reminder to adjudicators of the purpose of the Black Lung Benefits Act (BLBA). The Department rejected both suggestions. The Department concluded a ''true doubt'' evidentiary rule would not improve claims adjudication. Rather, the factfinder must conduct an in-depth analysis of the medical evidence in each case, and resolve credibility issues. The Department also noted that evidence is rarely in equipoise because a factfinder must consider such a wide variety of factors in weighing it: Physicians' qualifications, clinical documentation,

reasoning, relationship to other medical evidence, etc. With respect to paragraph (c) as a statement of principle, the Department considered the provision unnecessary because it would be unenforceable, and because the principles appear in the legislative history of the BLBA which may be cited by a party in litigation. Moreover, the Department noted it had addressed the difficulties confronted by claimants in proving their claims in other regulations, *e.g.,* by requiring substantial compliance rather than strict compliance with the quality standards for medical evidence. (iii) The Department has received four additional comments concerning the ''true doubt'' rule.

(b) Two comments observe that the Department has the regulatory authority to promulgate a ''true doubt'' rule which will comply with *Greenwich Collieries,* and three comments urge the need for such a rule to implement Congressional intent that all reasonable doubt be resolved in the claimant's favor. The Department recognizes that it has the statutory authority to depart from the requirements of the APA and allocate burdens of production and persuasion among the parties. The Department, however, does not believe codification of the ''true doubt'' rule is necessary to afford claimants the protections Congress intended in directing resolution of reasonable doubts in their favor. Rather than a statement of general principle, the Department has provided assistance to claimants in other ways. As noted in the second notice of proposed rulemaking, the Department eased the level of compliance with the quality standards for clinical tests and medical reports from strict adherence to ''substantial compliance.'' 64 FR 54974 (Oct. 8, 1999). The reduced standard allows the adjudicator more leeway to determine in each particular case whether any defects in compliance undermine the credibility of the test or report. Another example is the ''treating physician'' rule in § 718.104(d). The regulation enhances the weight an adjudicator may give to a miner's treating physician's opinion provided the opinion meets certain standards. In addition, § 725.406(d) provides each claimant with the opportunity to have his or her treating physician receive objective test results (such as a chest x-ray reading and pulmonary function study results), in substantial compliance with the regulations' quality standards. This provision ensures that the claimant's treating physician's opinion may be based on complying evidence. Finally, the Department has adopted burden-shifting presumptions such as the default onset date for the commencement of benefits, § 725.503(b), (d), and the presumption of coverage for pulmonary-related medical benefits, § 725.701(e), which assist claimants on medical treatment issues. These provisions significantly reduce the need for a ''true doubt'' rule.

(c) Three comments contend a ''true doubt'' rule is necessary because the limitations on the quantity of medical evidence imposed by the regulations will result in increased instances in which the evidence for and against entitlement is in equipoise despite scrupulous consideration of all relevant factors affecting credibility. The Department disagrees. The adjudicator must examine several variables in weighing the credibility of each item of medical evidence, especially physicians' opinions. Age of the opinion, reasoning, underlying clinical data, the physician's level of expertise, reliability of employment, social and medical histories, etc., are all factors to be considered in each report. As for clinical studies, the quality standards establish criteria to measure the reliability of the clinical results, and physicians' reviews of the results provide additional information on the studies' validity. When all available information is assembled, the Department believes few medical records for and against entitlement will be in equipoise. Furthermore, the limitations on evidence should prompt each party to bolster the credibility of its medical evidence and challenge the credibility of its opponent's case.

(d) One comment states the ''true doubt'' rule is especially needed for weighing chest x-rays because that type of evidence involves very few variables (film quality, readers' expertise) which can affect the credibility of the evidence. The Department believes no need exists to adopt a specialized ''true doubt'' rule for use in weighing only x-rays. Such a rule would place undue importance on one type of evidence, and would overemphasize the role of x-rays in determining whether the miner has pneumoconiosis. Chest x-rays are used to determine whether the miner has ''clinical'' pneumoconiosis, *i.e.,* ''the lung disease caused by fibrotic reaction of the lung tissue to inhaled dust, which is generally visible on chest x-rays as opacities.'' *Hobbs* v. *Clinchfield Coal Co.,* 917 F.2d 790, 791 n. 1 (4th Cir. 1990) (citation omitted). The BLBA explicitly prohibits the denial of a claim based solely on negative x-rays. 30 U.S.C. 923(b). The reason for this prohibition is Congress' reservations about the reliability of negative x-rays as trustworthy evidence that the miner does not have pneumoconiosis. *Usery* v. *Turner Elkhorn Mining Co.,* 428 U.S. 1, 31–34 (1976). Consequently, Congress has limited the use of negative x-rays in evaluating a miner's entitlement to benefits. Even if the x-ray readings in a particular claim appear to be truly balanced and therefore insufficient to meet the preponderance standard, however, the claimant may nevertheless establish the existence of clinical pneumoconiosis. For example, a factfinder might find one x-ray reading more credible than another based on a radiologist's explanation, contained in a supplemental report or deposition testimony, of the reasons for his x-ray diagnosis. Such reasons may include consideration of the miner's complete occupational history, including the length of his or her coal mine employment, and the absence of other injurious exposures, *see* 45 FR 13687, Discussion and changes, § 718.202 (Feb. 29, 1980). In addition, a claimant may prove the existence of ''legal'' pneumoconiosis. This broader category of compensable disease comprises ''all lung diseases which * * * [are] significantly related to, or substantially aggravated by, dust exposure in coal mine employment.'' *Hobbs,* 917 F.2d 4 791 n. 1; *see also Barber* v. *Director, OWCP,* 43 F.3d 899, 901 (4th Cir. 1995). In weighing medical evidence relevant to ''legal'' pneumoconiosis, the adjudicator may consider a variety of factors which affect the weight of the medical evidence, *e.g.*, the physicians' expertise, the reasoning and documentation in the medical reports, the comparative consistency or inconsistency of the opinions with other medical evidence such as hospital reports, etc. A claimant has ample opportunity to establish that (s)he has a lung disease caused by coal mine employment in addition to the narrow type of disease discoverable by x-rays. The Department therefore rejects the position that a ''true doubt'' rule should be available for the purpose of resolving conflicts in x-ray evidence.

(e) One comment suggests a ''true doubt'' rule would be useful in resolving conflicts between qualifying and nonqualifying pulmonary function and blood gas studies. The commenter acknowledges that more factors exist to determine the credibility of these types of clinical evidence than exist when chest x-ray evidence is in conflict, but nevertheless recommends making the rule applicable in the event the evidence is in equipoise. Both pulmonary function (§ 718.103) and

blood gas studies (§ 718.105) must comply with far more detailed quality standards than x-rays. Although only ''substantial compliance'' is required under the regulations, the more detailed standards necessarily provide more points of comparison between studies and more bases for preferring one study to another. A party may challenge another party's study by submitting expert opinion evidence demonstrating the study is unreliable or invalid. Given the numerous means of challenging or bolstering a study, the Department does not believe a ''true doubt'' rule would play a significant role in weighing pulmonary function studies and blood gas studies. No change in the regulation is appropriate.

(f) No other comments have been received concerning this section, and no changes have been made in it.

Subpart B

20 CFR 718.101

(a) In the initial notice of proposed rulemaking, the Department added subsection (b) to emphasize that the part 718 quality standards apply to all evidence developed by any party in connection with a claim filed after March 31, 1980, and to claims governed by part 727 if the evidence was developed after that date. 62 FR 3341 (Jan. 22, 1997). Paragraph (b) also established a single standard of compliance for all clinical tests and medical reports, in place of the varying standards contained in the former individual regulations. The Department revised paragraph (b) in the second notice of proposed rulemaking to clarify that the quality standards will apply only prospectively to evidence developed in connection with a claim, after promulgation of these regulations. The Department noted it wished to avoid invalidating evidence already submitted in pending claims based on the parties' settled expectations. 64 FR 54974–75 (Oct. 8, 1999). The Department also responded to numerous comments received after the initial notice of proposed rulemaking. It rejected comments opposing the general applicability of the quality standards to medical evidence and advocating consideration of noncomplying evidence, citing the need for technically accurate and reliable evidence for the adjudication of entitlement issues. For the same reason, the Department rejected comments disputing its authority to impose quality standards on medical evidence as inconsistent with the Black Lung Benefits Act's (BLBA) requirement that ''all relevant evidence'' be considered. *See* 30 U.S.C. 923(b). The Department concluded quality standards are consistent with the mandated consideration of all relevant evidence because noncomplying evidence is inherently unreliable, and therefore not relevant to the adjudication of a claim. The Department rejected the suggestion that the criteria enumerated in the quality standards should provide the only grounds for invalidating medical evidence; rather, parties may develop any evidence which addresses the validity of the evidence. The Department explained there was no need to add an exemption from the quality standards for hospitalization and treatment records because § 718.101 is clear that it applies quality standards only to evidence developed ''in connection with a claim'' for black lung benefits. Finally, the Department rejected as unnecessary a requirement that the Department notify a party if its evidence is noncomplying and allow it to rehabilitate the evidence because the responsibility for submitting complying evidence rests with the party submitting it. The district director is already responsible for ensuring the complete pulmonary examination required by 30 U.S.C. 923(b) complies with all applicable quality standards. In addition, if an opposing party challenges evidence as noncomplying, the party originally submitting it may rehabilitate the evidence by submitting an additional report from the author of the original report.

(b) Two comments reiterate the general argument that 30 U.S.C. 923(b) and the Administrative Procedure Act (APA), 5 U.S.C. 556(d), require consideration of ''all relevant evidence,'' and the Department therefore cannot exclude from the adjudicator's consideration noncomplying medical evidence. The Department previously addressed, and rejected, this argument in the second notice of proposed rulemaking. 64 FR 54974 (Oct. 8, 1999). The Department stated that noncomplying evidence is not ''relevant evidence'' because it is inherently unreliable, and cannot form the basis for awarding or denying a claim. Upon further consideration, the Department concludes this statement, while accurate in the majority of cases, should be qualified. Evidence which does not substantially comply with the applicable standard generally is not very reliable. Noncomplying evidence should only form the basis for awarding or denying a claim in limited circumstances. All three of the following requirements must be met: no evidence exists which does comply with the applicable standards; the defect(s) cannot be cured by a supplementary opinion or other evidence; and the death of the miner precludes developing evidence which would be in substantial compliance. In order for such evidence to support an award or denial, the adjudicator 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. The Department therefore rejects the commenters' general position that noncomplying evidence cannot be excluded under 30 U.S.C. 923(b), although the Department recognizes a limited exception to the standards' gatekeeping function for some claims involving deceased miners.

(c) Two comments cite specific examples of circumstances in which allegedly probative physicians' opinions could be disregarded on compliance grounds. (i) In one example, the commenter cites as potentially noncomplying a medical opinion diagnosing ''legal'' pneumoconiosis based on valid pulmonary function and arterial blood gas testing, but omitting any chest x-ray testing. The Department has previously considered the position that a medical report should not automatically be found noncomplying based on the absence of an x-ray. 64 FR 54977 (Oct. 8, 1999). In rejecting the comment that the quality standard applicable to reports of physical examination (§ 718.104) should not make a chest x-ray a standard requirement, the Department noted that an x-ray is an integral part of any examination for pneumoconiosis. The Department further noted, however, that medical evidence must only be in ''substantial compliance'' with the applicable quality standards; the party proffering the evidence may demonstrate that the evidence is reliable despite its failure to comply with every criterion in the standard. The Department reiterates that position. Whether any particular piece of evidence is in ''substantial compliance'' with the standards, and therefore reliable, is a matter for the adjudicator to determine taking into consideration all relevant circumstances. One important factor is the element(s) of entitlement for which the evidence is offered. In the example cited above, the lack of an x-ray is not necessarily fatal. The report may contain: valid and pertinent other tests and information upon which the physician can make a diagnosis; accurate medical, smoking and employment histories; results of a physical examination confirming the

presence of pulmonary symptoms or impairment; and pulmonary function study and/or blood gas studies demonstrating impairment. Based on this documentation, the physician may provide a documented and reasoned diagnosis of ''legal pneumoconiosis'' which the adjudicator considers reliable, *i.e.,* in ''substantial compliance'' with the quality standards. *See* 45 FR 13687 (Feb. 29, 1980), § 718.202, Discussion and changes (h). (ii) In another example, the commenter posits a ''positive'' medical opinion based on an invalid pulmonary function test, valid arterial blood gas testing, physical examination and other data. The lack of a valid pulmonary function study 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 study substantiate the presence of a pulmonary/respiratory impairment, the factfinder may deem the physician's diagnosis a reliable assessment of the miner's extent of impairment. If the employment, smoking and other personal information is accurate, the adjudicator may accept the physician's conclusions about the cause of the miner's pulmonary or respiratory impairment. If, however, the physician clearly relied on the invalid pulmonary function study (or other inaccurate data or information), the adjudicator may find the opinion unreliable in one or more respects. (iii) The Department emphasizes that the ''substantial compliance'' standard is a rule of reason. In each case in which an issue of noncompliance is raised, the factfinder must identify any failure to comply strictly with the applicable quality standard. The factfinder must then determine whether the test or report is reliable despite its failure to comply with every criterion in the standard. This 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. In the first example, the lack of an x-ray may be excused if the physician has offered a documented and reasoned diagnosis of ''legal'' pneumoconiosis. In the second example, the invalid pulmonary function study may or may not affect an otherwise documented and reasoned evaluation of the miner's respiratory/pulmonary condition. No categorical response, however, can be given to the hypotheticals since the reliability, and therefore the probative value, of the reports can only be evaluated in the context of an actual claim. No change in the regulation is warranted.

(d) One comment urges the Department to include a provision specifically exempting those medical tests and reports generated outside the black lung benefits claim context from the quality standards. Specifically, the commenter requests that the text of the regulation make clear that chest x-rays, pulmonary function tests and blood gas studies administered in the hospital or as part of the miner's routine care be exempted from quality standards applicability. The Department previously addressed this concern in the second notice of proposed rulemaking. 64 FR 54975 (Oct. 8, 1999). The Department noted that § 718.101 limits the applicability of the quality standards to evidence ''developed * * * in connection with a claim for benefits'' governed by 20 CFR parts 718, 725 or 727. Despite the inapplicability of the quality standards to certain categories of evidence, the adjudicator 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. Additional exclusionary language in the regulation is therefore unnecessary.

(e) One comment contends all medical evidence involving a deceased miner should be considered without regard to the quality standards because the miner is no longer available for further testing. The Department disagrees. The regulations provide that a deceased miner's noncomplying chest x-rays, pulmonary function studies and medical reports may form the basis of an award or denial of benefits under certain circumstances provided no complying study or report is available. *See* §§ 718.102(e) (x-rays), 718.103(c) (pulmonary function studies), 718.104(c) (medical reports). The Department has added a similar provision to § 718.105 (arterial blood gas studies). With respect to each category of evidence, the availability of tests or reports in substantial compliance with the applicable quality standards makes reliance on the noncomplying tests or reports unnecessary; the record already contains reliable evidence addressing the deceased miner's pulmonary condition, and reliable evidence is the fundamental purpose of the quality standards. Furthermore, excusing noncompliance for all evidence involving a deceased miner ignores the fact that existing evidence may be brought into substantial compliance despite the unavailability of the miner. The party offering the evidence may obtain a supplementary opinion from the physician who conducted the noncomplying test or authored the report, and cure the defect(s). Finally, the party may submit the noncomplying evidence in any event, ecognizing that it may be considered but cannot establish any fact for which complying evidence is in the record.

(f) One comment suggests that applying the quality standards only prospectively will sanction the acceptance of inferior evidence if the evidence was developed before the effective date of these regulations. The commenter also contends the Department's rationale for prospective application implies the former quality standards will not apply to evidence developed before the effective date of these regulations, especially for unrepresented claimants. The Department disagrees. In the initial notice of proposed rulemaking, proposed § 718.101(b) required all evidence developed in conjunction with a black lung benefits claim to comply with the applicable quality standards. 62 FR 3374 (Jan. 22, 1997). The Department stated that the purpose of § 718.101(b) was to make clear the Department's disagreement with Benefits Review Board precedent holding the former 20 CFR part 718 quality standards applied only to evidence developed by the Director. 62 FR 3341 (January 22, 1997). One comment, in response to the first proposal, noted that, as written, § 718.101(b) would invalidate evidence in claims pending before the Department which was valid under prevailing Board precedent at the time the evidence was generated. The Department responded to this concern in the second notice of proposed rulemaking by revising § 718.101 to apply the quality standards only to evidence developed after the effective date of the regulations. 64 FR 55010 (Oct. 8, 1999). In explaining the revision, the Department acknowledged the ''substantial hardship'' which might occur, especially for unrepresented claimants, if medical evidence which complied with the law when submitted into evidence became invalid after the regulations become effective. This explanation, however, is not a concession as to the correctness of the Board's decisions. Since 1980, the Department has consistently taken the position that the 20 CFR part 718 quality standards apply to all evidence

developed by any party in black lung benefits claim litigation. Although the Board has rejected the Department's position, *Gorzalka* v. *Big Horn Coal Co.,* 16 Black Lung Rep. 1–48, 1–51 (1990) (and cases collected), the only court of appeals to consider the issue has agreed with the Department. *Director, OWCP* v. *Mangifest,* 826 F.2d 1318 (3d Cir. 1987). The Department adheres to this view with respect to any evidence developed in conjunction with a claim by any party before the effective date of the proposed regulations.

(g) Two comments approve of the prospective application of the quality standards. One comment approves of the ''substantial compliance'' standard.

(h) No other comments have been received concerning this section, and no changes have been made in it.

20 CFR 718.102

(a) In the initial notice of proposed rulemaking, the Department proposed three minor changes to § 718.102: eliminating the reference to the compliance standard in light of the substantial compliance language of general applicability in § 718.101(b); adding language presuming compliance with the technical criteria for chest x-rays in Appendix A; and correcting a typographical error in subsection (e) which cited to a nonexistent regulation. 62 FR 3342 (Jan. 22, 1997). The Department did not propose any additional changes in the second notice of proposed rulemaking. 64 FR 54971 (Oct. 8, 1999). In the final rule, the Department has changed subsection (e) to clarify the probative value of noncomplying x-rays in the case of a deceased miner. Specifically, this provision states that an x-ray, which is not in substantial compliance with the quality standard, may still establish the presence or absence of pneumoconiosis if the x-ray is of sufficient quality for a board-eligible radiologist, board-certified radiologist, or ''B'' reader to interpret the film. The Department has also added a sentence to subsection (b) to inform interested parties where they may obtain a copy of the ILO classification.

(b) One comment argues that § 718.102(b) should state that an x-ray cannot establish the absence of pneumoconiosis unless it complies with the quality standards and is classified according to a recognized scheme. The commenter further argues that § 718.102(b) and (e), in conjunction with § 718.101(b), are insufficient to impose this requirement. Section 718.102(b) identifies the classification systems which are acceptable for black lung claims. Subsection (e) states that no x-ray may demonstrate either the presence or absence of pneumoconiosis unless it complies with reporting requirements, *i.e.,* paragraph (b). Section 718.101(b) reinforces this requirement by stating that ''any evidence'' which is not in substantial compliance with the applicable quality standard cannot ''establish the fact for which it is proffered.'' For purposes of the quality standards, ''substantial compliance'' may mean less than strict compliance with each and every requirement of the applicable quality standard if the evidence is nevertheless deemed reliable by the factfinder. The adjudicator 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 any of the reporting schemes in § 718.102(b). In some circumstances, the adjudicator may determine that the x-ray interpretation provides sufficient information to make a factual finding on the presence or absence of pneumoconiosis. For example, the physician may describe the film findings in terms of ''no pneumoconiosis,'' rather than classifying the film as ''0/-, 0/0 or 0/1.'' Such a reading may be considered sufficiently detailed to be in ''substantial compliance'' notwithstanding the lack of classification. Conversely, the physician's description or reporting of x-ray film findings may indicate (s)he read the film for reasons unrelated to diagnosing the existence of pneumoconiosis, *e.g.,* lung cancer or cardiac surgery. The adjudicator may consider that evidence not in substantial compliance because it does not reliably address the presence or absence of pneumoconiosis. Accordingly, the Department disagrees with the commenter's position that any unclassified x-ray is not in ''substantial compliance'' with § 718.102.

(c) Four comments suggest adding the phrase ''in and of itself'' to the subsection (e) prohibition on using unclassified x-rays to demonstrate the presence or absence of pneumoconiosis. The comments contend that the change would make clear that x-ray evidence of some disease process, in conjunction with other evidence, could be used to prove the miner has a lung disease caused by coal dust exposure, *i.e.,* ''legal'' pneumoconiosis. The recommended change is unnecessary. 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. An x-ray report, however, may also be part of a medical report which must be considered under § 718.202(a)(4). Even an unclassified x-ray may therefore provide some clinical basis for a diagnosis of a respiratory disease arising out of coal mine employment under that section. Consequently, provision is already made for consideration of the results of an unclassified x-ray in the context of a medical report. In this context, it may be used to support a diagnosis of legal pneumoconiosis.

(d) No other comments were received concerning this section, and no other changes have been made in it.

20 CFR 718.103

(a)(i) The Department proposed amending § 718.103 in the initial notice of proposed rulemaking to take into account proposed § 718.101(b), which would establish a single standard of ''substantial compliance'' for all of the quality standards. 62 FR 3342 (Jan. 22, 1997). The Department also proposed changes to § 718.103(c) to harmonize it with § 718.102(e) (X-rays). Both provisions operate in the same manner and for the same purposes: to presume compliance with technical requirements in the applicable appendices to part 718; to permit rebuttal of the presumed compliance with relevant evidence; and to permit exceptions to the quality standards for a deceased miner if the claim presents limited evidence. (ii) In response to comments received concerning the initial notice of proposed rulemaking, the Department recommended several additional changes to § 718.103 in the second notice of proposed rulemaking. 64 FR 54975–76 (Oct. 8, 1999). One physician testified at the Washington, D.C., hearing that a flow-volume loop provided a more acceptable basis for obtaining verifiable test results than the proposed prohibition on an initial inspiration from room air. The Department agreed, and proposed changing both § 718.103 and Appendix B to require flow-volume loops for every pulmonary function test obtained after the effective date of the final regulation. The Department invited additional comment on this proposal. The Department also announced its intention to survey clinics and facilities which specialize in the treatment of pulmonary conditions to ascertain the extent to which they already used spirometers capable of producing flow-volume loops. The same physician observed that 20 CFR 718.103(a) (1999) required that pulmonary function

testing produce either a Forced Vital Capacity (FVC) or a Maximum Voluntary Ventilation (MVV) result, yet also required a one-second Forced Expiratory Volume (FEV1) which must be derived from the FVC. The Department agreed the regulation was inconsistent, and proposed a revision to § 718.103(a) making the FVC a required result along with the FEV1 and the MVV optional. The Department also proposed increasing the allowable difference between the two largest MVV values from 5 percent to 10 percent in § 718.103(b) to harmonize the regulation with Appendix B. The former and initially proposed § 718.103(b) required submission of three tracings of the MVV maneuver unless the two largest MVV results were within 5 percent of each other, in which case only two tracings were necessary. By contrast, Appendix B has consistently stated that the variation between the two largest MVV shall not exceed 10 percent. The Department chose the more liberal variation. The Department agreed that the validity of the MVV and FEVl/FVC values must be assessed independently, and that the MVV maneuver is optional for compliance purposes. The Department, however, rejected the suggestion to remove certain technical requirements from the quality standards to avoid invalidating a pulmonary function test for less than strict compliance; the Department responded that the ''substantial compliance'' standard would allow a party to establish the credibility of the study, notwithstanding the absence of one or more of the § 718.103 requirements. Finally, the Department proposed revisions to §§ 718.104(a)(6) and 718.204(b)(2)(iv) to recognize that a medical report cannot be rejected for lack of a pulmonary function study if the performance of the test was medically contraindicated. (iii) For the final rule, the Department has changed the word ''submitted'' in § 718.103(b) to ''developed'' to conform the regulation to similar usage in § 718.101(b). The Department also changed the opening phrase of the first sentence in § 718.103(c) to clarify that paragraph (c) is an exception to the remainder of § 718.103. Finally, the Department amended the final sentence in subsection (c) to make clear that a noncomplying pulmonary function test involving a deceased miner may be used to establish the presence or absence of a respiratory or pulmonary impairment under limited circumstances. If no complying test is in the record and, in the adjudicator's opinion, the noncomplying test yielded technically valid results and the miner provided good cooperation, the party submitting the noncomplying test may rely on it.

(b) The Department announced its intention in the second notice of proposed rulemaking to conduct a survey of the physicians, clinics and facilities which perform pulmonary function testing (spirometry testing) to evaluate the prevalence of spirometers capable of producing a flow-volume loop. The Department considered the survey necessary in light of its conclusion that the flow-volume loop may provide a ''more reliable method of ensuring valid, verifiable results in pulmonary function testing.'' 64 FR 54975 (Oct. 8, 1999). The Department also cited the relatively inexpensive cost (approximately $2000) for a spirometer capable of producing the flow-volume loop. The Department sent out the survey, dated March 7, 2000, to approximately 1800 pulmonary clinics, facilities and physicians board-certified in internal medicine with a subspecialty in pulmonary disease (Rulemaking Record Ex. 107), and received 225 responses (Rulemaking Record Ex. 109). Of those responses, only nine indicated they did not perform pulmonary function testing on equipment producing a flow-volume loop. Of those nine, five indicated they would consider obtaining the necessary equipment. An additional 19 surveys did not respond to the questions concerning spirometric testing. The remaining respondents, 197 in all, unanimously used the flow-volume loop. Based on these survey results, the Department concludes the benefit to the claims adjudication process in obtaining reliable pulmonary function data warrants revising § 718.103(a) and Appendix B to make the flow-volume loop a mandatory requirement for any pulmonary function test conducted after the effective date of these regulations in connection with a claim for benefits under the Black Lung Benefits Act (BLBA).

(c) One comment opposes the flow-volume loop requirement because spirometric equipment which records this data may not be universally available. The Department disagrees. In the second notice of proposed rulemaking, the Department proposed using the flow-volume loop because it provides a reliable and relatively inexpensive means of producing valid, verifiable pulmonary function test results. 64 FR 54975 (Oct. 8, 1999). The Department's survey of physicians, clinics and facilities which perform pulmonary function testing confirmed the widespread use of spirometers capable of producing flow-volume loops. Although some clinics and individual physicians may not utilize such machines, the Department has concluded that the overall benefit to the claims adjudication process warrants required use of this technology. In any event, the claimant should always have access to one set of testing which complies with the quality standards, including the flow-volume loop requirement, as a result of the pulmonary examination authorized by 30 U.S.C. 923(b). This provision of the BLBA requires the Black Lung Disability Trust Fund to afford each miner-claimant the opportunity to substantiate his or her claim by means of a complete pulmonary examination at no expense to the claimant. *See* also § 725.406(a). Under § 725.406(c), the district director is responsible for ensuring that the examination authorized by 30 U.S.C. 923(b) is in ''substantial compliance'' with the requirements of part 718, including the quality standards. Section 725.406(d) requires the Department to make available to the claimant's physician, on the claimant's request, the clinical test results obtained in conjunction with the pulmonary examination. Thus, contrary to the commenter's concern, the claimant's physician should routinely be able to consider substantially complying clinical testing of the miner in formulating an opinion, despite the lack of capable technology in his or her own practice.

(d) One comment approves of the § 718.103 revisions generally, and particularly approves of the language making clear that the Maximum Voluntary Ventilation maneuver is optional. One comment supports the use of flow-volume loops and changes to § 718.103(a) which eliminate internal inconsistencies and clarify that the Maximum Voluntary Ventilation maneuver is optional. One comment approves of requiring pulmonary function test results using flow-volume loops and the increase from 5 percent to 10 percent in the maximum variation between the two largest MVV values.

(e) No other comments were received concerning this section, and no other changes have been made in it.

20 CFR 718.104

(a)(i) The Department proposed several changes to § 718.104 in the initial notice of proposed rulemaking. 62 FR 3342–43, 3375 (Jan. 22, 1997). One change required 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 study which comply with the applicable quality standards. Another change proposed

guidelines for the adjudicator to determine whether to afford special weight to an opinion from the miner's treating physician. The Department considered codification of the treating physician's special status appropriate, given its longstanding judicial recognition in the caselaw. In order to ensure a critical analysis of the physician-patient relationship, the guidelines described four basic factors the adjudicator must consider: 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. Finally, the Department emphasized that the adjudicator 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. (ii) In the second notice of proposed rulemaking, the Department responded to the extensive comments which the proposed regulation had elicited. 64 FR 54976–77 (Oct. 8, 1999). The Department revised the regulation to excuse mandatory pulmonary function testing if it was medically contraindicated and the physician conducted other types of medically accepted diagnostic tests; to make explicit that a treating physician's opinion could be used to establish all elements of a miner's entitlement; and to accept the physician's statement as to subsection (d)'s treating relationship criteria, absent contrary evidence from another party. The Department rejected comments which advocated the automatic acceptance of a treating physician's opinion if it satisfied the criteria of subsections (d)(1) through (5) and was documented and reasoned, regardless of the remaining medical evidence. The Department also rejected one comment which contended the regulation already mandated the automatic acceptance of a treating physician's opinion in violation of 30 U.S.C. 923(b) (requiring consideration of all relevant evidence). In response, the Department emphasized that § 718.104(d) only required the adjudicator to consider the possible enhanced value of a treating physician's opinion, and did not require a mechanistic acceptance of that opinion. The Department responded in similar fashion to several comments which contended that all medical opinions, including a treating physician's opinion, should be evaluated only on the strength of their documentation and reasoning and each physician's professional qualifications. With respect to a comment recommending placement of the treating physician rule in a separate regulation, the Department concluded no change was warranted; subsection (d)'s position in the quality standards governing reports of physician examinations underscored that a treating physician's opinion was required to satisfy the same quality standards as any other physician examination report developed in connection with a claim for benefits. The Department acknowledged some commenters' concern that unrepresented claimants would likely submit noncomplying reports from their treating physicians. The Department, however, rejected the suggestion that treating physicians' opinions should be exempted from the evidentiary limitations for that reason. Instead, the Department noted its own obligation to inform claimants in an understandable manner about the evidentiary limitations, and to provide any claimant's treating physician with the results of the § 725.406 objective testing upon the claimant's request. The Department denied one comment's suggestion that language in the initial notice of proposed rulemaking (*see* 62 FR 3339 (Jan. 22, 1997)) made an adjudicator's failure to consider a physician's training and specialization reversible error. In the Department's view, a physician's qualifications were an issue only when raised by a party. The Department also rejected the suggestion that a chest x-ray, administered and read in accordance with § 718.102, not be mandatory documentation for a complying report of physical examination. The Department cited the importance of such a diagnostic test and the flexibility of the ''substantial compliance'' standard in excusing noncompliance depending on the particular circumstances of the case. In response to two comments, the Department declined to remove a limitation on the use of noncomplying medical opinions. The regulation therefore allowed consideration of reports of physical examination not in substantial compliance with § 718.104 only if the miner was deceased, the physician was unavailable to cure the defects in the report, and there was no complying report in the record. In explanation, the Department emphasized that entitlement decisions must be based on the best available evidence. Finally, the Department invited additional public comment on alternative means of determining when a treating physician's opinion should receive ''controlling weight,'' including whether the Department should adopt the Social Security Administration's rule. (iii) For purposes of the final rule, the Department has altered subsection (c) to conform this provision to the general ''substantial compliance'' standard in § 718.101(b). As amended, § 718.104(c) makes clear that a noncomplying report of physical examination may nevertheless provide evidence for a factual finding in certain limited circumstances involving a deceased miner and the lack of any complying report of physical examination in the record. The report must have been prepared by a physician who is ''unavailable,'' *e.g.,* deceased, whose whereabouts are unknown, etc. The report must also be found to possess sufficient indicia of reliability that the adjudicator may reasonably rely on it for factual findings.

(b) Several comments oppose granting special weight to the opinion of a miner's treating physician, contending the rule either intrudes on the adjudicator's role in evaluating evidence or compels the acceptance of an opinion from the treating physician regardless of contrary opinions from physicians with greater expertise in pulmonary medicine. The Department responded to a similar criticism in the second notice of proposed rulemaking. 64 FR 54976 (Oct. 8, 1999). In rejecting a commenter's view that § 718.104(d) effectively precluded consideration of all relevant evidence in favor of the opinion of the miner's treating physician, the Department emphasized the real purpose of the rule: to recognize that a physician's professional relationship with the miner may enhance his or her insight into the miner's pulmonary condition. The Department does not believe that, as proposed, section 718.104(d) contained an outcome-determinative evidentiary rule. *See* 64 FR 54977 (Oct. 8, 1999). The Department has revised the language of section 718.104(d), however, in light of several commenters' continued confusion as to the role of § 718.104(d) in weighing reports of physical examinations. The Department hopes to clarify its original intent with this revision. Like the previously proposed version, subsection (d) acknowledges the special weight which the opinion of a miner's treating physician may receive from the adjudicator. Section 718.104(d)(1)–(4) provide criteria for evaluating the quality of that doctor-patient relationship as indicia of the potential insight the physician may have gained from on-going treatment of the miner.

Instead of compelling the automatic acceptance of the treating physician's opinion, section 718.104(d) is designed to force a careful and thorough assessment of the treatment relationship. The adjudicator may 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. For example, the physician may have provided only a short-term course of treatment, or have actually examined the miner only infrequently. The adjudicator should consider giving additional weight to the treating physician's opinion only when review of the regulatory criteria establishes the physician's thorough understanding of the miner's pulmonary condition. Subsection (d)(5) describes the next step in the adjudicator's inquiry: the adjudicator must consider whether the treating physician's opinion is supported by sufficient documentation and reasoning, and must weigh it with all other reasoned and documented medical opinions in the record. In addition, the fact finder must consider all other relevant evidence of record. The regulation provides that only after the adjudicator finishes this weighing may he, in appropriate cases, base his decision to give ''controlling weight'' to the opinion of the miner's treating physician on that physician's superior understanding of the miner's pulmonary condition. The Department recognizes that each case will present different issues regarding both the extent to which the treating physician meets the four criteria in subsection (d)(1)–(4), the documentation and reasoning of that physician's opinion, and the relative merits of the other relevant medical evidence of record. As a result, the regulation does not attempt to dictate the outcome of any particular case. The Department therefore rejects the position that § 718.104(d) intrudes on the fact-finding responsibilities of the adjudicator.

(c) One comment opposes requiring each physician's opinion to include an x-ray or pulmonary function study conducted according to the applicable quality standards. The commenter suggests these tests are not always necessary for a relevant and credible opinion, and cites three examples: (i) A physician diagnoses an obstructive lung impairment based on valid pulmonary function testing, examination, etc., but does not obtain an x-ray. With respect to the mandatory x-ray requirement, the Department has previously addressed this argument in the second notice of proposed rulemaking, 64 FR 54977 (Oct. 8, 1999), and reiterates its position in responding to comments under § 718.101 of this rule. X-rays are an integral part of any informed and complete pulmonary evaluation of a miner; a general requirement for inclusion of this test is therefore appropriate. The Department also notes, however, that 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 factfinder may conclude the omission of an x-ray does not undermine the overall credibility of the opinion, but this determination must be made on a case-by-case basis. The same commenter poses this example in the context of § 718.101. The Department's response to that hypothetical makes certain critical assumptions in concluding the physician's opinion may be found in ''substantial compliance'' with the quality standards: the valid pulmonary function study demonstrates the presence of a pulmonary/respiratory impairment; the physician's examination of the miner identifies signs or symptoms of a pulmonary condition; and the physician has an accurate understanding of the miner's employment, smoking and personal histories. If the clinical tests and other information provide a documented basis for a reasoned and reliable opinion, the factfinder may find the diagnosis of ''legal pneumoconiosis'' in ''substantial compliance'' with § 718.104 despite the absence of the x-ray. (ii) A physician finds complicated pneumoconiosis on an x-ray, but does not conduct a pulmonary function test. One means of diagnosing complicated pneumoconiosis is by x-ray. 30 U.S.C. 921(c)(3)(A). The x-ray evidence is relevant to §§ 718.202(a)(3) and 718.304(a); accordingly, § 718.102 provides the applicable quality standards, and not § 718.104. The lack of a pulmonary function study does not affect the probative value of the x-ray reading(s) as evidence of complicated pneumoconiosis under 30 U.S.C. 921(c)(3)(A), because a pulmonary function study is not relevant to that means of invoking the irrebuttable presumption. Although all relevant evidence must be weighed in determining whether the miner has complicated pneumoconiosis, *Melnick* v. *Consolidation Coal Co.,* 16 Black Lung Rep. 1–31, 1–33 (1991), the evidence must pertain to the means of diagnosing or refuting the existence of complicated pneumoconiosis as provided by 30 U.S.C. 921(c)(3)(B) and (C). *Cf. Double B Mining* v. *Blankenship,* 177 F.3d 240, 243 (4th Cir. 1999) (holding factfinder must determine whether evidence relevant to each method of invoking irrebuttable presumption is ''equivalent,'' and establishes same underlying condition). The physician's report may provide additional valuable insight into his or her reasons for interpreting the x-ray as positive for complicated pneumoconiosis rather than some other condition detectable by x-ray; to that extent, the report may be relevant to weighing the credibility of the x-ray evidence. As a report of physical examination, however, the hypothetical report does not satisfy the ''substantial compliance'' standard. (iii) In his report of physical examination, a physician relies in part on a noncomplying pulmonary function test, but another complying test yields comparable results. Again, ''substantial compliance'' is a test of evidentiary reliability based on all relevant circumstances of the particular case. The factfinder must evaluate those circumstances and determine whether the specific omission undermines the credibility of the evidence. In the hypothetical, the factfinder must consider not only the defects in the physician's pulmonary function study, but also the remaining documentation in the report (other clinical studies, the miner's employment, smoking and personal information, *etc.*). If the report otherwise complies with § 718.104, the invalid pulmonary function study may be mitigated by the presence of a complying study which confirms the physician's interpretation of the invalid study.

(d) One comment supports the revision of § 718.104(a)(6) in the second notice of proposed rulemaking, which exempts a miner from mandatory pulmonary function testing if the test is medically contraindicated, and allows a physician preparing a report of physical examination to substitute other medically acceptable clinical and laboratory diagnostic techniques in support of his conclusions. 64 FR 54976, 55011 (Oct. 8, 1999).

(e) One comment recommends the Department delete the conditions in § 718.104(c) that, in the case of a deceased miner, limit the consideration of a report from a physician who is not available if the report is not in substantial compliance with the quality standards. This provision permits the adjudicator to base a finding on such evidence only if the record does not contain any physician's report which is in substantial compliance. No change in the regulation is necessary. Although ''substantial compliance'' is a flexible

concept, it is also necessary to ensure that claims are adjudicated using the most reliable evidence available. Consequently, the Department has incorporated limitations throughout the quality standards on the use of noncomplying evidence in claims involving deceased miners in which there is no complying evidence of record. The fact that a miner is deceased is not necessarily a bar to rehabilitating noncomplying evidence. With respect to reports of physical examination, the physician who is available to review and further comment on his or her own report may cure the defect and bring the report into substantial compliance. If, however, the physician is unavailable, § 718.104(c) permits noncomplying evidence to be considered if there is no complying evidence of record. The Department believes noncomplying evidence should be used to establish facts about a deceased miner's condition only when no practical alternative is available. As long as complying evidence or the means of achieving compliance exist, noncomplying evidence should not be the basis for determining the validity of a claim.

(f) One comment objects to the retroactive application of the changes made to § 718.104. None of these changes, however, apply retroactively. Section 718.101(b) provides that the ''standards for the administration of clinical tests and examinations'' will govern all evidence developed in connection with benefits claims after the effective date of the final rule. Section 718.104 contains the quality standards for any ''[r]eport of physical examinations,'' including reports prepared by a miner's treating physician. Physicians' medical reports are expressly included in the terms of § 718.101(b). Consequently, the changes to § 718.104 apply only to evidence developed after the effective date of the final rule. With respect to treating physicians' opinions developed and submitted before the effective date of the final rule, the judicial precedent summarized in the Department's initial notice of proposed rulemaking continues to apply. *See* 62 FR 3342 (Jan. 22, 1997). These decisions recognize that special weight may be afforded the opinion of a miner's treating physician based on the physician's opportunity to observe the miner over a period of time.

(g) Two comments state the ''treating physician'' rule has no scientific basis because a treating physician is in no better position than any other physician to assess a miner's pulmonary status. The commenters note that a primary care physician will often, as a matter of medical practice, refer an individual to a physician with particular training for specialized care; the primary care provider may therefore have little, if any, qualified understanding of the patient's health problems. The commenters also state that the essential basis for a reasoned diagnosis is valid objective testing and sound interpretation of the data rather than patient complaints and physical examinations. Finally, the commenters conclude that frequency of contact alone does not provide any advantage for a physician in developing a comprehensive understanding of the patient's condition. The commenters' concerns do not provide a basis for abandoning the rule. First, the miner's ''treating physician'' is not necessarily the physician with whom the miner has a long-standing generalized relationship if another physician actually provides specialized treatment for respiratory or pulmonary problems. If the miner's primary care provider refers the miner to a pulmonary specialist for treatment, then that specialist may be considered the miner's ''treating physician'' for purposes of his or her pulmonary condition. If, however, the specialist provides an opinion to the primary care physician which forms the basis for the miner's treatment by the latter, the primary care physician's opinion is strengthened by reliance on the specialist's expertise. Second, the Department agrees that valid clinical testing and a reasoned medical report are necessary prerequisites for a credible medical opinion. A treating physician's opinion is subject to the Department's quality standards, which require the report to be based on specific clinical tests, findings and other data and information. See § 718.104(a)(l)-(6). A treating physician's report must be reasoned as well as documented (§ 718.104(d)(5)). In this regard, a treating physician's opinion is no different than any other physician's opinion developed in connection with a claim for benefits. The Department does not intend to displace the long-standing judicial precedent that sanctions the rejection of a treating physician's report if it fails the basic requirements for credible evidence. *See, e.g., Sterling Smokeless Coal Co.* v. *Akers,* 131 F.3d 43 8, 441 (4th Cir. 1997); *Lango* v. *Director, OWCP,* 104 F.3d 573, 577 (3d Cir. 1997); *Peabody Coal Co.* v. *Helms,* 901 F.2d 571, 573–74 (7th Cir. 1990); *see generally Halsey* v. *Richardson,* 441 F.2d 1230, 1236 (6th Cir. 1971) (rejecting ''a mechanical rule insulating a treating doctor's opinion from attack, no matter how respectable and persuasive may be opposing opinions by doctors who examined a claimant on only one occasion''). As for the commenters' statement that the frequency of patient contact provides no advantage to a physician, this view is too simplistic. Frequency of treatment is only one of the regulatory criteria (§ 718.104(d)(3)) the adjudicator must consider in assessing the treating physician relationship. The number of visits must be viewed in the context of the other criteria (nature of relationship, duration of relationship, type and extent of treatment). The totality of the information demanded by the criteria establishes the overall quality of the doctor-patient relationship, which guides the adjudicator in determining whether to accord the treating physician's opinion controlling weight. The comments do not state a basis for changing or eliminating the ''treating physician'' rule.

(h) Two comments contend the ''treating physician'' rule creates an ''evidentiary preference'' which violates section 7 of the Administrative Procedure Act (APA), 5 U.S.C. 556. Although the Social Security Administration (SSA) has also promulgated a regulation, 20 CFR 404.1527(d) (1999), addressing the weight to be given a treating physician's opinion, the commenters argue there is no adverse party in SSA claims, and the APA does not apply to SSA claims adjudication. By implication, the commenters suggest the Department cannot adopt a ''treating physician'' rule comparable to the SSA model, or any rule which affords special weight to a treating physician's opinion. The Department disagrees. As an initial matter, whether the APA does or does not apply to SSA claims adjudications is irrelevant to evaluating the validity of § 718.104(d). The Supreme Court has expressly refused to resolve the issue because ''the social security administrative procedure does not vary from that prescribed by the APA. Indeed, the latter is modeled upon the Social Security Act.'' *Richardson* v. *Perales,* 402 U.S. 389, 409 (1971). In any event, the commenters misapprehend both the nature of § 718.104(d) and the critical differences between that regulation and the SSA version. The commenters describe the ''treating physician'' rule as an ''evidentiary preference.'' The Department interprets this phrase to characterize the rule as a burden-shifting presumption which imposes on the party opposing the claim the burden to overcome the ''preference'' for the treating physician's opinion. The Department, however, has repeatedly emphasized in the second

notice of proposed rulemaking and its responses to comments in this rule that § 718.104(d) does not create a presumption in favor of the treating physician's opinion. *See* 64 FR 54976–77 (Oct. 8, 1999). The regulation provides a set of criteria to guide the adjudicator's evaluation of the treating physician's professional relationship with the miner, and ensure a critical and thorough factual determination whether that opinion should ultimately be given ''controlling weight.'' Aside from assessing the strength or weakness of the treating physician's report, the adjudicator must also weigh that report against all other relevant evidence in the record. Consequently, § 718.104(d) is not a strict, outcome-determinative rule like more traditional evidentiary presumptions. These characteristics also distinguish § 718.104(d) from SSA's version in 20 CFR 404.1527(d). Both regulations state that ''controlling weight'' may be given to a treating physician's report. Section 404.1527(d), however, provides that ''[g]enerally, we give more weight to opinions from your treating sources, * * *.'' 20 CFR 404.1527(d)(2) (1999). This language demonstrates an affirmative preference for reports from treating physicians; § 718.104(d) is more qualified in permitting ''controlling weight'' only if the regulatory criteria warrant it. Another significant difference between the regulations is the role the criteria play in determining the weight given the medical evidence. Section 404.1527(d) makes the criteria relevant only after the adjudicator refuses to give the treating physician ''controlling weight:'' ''Unless we give a treating source's opinion controlling weight * * * we consider all of the following factors in deciding the weight we give to any medical opinion.'' The regulation lists several criteria which are similar to those listed in § 718.104(d)(l)-(4). Section 718.104(d) makes the same criteria the basis for determining in the first place whether to give the treating physician controlling weight. To the extent 20 CFR 404.1527(d) operates like an evidentiary presumption, it does not affect the validity of § 718.104(d) because § 718.104(d) clearly is not a presumption in favor of the treating physician's opinions. Accordingly, the Department rejects the commenters' position that the rule violates the APA.

(i) Three comments oppose the requirement in § 718.104(d)(5) that the adjudicator must weigh a treating physician's opinion against the contrary relevant evidence in the record. One comment states that affording a treating physician's opinion ''controlling weight'' is meaningless unless the adjudicator may accept the opinion despite a reasoned and documented contrary opinion by a pulmonary specialist submitted by another party; otherwise, according to the commenter, a treating physician's opinion will prevail only when it echoes similar opinions from other physicians. Another comment interprets subsection (d) as a burden-shifting device which affords the treating physician's opinion presumptive controlling weight unless the opposing party overcomes that opinion by a preponderance of the evidence. The Department has previously responded to comments contending that a treating physician's opinion should receive conclusive weight once the adjudicator reviews the opinion in light of the criteria enumerated in subsection (d)(1)–(4). 64 FR 54976 (Oct. 8, 1999). The Department rejected this position because it artificially limits the adjudicator's consideration of the evidence, and may promote a mechanistic and uncritical acceptance of the treating physician's opinion at the expense of more credible contrary evidence. No basis for departing from this position is established by the new comments. The Department emphasizes that the ''treating physician'' rule guides the adjudicator in determining whether the physician's doctor-patient relationship warrants special consideration of the doctor's conclusions. The rule does not require the adjudicator to defer to those conclusions regardless of the other evidence in the record. The adjudicator must have the latitude to determine which, among the conflicting opinions, presents the most comprehensive and credible assessment of the miner's pulmonary health. For the same reasons, the Department does not consider subsection (d) to be an evidentiary presumption which shifts the burden of production or persuasion to the party opposing entitlement upon the submission of an opinion from a miner's treating physician. Accordingly, the Department declines to eliminate the requirement in subsection (d)(5) that a treating physician's opinion must be considered in light of all relevant evidence in the record.

(j) One comment objects to comparing a treating physician's qualifications to those of any other physician in the record. The commenter suggests comparative qualifications may provide a basis for refusing controlling weight to the treating physician's opinion if another physician has superior credentials. The Department responded to a similar comment in the second notice of proposed rulemaking, and noted that professional credentials are only one factor the adjudicator may consider in weighing medical opinions. 64 FR 54977 (Oct. 8, 1999). No basis exists, however, for insulating the treating physician from a consideration of his or her qualifications, or prohibiting giving additional weight to the opinion of a physician with specialized training in a relevant area of medicine. Although expertise is only one of several potentially relevant factors to consider, it is nonetheless a significant consideration. *See, e.g., Milburn Colliery Co.* v. *Hicks,* 138 F.3d 524, 536 (4th Cir. 1998). Furthermore, the commenter's concern over comparative qualifications overlooks an important consideration underlying the ''treating physician'' rule. In black lung benefits claims, the principal issue ordinarily is the miner's pulmonary condition. The treating physician may develop a more in-depth knowledge and understanding of that issue than a physician with greater academic credentials and minimal, or nonexistent, contact with the miner. The purpose of the § 718.104(d) criteria is to enable the adjudicator to determine whether the treating physician has such informed knowledge that his or her opinion merits special weight.

(k) One comment suggests a consultative physician's opinion should receive the same weight accorded a treating physician if the consultant relies on the treating physician's report, the results of clinical tests, medical records, etc., and the consulting report satisfies the § 718.104(d) criteria. The Department rejects this suggestion. If any physician (other than the treating physician) could receive enhanced weight by incorporating consideration of the treating physician's opinion into his or her consulting opinion, the consultative physician(s) for each party would stand on equal footing based on access to the treating physician's report. No reason would therefore exist for the rule. In any event, a consultative physician's reliance on the treating physician's report does not necessarily confer the same benefit the treating physician may derive from the nature, duration, frequency and extent of treatment during the physician-patient relationship with the miner.

(l) Two comments oppose making the quality standards applicable to the report of physical examination prepared by a miner's treating physician. The commenters suggest removing subsection (d) from § 718.104 and making it a separate regulation. The Department rejected the identical

argument in the second notice of proposed rulemaking. 64 FR 54976–77 (Oct. 8, 1999). The Department intends the quality standards to apply to any physician's report developed in connection with a claim for benefits, including any report prepared by a treating physician. Although a treating physician may have a superior perspective on the miner's health in certain circumstances, status alone does not guarantee the validity of the physician's opinion.

(m) Two comments recommend allowing a miner or a miner's family members to attest to the nature of the miner's relationship with his or her treating physician. The Department disagrees. Although persons other than the physician may have some direct knowledge of the miner's treatment, only the physician can provide a complete picture of the doctor-patient relationship, as well as documentary evidence of the specific clinical tests conducted. In addition, if representations as to the criteria in (d)(1) through (4) are challenged, it is the physician's records, including treatment notes, etc., which will enable the adjudicator to evaluate the quality of the relationship. Evidence from persons other than the physician may supplement the physician's characterization of the miner's treatment, but the physician (or the physician's records) remains the best primary source for depicting the miner's treatment.

(n) In the second notice of proposed rulemaking, the Department invited comment on alternatives to the revised ''treating physician'' rule, including whether to adopt a version of the rule comparable to the Social Security Administration's (SSA) regulation, 20 CFR 404.1527(d) (1999). 64 FR 54976 (Oct. 8, 1999). (i) Two comments oppose in general terms using the SSA regulation to evaluate the treating physician's opinion. (ii) One comment recommends incorporating language from the SSA regulation that more weight should ''generally'' be given a miner's treating physician. *See* 20 CFR 404.1527(d)(2) (1999). The commenter opposes any other use of the SSA regulation. The additional language is inappropriate. *See* paragraph (h), above. Section 718.104(d) outlines the circumstances in which a treating physician may be afforded ''controlling weight'' on entitlement issues. Although the regulation recognizes the special value which may attach to a treating physician's report in certain circumstances, the Department does not intend to deflect attention from the necessity for critical examination of the physician's reasoning and documentation. The Department has previously explained the intended limits of section 718.104(d) as an evidentiary rule which guides consideration of a treating physician's opinion but does not impose a strict outcome. 64 FR 54977 (Oct. 8, 1999). The recommended additional language does not further this purpose. Accordingly, the recommendation is rejected. (iii) No comment recommended adopting the SSA regulation in place of the regulation as proposed by the Department.

(o) Several comments approve generally of the ''treating physician'' rule.

(p) No other comments were received concerning this section, and no other changes have been made in it.

20 CFR 718.105

(a)(i) In the initial notice of proposed rulemaking, the Department proposed amending § 718.105 to address arterial blood gas studies which are administered during a miner's terminal hospitalization, *i.e.,* ''deathbed'' studies. 62 FR 3342–43 (Jan. 22, 1997). Specifically, the Department expressed concern that such studies may produce qualifying values for reasons unrelated to chronic pulmonary disease. The Department therefore suggested a new requirement that a claimant must submit a physician's report linking the blood gas study results to a chronic pulmonary condition caused by exposure to coal mine dust in order to rely on the qualifying results as evidence of total disability. 62 FR 3375 (Jan. 22, 1997). (ii) In response to comments received, the Department deleted the requirement that, in the case of blood gas studies administered during a hospitalization that ends in the miner's death, the chronic pulmonary condition must be shown to be related to the miner's exposure to coal mine dust; the Department agreed the causation requirement was inappropriate because § 718.105 addresses the existence of a chronic pulmonary impairment, and not its source. 64 FR 54977–78 (Oct. 8, 1999). The Department also agreed to a minor change in technical nomenclature by changing ''p'' to ''P'' to denote partial pressure. Finally, the Department rejected those comments which opposed requiring the claimant to establish a link between a miner's ''deathbed'' blood gas study and a chronic pulmonary condition. The Department concluded the proposed requirement was necessary because the miner's qualifying test results during a terminal hospitalization may be related to an acute non-pulmonary condition rather than a chronic pulmonary impairment. 64 FR 54977 (Oct. 8, 1999).

(b) One comment recommends the Department afford consideration to noncomplying blood gas studies in the case of a deceased miner since such consideration is given elsewhere in the regulations for x-rays (§ 718.102(e)) and pulmonary function studies (§ 718.103(c)). The regulations also outline specific circumstances under which a report of physical examination of a miner now deceased may be considered by an adjudication officer notwithstanding its failure to substantially comply with § 718.104(a) and (b). *See* § 718.104(c), above. The Department agrees, and has revised § 718.105 accordingly by adding subsection (e). This provision is comparable to § 718.103(c), and permits the adjudicator to consider a deceased miner's blood gas studies not in substantial compliance with subsections (a), (b) and (c) if they are the only available tests and, in the adjudicator's opinion, are technically valid. Subsection (e) also requires any such test to meet the requirements of subsection (d) if the test was obtained during a miner's hospitalization ending in death and yielded qualifying values. The claimant must submit a physician's opinion establishing that the qualifying values reflect a chronic pulmonary impairment and not some acute condition unrelated to a chronic pulmonary impairment.

(c) Two comments oppose requiring the claimant to prove a miner's chronic respiratory or pulmonary impairment caused his qualifying ''deathbed'' blood gas results. The commenters argue that the party opposing entitlement should bear the burden of proving a non-respiratory or non-pulmonary condition caused the qualifying results since that party has equal access to the miner's hospital records and physicians. The Department disagrees. The claimant bears the general burden of persuasion to establish entitlement to benefits by a preponderance of the evidence, except to the extent a presumption eases that burden. *See generally Director, OWCP* v. *Greenwich Collieries,* 512 U.S. 267 (1994). One facet of the claimant's burden is the responsibility to ensure that the clinical tests such as blood gas studies substantially comply with the quality standard. The quality standard provides some assurance to the adjudicator that the clinical test is valid, accurate and reliable evidence of the factual proposition for which it is proffered. The Department considers a physician's opinion necessary to establish a nexus between ''deathbed''

blood gas studies and a chronic pulmonary disease; raw clinical test results under these circumstances are not sufficiently instructive for a lay adjudicator to make such a determination. The fact that the party opposing entitlement may have equal access to relevant information about the circumstances and interpretation of the blood gas testing is not determinative in allocating the burden of persuasion. The Department does not perceive any basis for shifting the overall burden of proof from the claimant to the opposing party in the case of qualifying ''deathbed'' blood gas studies. The comments do not address the Department's explanation in the second notice of proposed rulemaking, 64 FR 54977–78 (Oct. 8, 1999), for imposing this requirement, beyond noting continued opposition. The Department therefore rejects the comments' position.

(d) No other comments were received concerning this section, and no other changes have been made in it.

20 CFR 718.106

(a) The Department proposed minor changes to § 718.106 in the initial notice of proposed rulemaking to account for the adoption of a general standard of substantial compliance with the quality standards (§ 718.101), and to adopt consistent terminology for evidence which is not in substantial compliance with the applicable standard. 62 FR 3343 (Jan. 22, 1997). The Department responded to several comments in the second notice of proposed rulemaking. 64 FR 54978 (Oct. 8, 1999). At the urging of several commenters, the Department restored subsection (c) to § 718.106, explaining that the omission of that provision from the initial proposed version of the regulation was inadvertent. Other comments expressed concern that the requirement for a gross macroscopic inspection of the lungs would preclude reliance on reviewing physicians, who ordinarily review only the autopsy protocol and inspect tissue samples microscopically. The Department responded that only the autopsy itself must include the gross macroscopic inspection of the lungs; the requirement does not extend to opinions prepared by reviewing physicians. Finally, the Department rejected the recommendation of some commenters to adopt the standards for diagnosing pneumoconiosis by autopsy or biopsy set forth in Kleinerman *et al.,* ''Pathologic Criteria for Assessing Coal Workers'' Pneumoconiosis,'' in the *Archives of Pathology and Laboratory Medicine* (1979). The Department emphasized its historic reluctance to adopt specific standards for such diagnoses; the lack of evidence in the record that the medical community agrees on a particular standard; and the lack of evidence indicating the Kleinerman article reflects an accepted standard.

(b)(i) One comment again recommends adopting the criteria for diagnosing pneumoconiosis by autopsy or biopsy contained in the Kleinerman article as the ''accepted'' pathologic standard. The Department has previously noted that the record does not substantiate the existence of a consensus among physicians for making diagnoses using these criteria, or the acceptance of the Kleinerman article as representative of the medical community's views. 64 FR 54978 (Oct. 8, 1999). Indeed, two other commenters commend the Department for refusing to accept these criteria, noting that other pathologists do not agree that this article represents a universal or prevailing standard. One commenter suggests, for example, that Dr. Kleinerman's view that a two-centimeter lesion on autopsy or biopsy is necessary for a diagnosis of complicated pneumoconiosis is not universally accepted, and that other pathologists would require only a one-centimeter lesion. The commenter urging adoption of the Kleinerman criteria does not supply any additional information in support of its recommendation. The Department therefore has no basis in the record for adopting the suggested standard. (ii) One comment cites *Double B Mining, Inc.* v. *Blankenship,* 177 F.3d 240 (4th Cir. 1999), as legal authority for rejecting the Kleinerman article. In that case, the Court considered whether a biopsy diagnosis of a certain-sized fibrotic nodule amounted to a ''massive lesion'' for purposes of proving the miner had complicated pneumoconiosis under 30 U.S.C. 921(c)(3) (irrebuttable presumption of total disability due to pneumoconiosis invoked by proof of complicated pneumoconiosis). The Court cited, among other sources, the Kleinerman article as requiring a minimum two-centimeter nodule to constitute a ''massive lesion.'' The Court declined to adopt the two-centimeter rule because ''[t]he [Black Lung Benefits Act] does not mandate use of the medical definition of complicated pneumoconiosis.'' 177 F.3d at 244. Instead, the Court held the adjudicator must determine whether a particular nodule discovered by biopsy would be equivalent to a one-centimeter opacity if diagnosed by x-ray. The *Blankenship* decision rejects only the mandatory use of the medical community's standards for diagnosing complicated pneumoconiosis by biopsy in view of the court's statutory analysis. The Court does not accept or reject any specific clinical criteria for biopsy diagnoses, and the Department does not interpret the decision as repudiating the Kleinerman article in particular.

(c)(i) Three comments approve of the restored paragraph (c). (ii) Two comments approve of the Department's clarification in the second notice of proposed rulemaking that the § 718.106(a) requirement for a gross macroscopic inspection of the lungs applies only to the autopsy itself and not to a reviewing physician's opinion. 64 FR 54978 (Oct. 8, 1999).

(d) No other comments were received concerning this section, and no other changes have been made in it.

20 CFR 718.107

(a) In the initial notice of proposed rulemaking, the Department proposed a clarification of § 718.107 which addresses medical evidence not otherwise covered by the quality standards. 62 FR 3343 (Jan. 22, 1997). Proposed subsection (b) required the party submitting such evidence to establish that the evidence is medically acceptable and relevant to proving the existence or nonexistence of pneumoconiosis, the sequelae of pneumoconiosis or a ''respiratory impairment.'' The Department responded to comments received from the public in the second notice of proposed rulemaking. 64 FR 54978 (Oct. 8, 1999). The Department changed the reference in subsection (a) from ''respiratory impairment'' to ''respiratory or pulmonary impairment.'' The Department rejected as unnecessary a recommendation that disability and disability causation should be added to the relevant issues because the regulation adequately stated the purposes for which ''other medical evidence'' could be submitted. One comment approved of § 718.107 as proposed in the initial notice of proposed rulemaking.

(b) For purposes of the final rule, the Department emphasizes that § 718.107 as a whole is intended to permit any party to offer any medical test or procedure which may be relevant to any disputed medical issue relating to a claimant's entitlement to benefits provided the requirements of subsection (b) are met.

(c) No other comments were received concerning this section, and no other changes have been made in it.

Subpart C

20 CFR 718.201

(a) In the initial notice of proposed rulemaking, the Department proposed amending § 718.201. 62 FR 3343–44, 3376 (Jan. 22, 1997). The amendments were designed to clarify the regulatory definition and conform it to the statute, which broadly defines pneumoconiosis as ''a chronic dust disease of the lung and its sequelae, including respiratory and pulmonary impairments, arising out of coal mine employment.'' 30 U.S.C. 902(b). To that end, the Department proposed three revisions.

First, the Department inserted the terms ''clinical'' and ''legal'' pneumoconiosis into the regulation to conform it to the terminology uniformly adopted by the courts to distinguish between the two forms of lung disease compensable under the statute: pneumoconiosis, as that disease is defined by the medical community, and any chronic lung disease arising out of coal mine employment. Second, the Department proposed revising the definition to make clear that both restrictive and obstructive lung disease may fall within the definition of pneumoconiosis if shown to have arisen from coal mine employment. Third, the Department proposed a revision to recognize the latent and progressive nature of the disease. The last two changes, for which the Department cited scientific evidence in support, 62 FR 3343–44 (Jan. 22, 1997), were proposed as a result of recent litigation on these issues. The Department specifically sought comments on these revisions.

The Department received numerous favorable and unfavorable comments and testimony on the proposals. 64 FR 54978–79 (Oct. 8, 1999). One commenter objected to the revised definition because it would include all obstructive pulmonary diseases. A number of commenters complained that the Department lacked the statutory authority to implement the proposals, and that the Department had violated the statute by failing to consult with the National Institute for Occupational Safety and Health (NIOSH) before proposing the changes. 30 U.S.C. 902(f)(1)(D). Several commenters also argued that the Department's proposed definition was scientifically unsound, and presented testimony from a panel of pulmonary physicians at the Department's July 22, 1997 hearing in Washington, D.C., to substantiate their views. Two commenters contended that because Congress had rejected an amendment to the statutory definition of pneumoconiosis which would have included obstructive lung disorders, the Department could not accomplish the same change through regulation. The Department also received numerous comments in support of the revised definition. Among the favorable comments was one from NIOSH, transmitted by letter dated August 20, 1997 and signed by Dr. Paul A. Schulte, Director of NIOSH's Education and Information Division. Rulemaking Record, Exhibit 5–173. NIOSH supported the Department's proposal to amend the definition to include chronic obstructive pulmonary disease and to reflect the scientific evidence that pneumoconiosis is a progressive condition that may become detectable only after cessation of coal mine employment in some cases. The Department also received favorable comments and testimony from physicians with expertise in pulmonary diseases.

Given the widely divergent comments and testimony received from medical professionals on the proposed regulation, the Department sought additional guidance from NIOSH, notwithstanding the fact that NIOSH had already commented in support of the initial proposal. The Department transmitted a copy of all of the testimony and commentary it had received to Dr. Linda Rosenstock, the Director of NIOSH, and asked NIOSH to determine, in light of the then existing record, whether NIOSH continued to support the Department's proposal. Rulemaking Record, Exhibit 66. NIOSH responded, in a December 7, 1998 letter from Dr. Schulte, that ''[t]he unfavorable comments received by DOL do not alter our previous position: NIOSH scientific analysis supports the proposed definitional changes.'' Dr. Schulte provided additional medical references to support NIOSH's conclusion. Rulemaking Record, Exhibit 72.

The Department responded to the comments it had received in its second notice of proposed rulemaking. 64 FR 54978–79 (Oct. 8, 1999). The Department emphasized that the proposed revision was designed to make clear that obstructive lung disease may fall within the definition of pneumoconiosis, but only if it is shown to have arisen from coal mine employment; thus, the proposed definition would not alter the former regulations' (20 CFR 718.202(a)(4), 718.203 (1999)) requirement that each miner bear the burden of proving that his lung disease arose out of his coal mine employment. The Department also notified the public of NIOSH's December 7, 1998 response, including the additional evidence NIOSH cited. 64 FR 54978–79 (Oct. 8, 1999). Recognizing that Congress created NIOSH as a source of expertise in occupational disease and the analysis of occupational disease research, the Department concluded it saw no scientific or legal basis upon which to alter its proposed change to the definition of pneumoconiosis. The Department further stated its disagreement that Congressional inaction invalidated its proposed revision of the definition since it was acting within the scope of Congress' grant of regulatory authority. Accordingly, the Department proposed no additional changes to this regulation in the second notice of proposed rulemaking. 64 FR 55012–13 (Oct. 8, 1999). The Department has now amended subsection (a)(1) by deleting a comma for grammatical reasons.

(b) The Department has again received both favorable and unfavorable comments on its proposed revision to the definition of pneumoconiosis. To the extent these comments are directed specifically to the Department's proposal to define pneumoconiosis as a latent and progressive disease, the Department's response is set forth in the preamble under § 725.309. The Department responds here to the remainder of the relevant comments, including those addressing the Department's proposal to include obstructive lung diseases arising out of coal mine employment within the definition of pneumoconiosis. Where a scientific article or treatise is cited, the Department has also cited to a Rulemaking Record Exhibit or, when appropriate, the **Federal Register,** where that source appears. This second citation is not an exhaustive list; thus, each source may appear at additional points in the Rulemaking Record.

(c) One comment objects to the Department's inclusion of the term ''legal pneumoconiosis'' in the revised definition because there is no such ''phenomenon.'' Another comment expresses the concern that the revised regulation would create a new medical diagnosis. The statute defines pneumoconiosis as ''a chronic dust disease of the lung and its sequelae, including respiratory and pulmonary impairments, arising out of coal mine employment.'' 30 U.S.C. 902(b). This broad definition encompasses not only coal workers' pneumoconiosis as that disease is contemplated by the medical community, but also any other chronic lung disease demonstrably related to coal mine employment but not typically denominated as pneumoconiosis in medical circles. Thus, the Department is making a legal distinction, rather than a medical one, by employing the phrase ''legal pneumoconiosis'' in order to

properly implement Congress' intent. In so doing, the Department is acknowledging the distinction already adopted by the circuit courts of appeals in construing and applying the statutory definition. *See, e.g., Gulf & Western Industries* v. *Ling,* 176 F.3d 226, 231–32 (4th Cir. 1999); *Bradberry* v. *Director, OWCP,* 117 F.3d 1361, 1368 (11th Cir. 1997); *Labelle Processing Co.* v. *Swarrow,* 72 F.3d 308, 315 (3d Cir. 1995); *Consolidation Coal Co.* v. *Hage,* 908 F.2d 393, 395–396 (8th Cir. 1990); *Campbell* v. *Consolidation Coal Co.,* 811 F.2d 302, 304 (6th Cir. 1987); *Peabody Coal Co.* v. *Lowis,* 708 F.2d 266, 268 n.4 (7th Cir. 1983).

(d) Several comments express concern over including obstructive pulmonary diseases in the definition of pneumoconiosis, believing such change will result in compensating miners for diseases caused by factors unrelated to coal mine employment. Whether coal mine dust exposure can cause chronic obstructive pulmonary disease is a question of medical and scientific fact that will not vary from case to case; thus, it is an appropriate question for the Department to answer by regulation. *See generally Peabody Coal Co.* v. *Spese,* 117 F.3d 1001, 1010 (7th Cir. 1997) (*en banc*); Davis, *Administrative Law Treatise,* § 6.7, 261–262 (3d ed. 1994). The revised definition will eliminate the need for litigation of this issue on a claim-by-claim basis, and render invalid as inconsistent with the regulations medical opinions which categorically exclude obstructive lung disorders from occupationally-related pathologies. The Department reiterates, however, that the revised definition does not alter the former regulations' (20 CFR 718.202(a)(4), 718.203 (1999)) requirement that each miner bear the burden of proving that his obstructive lung disease did in fact arise out of his coal mine employment, and not from another source. Thus, instead of attempting to force the conclusion, as one commenter contends, that all obstructive lung disorders are compensable, or to require responsible operators to compensate miners for non-occupationally related diseases, the language of the proposed regulation makes plain that only ''obstructive pulmonary disease arising out of coal mine employment'' falls within the definition of pneumoconiosis.

(e) Several comments criticize the Department's consultation with NIOSH. Calling the Department's solicitation of an opinion from NIOSH on the relevant medical questions a ''post-hoc attempt to rationalize the validity of its medical conclusions'' and a ''purely political act,'' one commenter states that Dr. Shulte's letter cannot substitute for ''genuine scientific review.'' Other commenters allege that NIOSH presented no serious medical or scientific analysis to support its position. To the extent these comments accuse the Department of obtaining assistance from NIOSH's information officer rather than its scientific staff, the Department's response is set forth in the preamble under § 725.309. NIOSH voluntarily submitted its first statement in support of the proposed revision to the definition of pneumoconiosis during the public comment period for the initial rulemaking proceeding. The Department then actively solicited an additional opinion from NIOSH in response to other comments the Department had received requesting such consultation and not, as the commenter suggests, to provide ''post-hoc'' rationalization for the proposed revisions to the regulation. NIOSH responded, and the Department set forth the substance of the response in the second notice of proposed rulemaking. 64 FR 54978–79. In response to the second notice, NIOSH once again submitted an unsolicited comment during the public comment period reaffirming its earlier statements that it had reviewed the proposed rule and supported it. Thus, NIOSH has supported the Department's proposal from the outset. Further, in each of its communications, NIOSH repeatedly provided concrete support for its comments by referencing appropriate studies and its own publication, National Institute for Occupational Safety and Health, *Criteria for a Recommended Standard, Occupational Exposure to Respirable Coal Mine Dust* (1995). 62 FR 3343 (Jan. 22, 1997); Rulemaking Record, Exhibit 2–1. This publication provides the most exhaustive review and analysis of the relevant scientific and medical evidence through 1995, including its evaluation of the evidence regarding the role smoking plays in a coal miner's respiratory status. The conclusions NIOSH reached there as a result of its analysis fully support the position it has taken in commenting during these rulemaking proceedings. Accordingly, the Department rejects these broad-based attacks on NIOSH's conclusions as a basis for altering this regulation.

(f) Various comments state, without specificity, that the Department's proposed revisions to the definition of pneumoconiosis lack valid scientific or medical support. Other comments attack the scientific basis of the conclusions that the Department and NIOSH have drawn from the evidence of record. In support, these commenters have submitted an analysis of some of the available medical literature from Dr. Gregory Fino, a Board-certified physician in Pulmonary Diseases, and Dr. Barbara Bahl, who has a doctorate in nursing and biostatistics. Their review of the literature regarding obstructive lung disease and pulmonary dysfunction in coal miners led them to conclude that virtually all of the articles they reviewed are flawed, and that there is no evidence of a clinically significant reduction in lung function resulting from coal mine dust exposure. (Rulemaking Record, Exhibit 89–37, Appendix C). They elaborate:

> There are a number of statements that can and cannot be said about obstruction in coal miners. Some of the articles discussed in Table 1 above do demonstrate a reduction in the FEV1 in highly selected cohorts of miners. Because of selection bias, the results cannot be applied to all miners in general. Since the reductions in the FEV1 are averages, it is statistically impossible to state whether a given miner would have FEV1 reductions greater than or less than the stated amount. The articles do not say and do not show that coal mine dust inhalation causes a clinically significant reduction in the FEV1. Just because a statistically significant reduction was encountered in the selected cohorts, there is no evidence at all that the reductions would participate in any respiratory impairment or disability.
>
> While there is no doubt that some miners do have clinically significant obstruction as a result of coal mine dust inhalation, it occurs in cases of severe fibrosis where a combined obstructive and restrictive defect is present. However, there is no evidence that there is a clinically significant reduction in the FEV1 as a result of chronic obstructive lung disease due to coal mine dust inhalation. None of the studies show that. None of the studies can be generalized to the average coal miner. Moreover, statistical significance neither implies nor infers clinical significance. As the above studies demonstrate, statistical significance has created many numbers that are not applicable to the evaluation of coal miners. The conclusions reached by Morgan (1, 24, 35) and published over two decades [ago] still hold true: coal mine dust may cause slight, clinically insignificant decreases in the FEV1 in some miners. There is no evidence that these decreases cause or contribute to pulmonary disability and no support for the assumption in the Department's regulation that coal dust causes or contributed to any miner's obstructive lung disease.

Rulemaking Record, Exhibit 89–37, Appendix C at 24–25. In a separate review of literature relating to emphysema in particular, Drs. Fino and Bahl conclude that ''[t]he amount of emphysema in the lungs of miners increases with the severity of simple coal workers' pneumoconiosis.'' This increase in severity as shown by chest

X-ray or autopsy ''is not correlated with a worsening of lung function,'' and the relevant studies ''have not shown clinically significant deterioration in lung function as the emphysema worsens.'' Rulemaking Record, Exhibit 89–37, Appendix C at 32–33.

The Department has reviewed all of the medical and scientific evidence referenced in the rulemaking record, and does not agree that the record lacks valid support for the proposition that coal mine dust exposure can cause obstructive pulmonary disease. The Department's position is fully supported by NIOSH, the statutory advisor to the black lung benefits program, which responded favorably to the Department's proposed revisions. Rulemaking Record, Exhibits 5–173, 72, 89–26. The considerable body of literature documenting coal mine dust exposure's causal effect on the development of chronic bronchitis, emphysema and associated airways obstruction constitutes a clear and substantial basis for this aspect of the revised definition of pneumoconiosis.

The term ''chronic obstructive pulmonary disease'' (COPD) includes three disease processes characterized by airway dysfunction: chronic bronchitis, emphysema and asthma. Airflow limitation and shortness of breath are features of COPD, and lung function testing is used to establish its presence. Clinical studies, pathological findings, and scientific evidence regarding the cellular mechanisms of lung injury link, in a substantial way, coal mine dust exposure to pulmonary impairment and chronic obstructive lung disease. In discharging its congressionally-mandated duty to recommend a permissible exposure limit for coal mine dust, NIOSH conducted a comprehensive review of the available medical and scientific evidence addressing the impact of coal mine dust exposure on coal miners. It published its findings in National Institute for Occupational Safety and Health, *Criteria for a Recommended Standard, Occupational Exposure to Respirable Coal Mine Dust* (1995) (*Criteria*). 62 FR 3343 (Jan. 22, 1997); Rulemaking Record, Exhibit 2–1. NIOSH concluded that ''[i]n addition to the risk of simple CWP and PMF [progressive massive fibrosis], epidemiological studies have shown that coal miners have an increased risk of developing COPD.'' *Criteria* 4.2.3.2, Rulemaking Record, Exhibit 2–1 at 57.

Drs. Fino and Bahl disagree, but the Department believes that their opinions are not in accord with the prevailing view of the medical community or the substantial weight of the medical and scientific literature. For example, Seaton, in ''Coal Workers' Pneumoconiosis,'' in Morgan WKC, Seaton A, eds., *Occupational Lung Diseases* (WB Saunders Co., 3d ed. 1995) 374–406, *see also* Rulemaking Record, Exhibit 89–37, Appendix C at 34, 42, reviewed much of the same published evidence and made the following analysis:

> Lung function, measured as the forced expiratory volume in 1 second (FEV1) has been shown both in cross-sectional and longitudinal studies to decline in relation to increasing underground dust exposure but not in relation to estimates of exposure to oxides of nitrogen. This decline occurs at a similar rate in smokers and nonsmokers, although the loss of lung function overall is greater in smokers, the two effects being additive.

Similarly, Becklake, in ''Pneumoconiosis,'' in Murray J, Nadel J, eds., *Textbook of Pulmonary Medicine* (1st ed. 1988) 1556–1592, *see also Criteria,* Rulemaking Record, Exhibit 2–1 at 204, concludes:

> Most evidence to date indicates that exposure to coal mine dust can cause chronic airflow limitation in life and emphysema at autopsy, and this may occur independently of CWP * * * The relationships between hypersecretion of mucus (chronic bronchitis) and chronic airflow limitation (emphysema) on the one hand and environmental factor of coal mining exposure on the other appear to be similar to those found for cigarette smoking.

Oxman and colleagues analyzed the available literature assessing the relationship between occupational dust exposures and COPD in 1993. Oxman AD, Muir DCF, Shannon HS, Stock SR, Hnizdo E, Lange HJ, ''Occupational dust exposure and chronic obstructive pulmonary disease: A systematic overview of the evidence,'' Am Rev Resp Dis, 148:38–48 (1993); see also Rulemaking Record, Exhibit 5–174, Appendix 8. Reports were analyzed for methodological criteria including dust exposure, control for smoking, exclusion of confounding pulmonary conditions, referral bias, and adequate follow-up. Thirteen reports that met their rigorous screening criteria were analyzed. They concluded that all of the studies found a statistically significant association between cumulative dust exposure and decline in lung function, and that coal mine dust can be a cause of chronic bronchitis. Unlike Drs. Fino and Bahl, the Oxman analysis concluded there was also a clinically significant loss of lung function in smokers and nonsmokers.

Drs. Fino and Bahl state that all of the studies identifying a decline in lung function ''are flawed because of selection bias. The results are not generalizable to the general population of miners.'' Rulemaking Record, Exhibit 89–37, Appendix C at 21. As recognized by many of the authors of these studies, the results are susceptible to a selection bias caused by miners leaving the industry between the time of initial pulmonary function measurement and those taken later during the follow-up period. Because of the ''healthy worker effect,'' it would be expected that workers more prone to the respiratory impairments caused by coal mine dust inhalation would leave mining and the healthier workers would continue working. Oxman concluded that ''[a]lthough it is impossible to estimate precisely the magnitude of this bias,'' its direction ''is towards underestimating the association between dust and loss of lung function, or failure to recognize a more susceptible subgroup of workers.'' Oxman at 46. Thus, this selection bias actually *underestimates* the association between inhalation of coal mine dust and loss of lung function. As Oxman explains, ''it is likely that the results underestimate the effect of occupational dust exposure on lung function, COPD, and chronic bronchitis. The magnitude of the bias is not clear, but it might, in some cases, result in estimates that are 50% or more of the true coefficients.'' Oxman at 47. Moreover, as Coggon and Newman Taylor remarked in the course of surveying the relevant medical literature, such selection effects are relatively unimportant because ''[t]here is no obvious reason why the relation of symptoms and lung function to dust should have been weaker in those omitted from investigation.'' Coggon D, Newman Taylor A, ''Coal mining and chronic obstructive pulmonary disease: a review of the evidence,'' Thorax 53:398–407, 400 (1998); *see also* 64 FR 54979 (Oct. 8, 1999) Simply stated, there is a clear relationship between coal mine dust and COPD and lung dysfunction, and that relationship is likely to be *stronger* than what we are able to measure.

Drs. Fino and Bahl conclude that any minimal obstruction resulting from coal mine dust exposure is not clinically significant. Marine's cross-sectional 1988 study of coal miners, however, found clinically significant decreases in pulmonary function in both smokers and nonsmokers. Marine WM, Gurr D, Jacobsen M, ''Clinically important respiratory effects of dust exposure and smoking in British coal miners,'' Am Rev Resp Dis, 137:106–112 (1988); *see also Criteria,* § 4.2.2.1, Rulemaking Record, Exhibit 2–1 at 52. This study also noted that the presence of chronic

bronchitis was clearly related to cumulative dust exposure. The table below summarizes the study's data:

Measure of respiratory dysfunction	Cumulative dust exposure (in percent)					
	Zero exposure		Intermediate exposure (174 ghm $^{-3}$)		High exposure (348 ghm $^{-3}$)	
	Smoker	Nonsmoker	Smoker	Nonsmoker	Smoker	Nonsmoker
FEV1 <80%	17.1	9.7	24.2	15.5	40.0	23.9
Chronic bronchitis	30.5	7.9	41.2	14.8	52.8	26.3
Chronic bronchitis+FEV1 <80%	7.6	1.5	14.9	3.9	27.3	9.8
FEV1 <65%	5.0	3.2	8.5	5.0	14.2	7.7

NOTE TO TABLE: *Percentages are estimates of prevalence of measures of respiratory dysfunction based on linear logistic models at an age of 47 years at varying amounts of cumulative dust exposure.*

As can be seen from this table, the incidence of nonsmoking coal miners with intermediate dust exposure developing moderate obstruction (FEV1 of less than 80%) is roughly equal to the incidence of moderate obstruction in smokers with no mining exposure (15.5% v. 17.1%). Similarly, the incidence of non-smoking miners with intermediate exposure developing severe airways obstruction (FEV1 of less than 65%) is equal to the incidence of severe obstruction in non-mining smokers (5.0% for both groups). Nonsmokers with high exposure are at greater risk for developing moderate or severe obstruction than unexposed smokers. Smokers who mine have additive risk for developing significant obstruction. The risk of chronic bronchitis clearly increases with increasing dust exposure; again smokers who mine have an additive risk of developing chronic bronchitis. The message from the Marine study is unequivocal: Even in the absence of smoking, coal mine dust exposure is clearly associated with clinically significant airways obstruction and chronic bronchitis. The risk is additive with cigarette smoking.

Drs. Fino and Bahl criticize the Marine study because it used the mean of each miner's three FEV1 values rather than the highest. Rulemaking Record, Exhibit 89–37, Appendix C at 17, 21. This, however, does not appear to be a significant problem given that a number of other studies which used the highest FEV1 value for analysis also showed the same adverse relationship between coal dust inhalation and pulmonary impairment. One such study was reported by Attfield and Hodous in 1992. Attfield MD, Hodous TK, ''Pulmonary function of U.S. coal miners related to dust exposure estimates,'' Am Rev Respir Dis 145:605–609 (1992); *see also* Criteria, § 4.2.2, Rulemaking Record, Exhibit 2–1 at 51. Attfield and Hodous analyzed pulmonary function data (specifically, FEV1, FVC and FEV1/FVC ratio) drawn from Round 1 of the National Study of Coal Workers' Pneumoconiosis, along with job-specific cumulative dust exposure estimates for U.S. underground coal miners, to determine whether there was an exposure-response relationship. This group of 7,139 miners worked both before and after 1970, when federally-mandated dust control standards were implemented. Allowing for decrements due to age and smoking history, Attfield and Hodous demonstrated a clear relationship between dust exposure and a decline in pulmonary function of about 5 to 9 milliliters a year, even in miners with no radiographic evidence of clinical coal workers' pneumoconiosis. These results were similar to those reached in studies of British coal miners.

Drs. Fino and Bahl (Rulemaking Record, Exhibit 89–37, Appendix C at 22), as well as other commenters, criticize this study and similar ones that are based on exposures prior to 1970, when federally-mandated dust control standards were implemented, on the grounds of selection bias. Their theory is that only those miners who worked in a dust-controlled environment are representative of the current adverse effects of coal mine dust exposure. This theory is flawed. While lower dust exposure should reduce both the occurrence and the severity of lung disease, the *kinds* of diseases will remain the same. Indeed, Attfield and Hodous specifically chose to use data from miners with presumably higher dust exposures so as to facilitate the detection of exposure-response relationships. Attfield and Hodous, Am Rev Respir Dis 145:605.

In any event, analysis of data from miners who worked only in dust-controlled conditions confirm the connection between coal mine dust exposure and obstructive lung disease. Seixas and colleagues considered a group of 1,185 miners who began working in 1970 or later. Seixas NS, Robins TG, Attfield MD, Moulton LH, ''Exposure-response relationships for coal mine dust and obstructive lung disease following enactment of the Federal Coal Mine Health and Safety Act of 1969,'' Am J Ind Med 21:715–732 (1992); *see also* Criteria, § 4.2.2.3.1, Rulemaking Record, Exhibit 2–1 at 54. The data they reviewed was collected during Round 4 of the National Study of Coal Workers' Pneumoconiosis, and included chest X-rays, ventilatory function tests (including FEV1, FVC and FEV1/FVC ratio), and relevant histories for each miner. The results of this cross-sectional analysis, when adjusted for age, race/ethnicity and smoking, demonstrated a declination in pulmonary function attributable to coal mine dust-induced obstructive lung disease.

Longitudinal studies have confirmed these results. *See generally Criteria,* § 4.2.2.3.1.2, Rulemaking Record, Exhibit 2–1 at 55. One noteworthy study is Attfield MD, ''Longitudinal decline in FEV1 in United States coalminers,'' Thorax 40:132–137 (1985); *see also Criteria,* § 4.2.2.3.1.2, Rulemaking Record, Exhibit 2–1 at 55. Using medical data from two National Coal Study surveys held nine years apart, Attfield evaluated the effects of dust exposure on a group of 1,072 miners aged 20–49 years. The data included chest X-rays, smoking and work histories, and spirometry, as well as dust exposure estimates. After accounting for age, height and smoking, Attfield found a coal mine dust-related FEV1 loss of 36 to 84 ml over 11 years, with an additional loss among smokers. Attfield's results confirmed similar studies analyzing data from miners in the U.K. *See, e.g.,* Love RG, Miller BG, ''Longitudinal study of lung function in coal-miners,'' Thorax 37:193–197 (1982); *see also* Criteria, § 4.2.2.3.1.2, Rulemaking Record, Exhibit 2–1 at 55.

Drs. Fino and Bahl contend, however, that the average decline shown in these studies, while perhaps statistically

relevant, is not clinically relevant and does not result in any impairment. Attfield and Hodous responded succinctly to such criticism, equating pulmonary function decrements in miners to the decline of lung function in non-mining smokers from the general population: ''If it is thought that a 5- to 9-ml decrement of FEV1 per year is clinically insignificant, it must be remembered that the average decrement for smokers was only 5 ml per pack year. This, in itself, is also a minor loss of lung function. However it is well known that smoking can cause severe effects in some smokers.'' Attfield and Hodous, Am Rev Respir Dis 145:608. Just as not all smokers develop COPD and pulmonary dysfunction, pulmonary impairment is not universal in coal miners. Drs. Fino and Bahl state that ''an average loss of FEV1 means that 50% of the miners will have losses in excess of the average and 50% will have losses smaller than the average.'' Rulemaking Record, Exhibit 89–37, Appendix C at 21. This conclusion does not stand up to scrutiny because it confuses the *average* with the *median.* As can be seen from Marine's table above, only a minority of miners will have significant decrements in pulmonary function. As the majority of miners may have small or, perhaps in some cases, no decline in pulmonary function, the average decline of the population studied can appear to be relatively small. Despite this, the individual miners affected can have quite severe disease, and statistical averaging hides this effect. The amended definition clarifies that these miners have a right to prove their case with evidence of a disabling obstructive lung disease that arose out of coal mine employment.

Pointing to Coggon and Newman Taylor's statement that ''some scientists have expressed doubts as to whether coal mine dust can cause clinically important loss of lung function,'' Coggon D, Newman Taylor A, ''Coal mining and chronic obstructive pulmonary disease: A review of the evidence,'' Thorax 53:398–407 (1998); *see also* 64 FR 54979 (Oct. 8. 1999); Rulemaking Record, Exhibit 89–37, Appendix C at 24, Drs. Fino and Bahl state that the studies have not shown this type of loss of pulmonary function. Rulemaking Record, Exhibit 89–37, Appendix C at 24. The implication that Coggon and colleague agree with this conclusion is misleading. The paragraph containing the quoted sentence notes that there is evidence connecting COPD with coal mining and that ''in view of this continuing controversy, it is helpful to review the evidence as it now stands.'' The authors reviewed data from the National Study of Coal Workers' Pneumoconiosis, the Pneumoconiosis Field Research Programme (U.K.), studies from Sardinia and Germany, and mortality and necropsy studies. They concluded:

> Reductions in lung function have been found in relation to coal mining with remarkable consistency. * * * Individually, all of the studies that have addressed the relation of coal mining to lung function have limitations, but these vary from one investigation to another and often would tend to obscure rather than exaggerate any effect of dust. The balance of evidence points overwhelmingly to impairment of lung function from coal mine dust exposure.

Coggon, Thorax 53:405. Coggon and Newman Taylor further concluded that: Coal mine dust inhalation can be disabling, and arguments against this thesis are ''unconvincing'; and ''the combined effects of coal mine dust and smoking on FEV1 appear to be additive.'' Coggon, Thorax 53:405–406. Thus, this study supports the Department's position.

Similarly, several of the medical treatises and studies cited by another commenter in support of its contention that there is no such causal link between coal mine dust exposure and obstructive lung disease do not negate (and, in fact, support) the conclusion the Department and NIOSH have reached. *See, e.g.*, Morgan WKC, ''Pneumoconiosis,'' in Brewis RAL, Corrin B, Geddes DM, Gibson GJ, eds., *Respiratory Medicine* (WB Saunders Co., 2d ed. 1995) 581; *see also* Rulemaking Record, Exhibit 89–21, attachment 1 (''it is clear that bronchitis induced by coal-mine dust, henceforth referred to as industrial bronchitis, leads to a reduction in ventilatory capacity''); Green FHY, Vallyathan V, ''Coal Workers'' Pneumoconiosis and Pneumoconiosis Due to Other Carbonaceous Dusts,'' in Chung A, Green FHY, eds., *Pathology of Occupational Lung Disease* (2d ed. 1998) 189; *see also* Rulemaking Record, Exhibit 89–21, attachment 2 (coal dust exposure is ''associated with significant deficits in lung function in the absence of [clinical] CWP, reinforcing the view that COPD and CWP have independent risk factors''); ''Occupational Lung Disease,'' in Hasleton PS, ed., *Spencer's Pathology of the Lung* (5th ed. 1996) 482; *see also* Rulemaking Record, Exhibit 89–21, attachment 4 (''A considerable body of evidence indicates that chronic bronchitis and emphysema in coal workers is directly related to tobacco usage and cumulative exposure to respirable dust during life.''); Roy TM *et al.,* ''Cigarette Smoking and Federal Black Lung Benefits in Bituminous Coal Miners,'' J Occ Med 31(2):100 (1989); *see also* Rulemaking Record, Exhibit 89–21, attachment 5 (''Well-designed investigations have now documented that coal dust exposure can cause reductions in FEV1 that are independent of age and cigarette smoking. * * * it appears that the major damage caused by cigarette smoking is additive to the minor damage which can be attributed to coal dust.''); Surgeon General, U.S. Department of Health and Human Services, ''Respiratory Disease in Coal Miners,'' *The Health Consequences of Smoking: Cancer and Chronic Lung disease in the Workplace*, 313 (1985); *see also* Rulemaking Record, Exhibit 89–21, attachment 11 (concluding that ''increasing coal dust exposure is associated with increasing airflow obstruction in both smokers and nonsmokers''). To the extent this commenter advocates that tobacco smoking, rather than coal mine dust exposure, causes the only significant obstructive disorders miners develop, and that the definition of pneumoconiosis ''must be tightened to deal with the truth of tobacco's role in causing what has been compensated as black lung,'' the Department reiterates that the studies cited above, as well as others, found a significant decrement in coal miners' pulmonary function in addition to that caused by smoking. Whether a particular miner's disability is due to his coal mine employment or smoking habit must be resolved on a claim-by-claim basis under the criteria set forth at § 718.204.

Drs. Fino and Bahl find no scientific support that clinically significant emphysema exists in coal miners without progressive massive fibrosis, Rulemaking Record, Exhibit 89–37, Appendix C at 31, but the available pathologic evidence is to the contrary. Cockcroft evaluated 39 coal workers and 48 non-coal worker controls dying of cardiac causes in 1979. Cockcroft A, Wagner JC, Ryder R, Seal RME, Lyons JP, Andersson N, ''Post-mortem study of emphysema in coalworkers and non-coalworkers,'' Lancet 2:600–603 (1982); *see also* Criteria, § 4.2.2.2, Rulemaking Record, Exhibit 2–1 at 52. Centrilobular emphysema (the predominant type observed) was significantly more common among the coal workers. The severity of the emphysema was related to the amount of dust in the lungs. These findings held even after controlling for age and smoking habits.

Similarly, Leigh and colleagues analyzed 886 miners who died between 1949 and 1982. Leigh J, Outhred KG, McKenzie HI, Glick M, Wiles AN,

''Quantified pathology of emphysema, pneumoconiosis and chronic bronchitis in coal workers,'' BR J Indust Med 40:258–263 (1983); *see also Criteria*, § 4.2.2.2, Rulemaking Record, Exhibit 2–1 at 53. They found that miners with more years of face work had worse emphysema pathologically. In a subsequent study of 264 underground coal miners exposed to mixed coal and silica dust, Leigh performed a multiple regression analysis to assess the effects of total lung coal content, total lung silica content, smoking history, and years at the coal face on pulmonary function, extent of emphysema, and extent of fibrosis. Leigh J, Driscoll TR, Cole BD, Beck RW, Hull BP, Yang J, ''Quantitative relation between emphysema and lung mineral content in coalworkers,'' Occ Environ Med 51:400–407 (1994); *see also Criteria*, § 4.2.2.2, Rulemaking Record, Exhibit 2–1 at 53. Multiple regression analysis is a powerful statistical tool used to identify which of a series of variables is responsible for an observed correlation, and to eliminate apparent correlations that can be explained by other true relationships. He made the following important findings: (1) The extent of emphysema was strongly related to the total coal content of the lung, age and smoking; (2) in miners who were lifelong non-smokers, the extent of emphysema was strongly related to coal content and age; (3) the extent of emphysema was unrelated to lung silica content; and (4) the extent of lung fibrosis was related to silica content. The authors concluded that ''these results provide strong evidence that emphysema in coalworkers is causally related to lung coal content.'' Leigh, Occ Environ Med 51:400.

Ruckley and colleagues achieved similar results in examining the lungs of 450 coal workers to determine the association between coal mine dust exposure and dust-related fibrosis and emphysema. Ruckley VA, Gauld SJ, Chapman JS, *et al.,* ''Emphysema and dust exposure in a group of coal workers,'' Am Rev Resp Dis 129:528–532 (1984); *see also Criteria*, § 4.2.2.2, Rulemaking Record, Exhibit 2–1 at 53. Emphysema was graded by standard techniques, smoking histories were obtained by questionnaire and Pneumoconiosis Panel records, and lung dust content was analyzed pathologically. Relationships between emphysema and possible explanatory variables were tested by multiple logistic regression models, which exclude confounding variables in analyzing causal effects. The authors found emphysematous changes in 72% of miners who smoked, 65% of ex-smokers, and 42% of nonsmoking miners; emphysema scores were higher in patients with increasing evidence of pneumoconiotic disease; and increasing coal lung dust was associated with the presence of emphysema. Forty-seven percent of miners with no fibrotic lesions had emphysema. Ruckley concluded that ''the results support the conclusion that the relationship observed between respirable dust and emphysema in coal workers is, in some way, causal.'' Ruckley, Am Rev Resp Dis 129:532.

Drs. Fino and Bahl point to several other sources in support of their view that clinically significant emphysema is not related to coal dust exposure in the absence of PMF. They quote Morgan's textbook, *Occupational Lung Diseases*, as saying that changes of focal emphysema cannot be equated with airways obstruction. The commenters fail to note additional comments in the same textbook:

> The increased risk of centriacinar emphysema in PMF cases away from the lesion, and, in simple pneumoconiosis, in relation to dust exposure supports the hypothesis that coal dust exposure sufficient to cause alveolar inflammation and fibrosis also initiates centriacinar emphysema. This seems a likely explanation for the consistent epidemiologic finding of decrements in FEV1 and FVC and a rise in residual volume in relation to the indices of dust exposure in coal miners.

Seaton, *Occupational Lung Diseases* at 400–401. Morgan's conclusions are also somewhat suspect because he has admitted that at least in commenting on the Cockcroft paper, some of his criticisms were inaccurate and not valid or fair. Judgement of Mr. Justice Turner, The British Coal Respiratory Disease Litigation, Jan. 23, 1998, Rulemaking Record, Exhibit 72. Dr. Fino and Bahl's citation to Snider, Snider GL, ''Emphysema: the first two centuries-and beyond. A historical overview, with suggestions for future reference,'' Am Rev Resp Dis 146:1333–1344 (Part 1) and 146:1615–1622 (Part 2) (1992); *see also* Rulemaking Record, Exhibit 89–37, Appendix C at 34, is also unhelpful because the articles contain no opinion as to whether emphysema in coal miners can be clinically significant or affects pulmonary function. Coal dust exposure was plainly not the focus of these articles.

The Department's proposed revision to the definition of pneumoconiosis is also supported by the growing evidence of the adverse affects of coal mine dust exposure at the cellular level leading to obstructive lung disease. *Criteria*, 4.3, Rulemaking Record, Exhibit 2–1 at 65–69; *see generally* Coggon, Thorax 53:404. Alveolar macrophages are cells that are normally situated in the alveoli, or gas-exchange units of the lung. Their normal function is to recognize foreign substances, phagocytize (ingest) these substances, and activate other inflammatory cells. Coal dust, in turn, causes leakage of destructive protease and elastase enzymes from alveolar macrophages. These enzymes can destroy the network of elastin and collagen proteins that comprise the underlying support structure of the lung architecture; the release of these enzymes from inflammatory cells is thus associated with the production of emphysema. Lung lavage studies are performed by washing an area of lung with saline instilled through a fiberoptic bronchoscope placed through a subject's throat and wedged into the lung. These studies of nonsmoking coal miners with simple CWP showed activation of macrophages with evidence of ingestion of dust particles, a finding not present in normal controls. Takemura T, Rom WM, Ferrans VJ, Crystal RG, ''Morphologic characterization of alveolar macrophages from subject with occupational exposure to inorganic particles,'' Am Rev Resp Dis 140:1674–1685 (1989); *see also Criteria*, § 4.3.3, Rulemaking Record, Exhibit 2–1 at 69. A subsequent lavage study of nonsmoking coal miners found that the macrophages spontaneously released substances toxic to the lung, including reactive oxygen species and elastase. These substances were released in significantly higher quantities in miners than in non-mining smokers or in non-mining nonsmokers without lung disease. Rom WN, ''Basic mechanisms leading to focal emphysema in coal workers'' pneumoconiosis,'' Environ Res 53:16–28 (1990); *see also* Rulemaking Record, Exhibit 5–174, Appendix 8. As noted, the reactive oxygen species damage cell membranes, cell proteins, and DNA. Over-secretion of these substances may overwhelm the lung's natural defenses (such as anti-oxidants and anti-proteases). The unopposed proteases and elastases can destroy lung tissue, causing emphysema.

Reactive oxygen substances have been shown to damage anti-proteases in the lung. Anti-proteases are enzymes that protect the lung from proteases and elastases that are released during an inflammatory reaction (such as that produced by inhalation of coal mine dust). Without this protection, the proteases and elastases can destroy the elastin and collagen that comprise the structure of the lung, resulting in

emphysematous changes. This was demonstrated in an animal model of coal dust inhalation, where the coal dust was found to increase elastase levels and cause degradation of alpha-1 antitrypsin (one of the protective enzymes) in association with pathologic findings of emphysema. *In vitro* studies have also demonstrated that the protective anti-protease activity of alpha-1 antitrypsin is decreased by exposure to coal dust. These observations support the theory that dust-induced emphysema and smoke-induced emphysema occur through similar mechanisms—namely, the excess release of destructive enzymes from dust- (or smoke-) stimulated inflammatory cells in association with a decrease in protective enzymes in the lung.

Animal and human studies have also shown that coal mine dust inhalation can recruit neutrophils, another inflammatory cell, into the lung. Rom WN (1990). Activated neutrophils produce elastase as well as other inflammatory mediators. The recruitment of neutrophils and the activation of alveolar macrophages is greater in nonsmoking coal miners with pulmonary impairment than either non-miners or nonsmoking miners without pulmonary impairment. This suggests that a combination of coal mine dust exposure and host susceptibility may be required to produce disease. Thus, although many of the studies evaluating mechanisms of pathogenesis of coal mine dust exposure concentrate on the development of fibrosis, there is considerable basic scientific data linking coal mine dust to the development of obstructive airways disease.

Moreover, cytokines, which are chemical substances released from a number of cells in the lung, have been implicated in the development of lung disease in coal miners. *Criteria,* § 4.3.1, Rulemaking Record, Exhibit 2–1 at 65–69. Tumor necrosis factor-α (TNF) and Interleukin 6 (IL–6) are two of them. TNF is released by alveolar macrophages as well as other cells in response to coal dusts (as well as other mineral dusts). TNF stimulates lung fibrosis. Patients with progressive CWP have higher TNF release from lung monocytes. TNF release is also increased in coal miners with airflow obstruction. TNF has been demonstrated to be an important mediator in obstructive airways diseases including COPD and asthma. Alveolar macrophages have been shown to release IL–6 in response to exposure to coal mine dust. Increased IL–6 levels were noted in lungs of coal miners with CWP. IL–6 has been implicated in the creation of inflammatory changes of the lower respiratory tract in chronic bronchitis as well as reactive airways disease. In addition, other cellular mediators, including leukotriene B4, thromboxane A2, prostaglandin E2, and platelet activating factor, have been shown to be produced by alveolar macrophages or other pulmonary cells in response to coal mine dust and are well known to play a role in the production of reactive airways disease. Thus, there is considerable basic scientific data linking coal dust to the development of obstructive airways disease.

One commenter repeatedly accuses the Department of not supporting its definitional change with ''peer-reviewed'' scientific and medical studies, but does not point to any study or article in particular. The Department rejects this assertion. Each of the articles and studies cited above, as well as the majority relied upon by NIOSH in the Criteria document, appeared in a peer-reviewed journal: American Review of Respiratory Disease, American Journal of Industrial Medicine, Thorax, Journal of Occupational Medicine, Lancet, British Journal of Industrial Medicine, Occupational Environmental Medicine, Environmental Research, and others. The textbooks relied upon are authored and edited by highly respected professionals in the field. Textbook editors serve as peer-reviewers of the relevant published literature because they comprehensively survey, evaluate the validity of, and comment on, the literature. Seaton's review in Morgan and Seaton's *Occupational Lung Disease* is a good example. Moreover, the NIOSH *Criteria* document, Rulemaking Record, Exhibit 2–1, received extensive peer review prior to its publication. *See Criteria,* Rulemaking Record, Exhibit 2–1 at xxii–xxiv.

It bears repeating that in developing its recommended dust exposure standard, NIOSH carefully reviewed the available evidence on lung disease in coal miners. NIOSH also considered the strength of the evidence, including the sampling and statistical analysis techniques used, *Criteria,* § 7.3.4, Rulemaking Record, Exhibit 2–1 at 124, and concluded that the science provided a substantial basis for adopting a permissible dust exposure limit. NIOSH summarized its findings based on some of the studies detailed above, along with others, as follows:

> In addition to the risk of simple CWP and PMF, epidemiological studies have shown that coal miners have an increased risk of developing COPD. COPD may be detected from decrements in certain measures of lung function, especially FEV1 and the ratio of FEV1/FVC. Decrements in lung function associated with exposure to coal mine dust are severe enough to be disabling in some miners, whether or not pneumoconiosis is also present. A severe or disabling decrement in lung function is defined here as an FEV1 <65% of expected normal values; an impairment in lung function is defined as an FEV1 <80% of predicted normal values. An exposure-response relationship between respirable coal mine dust exposure and decrements in lung function has been observed in cross-sectional studies and confirmed in longitudinal studies.

Criteria, 4.2.3.2 (citations omitted), Rulemaking Record, Exhibit 2–1 at 57. That coal mine dust exposure can cause obstructive lung disease is now a well-documented fact.

Finally, the Department's position is consistent with the growing body of case law recognizing that obstructive lung diseases can arise from coal mine dust exposure. *See generally Labelle Processing Co.* v. *Swarrow,* 72 F.3d 308, 315 (3d Cir. 1995) (''Chronic bronchitis, as a chronic pulmonary disease, falls within the legal definition of pneumoconiosis.''); *Kline* v. *Director, OWCP,* 877 F.2d 1175, 1178 (3d Cir. 1989) (The legal definition of pneumoconiosis ''encompasses a wider range of afflictions than does the more restrictive medical definition of coal workers' pneumoconiosis.''); *Richardson* v. *Director, OWCP,* 94 F.3d 164, 166 n.2 (4th Cir. 1996) (''COPD, if it arises out of coal-mine employment, clearly is encompassed within the legal definition of pneumoconiosis, even though it is a disease apart from clinical pneumoconiosis.''); *Warth* v. *Southern Ohio Coal Co.,* 60 F.3d 173, 175 (4th Cir. 1995) (''Chronic obstructive lung disease * * * is encompassed within the definition of pneumoconiosis for purposes of entitlement to Black Lung benefits.''); *Barber* v. *Director, OWCP,* 43 F.3d 899, 901 (4th Cir. 1995) (''physicians generally use 'pneumoconiosis' as a *medical* term that comprises merely a small subset of the afflictions compensable under the Act''); *Bethlehem Mines Corp.* v. *Massey,* 736 F.2d 120, 124 (4th Cir. 1984) (recognizing that emphysema can be aggravated by coal dust exposure); *Peabody Coal Co.* v. *Holskey,* 888 F.2d 440, 442 (6th Cir. 1989) (substantial evidence supported ALJ's decision to credit doctor who believed miner's chronic obstructive pulmonary disease was related to coal dust exposure over doctor who believed the disease was caused solely by cigarette smoking); *Campbell* v. *Consolidation Coal Co.,* 811 F.2d 302, 304 (6th Cir. 1987) (where miner had obstructive lung disease and no evidence demonstrated it was not

related to coal mine employment, employer failed to rebut interim presumption of entitlement); *Freeman United Coal Mining Co.* v. *OWCP,* 957 F.2d 302, 303 (7th Cir. 1992) (recognizing that the Act's definition of pneumoconiosis encompasses obstructive disease caused in whole or in part by exposure to coal dust); *Old Ben Coal Co.* v. *Prewitt,* 755 F.2d 588, 591 (7th Cir. 1985) (recognizing that chronic obstructive pulmonary disease ''fits the statutory definition'' of pneumoconiosis); *Associated Elec. Coop., Inc.* v. *Hudson,* 73 F.3d 845, 847 (8th Cir. 1996) (affirming award of benefits based on medical evidence of ''severe obstructive lung disease caused by coal dust exposure''); *Consolidation Coal Co.* v. *Hage,* 908 F.2d 393, 395 (8th Cir. 1990) (chronic obstructive lung disease ''constitutes a type of ailment which Congress deems sufficient to entitle a claimant to Black Lung benefits''); *Bradberry* v. *Director, OWCP,* 117 F.3d 1361, 1368 (11th Cir. 1997) (''COPD that arises from coal-mine employment falls within the legal definition of pneumoconiosis.''); *Stomps* v. *Director, OWCP,* 816 F.2d 1533, 1536 (11th Cir. 1987) (ordering award of benefits on strength of medical opinion that miner's totally disabling chronic obstructive pulmonary disease was caused in part by coal mine employment).

Contrary to the commenters' argument, then, the record does contain overwhelming scientific and medical evidence demonstrating that coal mine dust exposure can cause obstructive lung disease. The Department therefore declines to change the definition of pneumoconiosis as proposed.

(g) One comment suggests that the Department delete the term ''anthracosis'' from the definition of pneumoconiosis, contending that it is a term commonly used to denote anthracotic pigmentation, without associated disease process, on biopsy or autopsy of the lungs. The Department has accommodated this concern in the proposed revisions to § 718.202(a)(2). The revised version of § 718.202(a)(2) explicitly provides that ''[a] finding in an autopsy or biopsy of anthracotic pigmentation * * * shall not be sufficient, by itself, to establish the existence of pneumoconiosis.'' 64 FR 55013 (Oct. 8, 1999). Thus, the Department does not believe that a change to the definition of pneumoconiosis is necessary.

(h) Several comments suggest that the Department appoint an expert panel to review the scientific and medical evidence on the obstructive disease, latency and progressivity proposed revisions to the regulation. The Department declines to follow this suggestion. As set forth above, the relevant scientific and medical information available on these topics has been thoroughly reviewed by highly-qualified experts, including NIOSH, the advisor designated by Congress to consult with the Department in developing criteria for total disability due to pneumoconiosis under the Black Lung Benefits Act. 30 U.S.C. 902(f)(1)(D). Accordingly, to the extent these commenters note that ''since coal-workers'' pneumoconiosis is a medical condition, * * * this determination [establishing a proper definition of pneumoconiosis] should be left to the medical experts,'' the comment ignores both the statutory definition of pneumoconiosis and the large body of scientific evidence already reviewed by medical experts, as outlined above.

(i) One comment criticizes the Department for not considering two major sources of information regarding U.S. coal miners: the National Coal Study, which the commenter states has provided a wealth of longitudinal information about the health of miners, and the NIOSH X-ray Surveillance Program. The commenter is incorrect. The information from both of these programs is a major focus of NIOSH's *Criteria* document, Rulemaking Record, Exhibit 2–1, and is further analyzed in many of the articles considered by the Department and NIOSH in proposing the revisions.

(j) One comment generally objects to the proposed revisions and urges the Department to collect data developed by the Universities of Kentucky and Louisville since the 1996 comprehensive reform of the Kentucky state workers' compensation law, a program the commenter states is based on objective medical findings of ''certified B readers.'' The commenter believes that this data would more accurately reflect modern day dust control in coal mining than the studies relied upon by the Department. As discussed above, the Department's conclusions are fully supported by the ample data it has already reviewed, including data generated from time periods post-dating implementation of federally-mandated dust control measures. Moreover, the Department does not believe this information would be particularly relevant to the proposed revisions of the definition of pneumoconiosis. A ''certified B reader'' is a physician proved by examination to be proficient in assessing the quality of chest X-rays and in using the ILO–U/C system to classify X-rays for pneumoconiosis. 20 CFR 718.202(a)(1)(ii)(E) (1999). While this information may show the incidence of clinical pneumoconiosis in a given population of coal miners, it is not particularly relevant to the other subset of diseases compensable under the Black Lung Benefits Act, namely, any chronic lung disease arising out of coal mine employment.

(k) Another comment implies that the proposed definitional changes adopt arbitrary medical ''presumptions'' without consultation with any pulmonary experts. As discussed above, all of the scientific and medical evidence upon which the Department relies has been thoroughly reviewed and evaluated by experts in the field. It is not the Department's intent to create a ''presumption'' with the proposed revisions to the definition. Instead, the revisions are designed to define pneumoconiosis in accordance with the best science currently available to the Department while leaving with the miner the burden of persuading the factfinder that he has a lung disease falling within this definition.

(l) Two comments note that the proposed definition (at least insofar as it recognizes that both obstructive and restrictive lung disease may be caused by exposure to coal mine dust) was rejected by Congress and should not be adopted. The Department has already responded to this criticism. 64 FR 54972 (Oct. 8, 1999). No further discussion is necessary.

(m) Two comments, while supporting the proposed changes, ask the Department to amend the regulation further by requiring factfinders to categorically reject as non-conforming any physician's opinion stating either that coal dust cannot cause, or causes only trivial, obstructive lung impairments, or that coal dust-induced lung diseases cannot manifest themselves after a miner's exposure to coal mine dust ceases. The commenters state that such a change would forestall parties opposing miners' entitlement from needlessly prolonging litigation. A physician's opinion based on a premise fundamentally at odds with the statute and regulations is flawed, and the factfinder must weigh that physician's opinion accordingly. *See, e.g., Robinson* v. *Missouri Mining Co.,* 955 F.2d 1181, 1183 (8th Cir. 1992); *Penn Allegheny Coal Co.* v. *Mercatell,* 878 F.2d 106, 109–110 (3d Cir. 1989). This principle will continue to govern under the revised regulation. Thus, the Department does not believe a change to the proposed regulation is necessary.

(n) Several comments support the proposal, noting that the revisions to the

definition of pneumoconiosis are supported by the current state of medical knowledge.

(o) Two comments urge the Department to join the lawsuit filed by the Department of Justice to recover money from the tobacco industry for costs incurred by the black lung program for compensating and treating smoking-related disabilities. The comment is not directed to any regulatory proposal, and no response is warranted.

(p) No other comments were received concerning this section, and no further changes have been made in it.

20 CFR 718.202

(a) In the initial notice of proposed rulemaking, the Department proposed changing § 718.202 only to the extent of clarifying that a diagnosis of anthracotic pigment by biopsy, standing alone, is not equivalent to a diagnosis of pneumoconiosis. Former § 718.202(a)(2) imposed this limitation with respect to autopsy evidence only, and the Department noted there was no reason to treat the two types of evidence differently. 62 FR 3345, 3376 (Jan. 22, 1997). The Department did not propose any further changes to § 718.202 in the second notice of proposed rulemaking, although the regulation remained open for comment. 64 FR 54971 (Oct. 8, 1999).

(b) One comment supports the Department's proposed change as consistent with mainstream scientific findings. Several other comments support this change, but also advocate adopting the criteria for diagnosing pneumoconiosis by autopsy or biopsy developed by the American College of Pathologists and Public Health Service. For the reasons set out in the preamble to § 718.106, the Department cannot make this change.

(c) Two comments urge the inclusion of language stating that a negative chest x-ray cannot form the basis of a physician's reasoned finding of no pneumoconiosis as the disease is defined in the statute and regulations. The suggested addition is unnecessary for several reasons. The Black Lung Benefits Act already prohibits the denial of a claim solely on the basis of a negative x-ray. 30 U.S.C. 923(b). A physician's opinion ruling out the presence of the disease based solely on a negative x-ray would be similarly insufficient; such an opinion would amount to no more than a repetition of the x-ray findings. *See Worhach* v. *Director, OWCP,* 17 Black Lung Rep. 1–105, 1–110 (1993) (physician's opinion which merely restates x-ray findings is not a diagnosis of pneumoconiosis for purposes of § 718.202(a)(4)). Furthermore, § 718.202(a)(4) already recognizes that a diagnosis of pneumoconiosis may be made based on a documented and reasoned medical opinion despite a negative x-ray. *Warth* v. *Southern Ohio Coal Co.,* 60 F.3d 173, 174–75 n.* (4th Cir. 1995) (holding physician's opinion that pneumoconiosis cannot be diagnosed absent positive x-ray or tissue samples conflicts with § 718.202(a)(4) because physician's diagnosis may be based on other clinical evidence notwithstanding negative x-ray). Finally, only a physician can determine the diagnostic value of a negative x-ray in assessing the presence or absence of a respiratory or pulmonary disease in a particular miner. The law only prohibits making the negative x-ray the sole and conclusive basis for ruling out the disease.

(d) One comment would limit relevant radiological qualifications to board-certification in radiology and certification as a B-reader. Although these two qualifications may encompass most physicians' expert training, a rigid rule prohibiting consideration of any other aspect of a physician's background is undesirable. The adjudicator should consider any relevant factor in assessing a physician's credibility, and each party may prove or refute the relevance of that factor. *See Worhach* v. *Director, OWCP,* 17 Black Lung Rep. 1–105, 1–108 (1993) (holding adjudicator may properly consider physician's professorship in radiology in weighing radiological qualifications under § 718.202(a)(1)); *compare Melnick* v. *Consolidation Coal Co.,* 16 Black Lung Rep. 1–31, 1–37 (1991) (*en banc*) (holding adjudicator may not consider physician's ''prestigious teaching position'' outside the field of radiology under § 718.202(a)(1) in assessing physician's radiological competence).

(e)(i) Three comments favor language recognizing that CT scans are not reliable diagnostic tools for evaluating the presence or absence of pneumoconiosis because no standardized criteria exist for interpreting them. Another comment, however, argues that a negative CT scan effectively precludes a diagnosis of pneumoconiosis because of its level of clinical sophistication. General language accepting or rejecting the use of CT scans is not necessary. The Department did not propose any such language, or develop the record to ascertain the medical community's views. The comments take diametrically opposite views on the use of these tests, which provides no basis for adopting either view. Furthermore, the Department favors consideration of new and more accurate diagnostic technologies as they become available in the future. *See* preamble to § 718.107, 62 FR 3343 (Jan. 22, 1997). Any party may support or challenge the probative value of a particular test with expert opinions. No useful purpose would therefore be served by adopting a blanket exclusion of any particular type of testing. (ii) Based on the alleged unreliability of CT scans, two comments urge the Department to make clear that a claimant may refuse to undergo a CT scan without prejudicing the adjudication of his or her claim. The Department rejects this position. The adjudicator should determine whether a claimant's refusal to undergo a CT scan (or any other medical test) is reasonable in light of all relevant circumstances in the particular case. A general exoneration for all claimants refusing CT scans is not warranted, especially since the Department does not endorse the commenters' premise that this technology is necessarily unreliable in the absence of standardized criteria for interpreting it. (iii) One comment contends the CT scan is sufficiently reliable that a negative result effectively rules out the existence of pneumoconiosis. The statutory definition of ''pneumoconiosis,'' however, encompasses a broader spectrum of diseases than those pathologic conditions which can be detected by clinical diagnostic tests such as x-rays or CT scans. *See generally Island Creek Coal Co.* v. *Compton,* F.3d, No. 98–2051, 2000 WL 524798, *4 (4th Cir. May 2, 2000) (reviewing medical and legal definitions of ''pneumoconiosis,'' the latter of which is broader). For purposes of the Black Lung Benefits Act, ''pneumoconiosis'' includes any ''chronic dust disease of the lung and its sequelae, including respiratory and pulmonary impairments, arising out of coal mine employment.'' 30 U.S.C. 902(b). A CT scan may provide reliable evidence in a particular claim that the miner does not have any evidence of the disease which can be detected by that particular diagnostic technique. The record, however, does not contain any medical evidence demonstrating the capacity of CT scans to rule out the existence of all diseases ''arising out of coal mine employment.'' *See Compton,* F.3d, 2000 WL 524798, *4 (noting that a medical diagnosis of no pneumoconiosis is not equivalent to a diagnosis of no legal pneumoconiosis), *citing Hobbs* v. *Clinchfield Coal Co.,* 45 F.3d 819, 821 (4th Cir. 1995). The Department therefore cannot accept the commenter's

position that a negative CT scan is self-sufficient evidence that the miner does not have ''pneumoconiosis'' for purposes of the statute.

(e) No other comments were received concerning this section, and no changes have been made in it.

20 CFR 718.204

(a)(i) The Department proposed several significant changes to § 718.204 in the initial notice of proposed rulemaking. 62 FR 3344–45, 3377–78 (Jan. 22, 1997). One revision clarified that ''total disability'' does not take into consideration any disabling non-respiratory conditions, *i.e.,* a miner may be totally disabled for purposes of the Black Lung Benefits Act (BLBA) notwithstanding the existence of any independently disabling non-respiratory/pulmonary impairments. This change emphasized the Department's disagreement with *Peabody Coal Co.* v. *Vigna,* 22 F.3d 1388 (7th Cir. 1994) (holding claimant's entitlement precluded by disabling stroke which was unrelated to coal mine employment and occurred before evidence of disability due to pneumoconiosis); *contra Youghiogheny & Ohio Coal Co.* v. *McAngues,* 996 F.2d 130 (6th Cir. 1993), *cert. den.* 510 U.S. 1040 (1994) (holding miner's disabling injuries from automobile accident irrelevant to disability determination under BLBA). Another revision codified holdings in two circuits that ''disability'' for purposes of the BLBA is a totally disabling respiratory or pulmonary impairment, and not ''whole person'' disability. The Department also proposed a definition for ''disability causation'' to harmonize the various formulations of that standard in circuit court decisions: a miner is totally disabled ''due to pneumoconiosis'' if the disease is a ''substantially contributing cause'' of the miner's disability. Similarly, the Department proposed recognizing that pneumoconiosis may worsen a totally disabling respiratory or pulmonary impairment which is itself unrelated to coal mine employment. Finally, the Department proposed a number of editorial changes to § 718.204 to rationalize its structure. 62 FR 3344–45 (Jan. 22, 1997). (ii) In the second notice of proposed rulemaking, the Department proposed a minor revision to § 718.204(b)(2)(iv) by restoring language from 20 CFR 718.204(c)(4) (1999), which had been omitted inadvertently. The language set forth the circumstances under which a medical report may establish the miner's total disability. 64 FR 54979, 55014 (Oct. 8, 1999). The Department also responded to numerous comments it had received concerning the proposed regulation. 64 FR 54979–80 (Oct. 8, 1999). Several comments expressed both support for, and opposition to, the Department's rejection of *Vigna's* holding that a pre-existing totally disabling impairment which is unrelated to coal mine employment precludes entitlement under the BLBA. The Department concluded the commenters had provided no reason for changing the proposed regulation. The Department also rejected comments which recommended adopting a ''whole person'' standard for total disability, rather than the proposed definition limiting disability to pulmonary and respiratory impairments. The commenters offered no rationale in support of the requested change other than a statutory interpretation of ''total disability'' previously rejected by two circuit courts in favor of the Department's position. With respect to ''disability causation,'' the Department rejected: challenges to its authority to define ''disability due to pneumoconiosis'' given the statute's broad grant of rulemaking authority and the ambiguity in the statutory term; various alternative formulations of the disability causation standard in place of ''substantially contributing cause'' inasmuch as the Department's definition reflected a general consensus in the existing caselaw; and arguments that the ''substantially contributing cause'' standard permitted awards based solely on smoking-related disability because such awards are contrary to both the BLBA and judicial precedent. Other than the restoration of language to § 718.204(b)(2)(iv), the Department did not propose any additional changes to § 718.204. 64 FR 54979–80 (Oct. 8, 1999).

(b) In both the first and second notices of proposed rulemaking, the Department proposed identical language defining total disability due to pneumoconiosis. 62 FR 3345, 3377; 64 FR 54979–54980, 55014. The Department explained its authority to define this statutory element of entitlement and proposed using a substantially contributing cause standard. Thus, a miner would be found totally disabled due to pneumoconiosis if he establishes that his pneumoconiosis is a substantially contributing cause of his totally disabling respiratory or pulmonary impairment. In both proposals, the Department explained that this standard was based on court of appeals precedent which had developed since 1989 and varied very little from circuit to circuit.

The Department also proposed that pneumoconiosis be considered a substantially contributing cause of the miner's disability if it either has an adverse effect on the miner's respiratory or pulmonary condition or worsens a totally disabling respiratory or pulmonary impairment caused by a disease or exposure unrelated to coal mine employment. §§ 718.204(c)(1)(i), 718.204(c)(1)(ii). In neither proposal did the Department describe the extent to which pneumoconiosis must have produced an adverse effect or worsened a totally disabling respiratory impairment. The Department did not mean to alter the current law through its proposals, however, or to suggest that *any* adverse effect, no matter how limited, was sufficient to establish total disability due to pneumoconiosis. Rather, the Department meant only to codify the numerous decisions of the courts of appeals which, in the process of deciding when a miner is totally disabled due to pneumoconiosis, have also ruled on what evidence is legally sufficient to establish that element of entitlement. In order to clarify this consistent intent, the Department has added the word ''material'' to § 718.204(c)(1)(i) and ''materially'' to § 718.204(c)(1)(ii). In so doing, the Department intends merely to implement the holdings of the courts of appeals. Thus, evidence that pneumoconiosis makes only a negligible, inconsequential, or insignificant contribution to the miner's total disability is insufficient to establish that pneumoconiosis is a substantially contributing cause of that disability.

The Department is also mindful, however, that Congress enacted the Act in large part to permit benefit awards to miners whose entitlement under state workers' compensation laws was precluded by burdensome causation requirements. *Adams* v. *Director, OWCP,* 886 F.2d 818, 825 (6th Cir. 1989); *Mangus* v. *Director, OWCP,* 882 F.2d 1527, 1530–1531 (10th Cir. 1989). Moreover, the courts have also recognized the difficulties that would confront a miner who must prove the relative amounts that various causal elements contribute to his totally disabling respiratory or pulmonary impairment. *See Compton* v. *Inland Steel Coal Co.,* 933 F.2d 477, 481–483 (7th Cir. 1991); *Adams,* 886 F.2d at 825; *Mangus,* 882 F.2d at 1530–1531. The courts have held that a claim will not be denied simply because a physician reasonably may be unwilling or unable to account, as a percentage or otherwise, for the exact degree of impairment caused by pneumoconiosis. *See, e.g., Barger* v. *Abston Constr. Co.,* 196 F.3d 1261 (11th Cir. 1999) (Table) (opinion

that pneumoconiosis was ''at least a partial contributing cause'' of miner's disability sufficient to prove disability due to pneumoconiosis); *Cross Mountain Coal Co.* v. *Ward,* 93 F.3d 211, 218 (6th Cir. 1996) (opinion that miner's ''impairment is due to his combined dust exposure, coal workers'' pneumoconiosis as well as his cigarette smoking history'' sufficient); *Benjamin Coal Co.* v. *McMasters,* 27 F.3d 555 (3d Cir. 1994) (Table) (opinions that (1) pneumoconiosis was the ''least significant'' factor contributing to miner's disability, and (2) coal dust exposure and cigarette smoking contributed to miner's impairment but doctor was unable ''to differentiate between the effects of the two causes'' sufficient); *Compton* v. *Inland Steel Coal Co.,* 933 F.2d 477, 479 (7th Cir. 1991) (opinion that ''pneumoconiosis * * * was one of the conditions that brought about the pulmonary impairment'' sufficient); *Robinson* v. *Pickands Mather & Co.,* 914 F.2d 35, 36 (4th Cir. 1990) (opinion that miner's ''disability was consistent with occupational pneumoconiosis'' sufficient); *Lollar* v. *Alabama By-Products Corp.,* 893 F.2d 1258, 1267 (11th Cir. 1989) (physician's diagnosis of ''restrictive pulmonary functions and pleural disease by chest x-ray with minimal parenchymal disease, all of which is consistent with coal workers' pneumoconiosis,'' sufficient); *Adams* v. *Director, OWCP,* 886 F.2d 818, 826 (6th Cir. 1989) (diagnosis of ''total disability resulting from a combination of pneumoconiosis, emphysema and chronic obstructive lung disease'' sufficient); *Bonessa* v. *United States Steel Corp.,* 884 F.2d 726 (3d Cir. 1989) (opinion that pneumoconiosis made a ''substantial contribution'' to miner's disability sufficient); *Mangus* v. *Director, OWCP,* 882 F.2d 1527 (10th Cir. 1989) (evidence that miner's pneumoconiosis caused complications requiring removal of entire lung during surgery intended to remove only part of lung as treatment of lung cancer, sufficient).

(c)(i) One comment states the Department has not justified its revision of § 718.204(a) making disabling non-pulmonary/respiratory impairments irrelevant in determining whether a miner is totally disabled under the BLBA. The Department has previously addressed this issue in both the initial and second notices of proposed rulemaking. 62 FR 3344–45 (Jan. 22, 1997); 64 FR 54979 (Oct. 8, 1999). In both instances, the Department cited *McAngues,* 996 F.2d 130, as authority for its view that non-pulmonary/respiratory impairments cannot be considered in a disability determination. *McAngues,* 996 F.2d at 134–35, quotes with approval the following language from *Twin Pines Coal Co.* v. *U.S. Dept. of Labor,* 854 F.2d 1212 (10th Cir. 1988):

> * * * [A] review of the cases, the statute, its legislative history, and its interpretation by the benefits review board * * * shows that the statute is intended to confer special benefits on miners who are disabled due to pneumoconiosis whether or not they are disabled from a different cause. Even when other causes are themselves independently disabling '[t]he concurrence of two sufficient disabling medical causes one within the ambit of the Act, and the other not, will in no way prevent a miner from claiming benefits under the Act.'

854 F.2d at 1215, *quoting Peabody Coal Co.* v. *Director, OWCP* [*Huber*], 778 F.2d 358, 363 (7th Cir. 1985); *see also Cross Mountain Coal Co.* v. *Ward,* 93 F.3d 211, 217 (6th Cir. 1996). This line of authority from three federal courts of appeals fully supports the Department's revision of § 718.204(a). Although *Vigna* adopts a contrary interpretation of the BLBA, the Seventh Circuit did not address its own precedent in *Huber* or the contrary decisions in *McAngues* and *Twin Pines.* Accordingly, the Department does not consider *Vigna* a sufficient basis for altering the regulation. (ii) Several comments support the Department's position.

(d) One comment contends the limitations on introducing evidence concerning non-respiratory or pulmonary impairments deprive the ''but for'' disability causation standard of any practical meaning in terms of proving that pneumoconiosis played little, if any, role in the miner's disability. The Department disagrees with the commenter's position for two reasons. First, the Department has adopted a ''substantially contributing cause'' standard, which is not the equivalent of a ''but for'' standard. ''Substantially contributing cause'' means pneumoconiosis has a material adverse effect on a miner's respiratory or pulmonary condition (§ 718.204(c)(1)(i)). This standard is less rigorous than a ''but for'' test. Second, only respiratory and pulmonary impairments are relevant to determining whether the miner is totally disabled for purposes of the Black Lung Benefits Act, and identifying the causes of that disability. The commenter's position effectively rests on the Seventh Circuit's interpretation of disability causation in *Peabody Coal Co.* v. *Vigna,* 22 F.3d 1388 (7th Cir. 1994). In that decision, the Court held a miner's entitlement to benefits was precluded by his disabling stroke because the stroke was unrelated to coal mine employment and occurred before any evidence the miner was disabled by pneumoconiosis. The Department disagrees with *Vigna.* Non-respiratory or pulmonary disabilities may co-exist with total disability due to pneumoconiosis, but the former are irrelevant for purposes of determining whether a miner is entitled to black lung benefits. Consequently, non-respiratory or pulmonary impairments have no relevance to the disability causation standard, and the limitation on introducing evidence concerning such conditions is appropriate.

(e) Three comments oppose the revised definition of ''total disability'' to the extent it requires proof of a totally disabling respiratory or pulmonary impairment. The commenters urge the Department to adopt a definition which incorporates a ''whole person'' definition of disability, *i.e.,* total disability based on a combination of pneumoconiosis and any other physical impairments which prevent the miner from performing his or her usual coal mine work or comparable and gainful work. The Department has previously rejected the ''whole person'' standard in both the initial and second notices of proposed rulemaking. 62 FR 3345 (Jan. 22, 1997); 64 FR 54979 (Oct. 8, 1999). The Department has consistently taken the position that proof of a totally disabling respiratory or pulmonary impairment is an essential element of a miner's claim for black lung benefits. *See, e.g., Beatty* v. *Danri Corp. & Triangle Enter.,* 49 F.3d 993, 1001 (3d Cir. 1995); *Jewell Smokeless Coal Corp.* v. *Street,* 42 F.3d 241, 243 (4th Cir. 1994); *Lollar* v. *Alabama By-Products Corp.,* 893 F.2d 1258, 1262–1263 (11th Cir. 1990); *Bosco* v. *Twin Pines Coal Co.,* 892 F.2d 1473, 1480 (10th Cir. 1989); *Adams* v. *Director, OWCP,* 886 F.2d 818, 820 (6th Cir. 1989). Adoption of a ''whole person'' definition of total disability would greatly expand the black lung benefits program and transform it into a general disability program for coal miners. The Department is convinced such a result has never been the intent of Congress. Moreover, unlike the Social Security Administration which has regulations, procedures, and personnel devoted to the evaluation of impairments from the ''whole person'' perspective, the Department simply is not equipped to evaluate such impairments. The Department's approach to the definition of total disability is not undermined by the allowance of survivors' claims where death was due in part to nonrespiratory or nonpulmonary

conditions but was actually hastened by pneumoconiosis.

Allowance of survivors' claims in such situations is consistent with the legislative history of the 1981 amendments to the BLBA. 62 FR 3345 (Jan. 22, 1997); 48 FR 24276–77 (May 31, 1983), In addition, the determination of whether pneumoconiosis actually hastened death in a given case does not require the types of regulations, procedures and personnel that would be required by a ''whole person'' disability definition.

(f) One comment opposes the requirement in § 718.204(b)(2)(iv) that a physician's opinion must be documented as well as reasoned in order to establish the existence of a totally disabling respiratory or pulmonary impairment. The commenter states that an opinion should be considered sufficient if it is ''reasoned.'' The commenter also criticizes the regulation for failing to define the requisite documentation. The commenter does not state a basis for changing the regulation. The most fundamental requirement for any physician's opinion is that it identify the information and data upon which the physician relies in order to form a judgment about the miner's pulmonary condition. Unless the adjudicator is aware of the documentation, (s)he is in no position to determine whether the opinion is ''reasoned.'' A physician provides a ''reasoned'' opinion by explaining conclusions in light of factual premises which consist of personal and occupational information about the miner and the results of clinical tests and a physical examination, *i.e.,* the ''documentation.'' *See generally Director, OWCP* v. *Rowe,* 710 F.2d 251, 255 (6th Cir. 1983). If one or more of the premises is faulty or inconsistent with the conclusions reached by the physician, the adjudicator may find the opinion not credible. Contrary to the commenter's position, a physician's reasoning cannot be divorced from the underlying documentation. As for defining the necessary documentation, § 718.104(a) sets forth the basic requirements for any report of physical examination obtained in connection with a claim for black lung benefits, and subsection (b) accommodates any additional testing the physician may consider useful.

(g) One comment challenges the Department's authority to promulgate a disability causation standard. The commenter also contends the Department cannot adopt a causation standard which permits a finding of total disability due to pneumoconiosis if the miner's pneumoconiosis worsens a totally disabling respiratory or pulmonary impairment which is itself unrelated to coal mine employment. § 718.204(c)(1)(ii). The Department rejects both positions. The Department has previously addressed comments contesting its authority to issue a regulation defining disability causation in the second notice of proposed rulemaking. 64 FR 54979–80 (Oct. 8, 1999). The Department cited the explicit rulemaking authority conferred by Congress in 30 U.S.C. 902(f)(1), which makes ''total disability'' subject to the meaning established by the Department through regulations. The Department also noted that benefits may be paid for total disability ''due to pneumoconiosis,'' 30 U.S.C. 922(a)(1), but that ''due to'' is ambiguous and therefore a valid subject for regulatory interpretation. With respect to the ''worsening'' standard, the Department adopted this definition in response to the Fourth Circuit's decision in *Dehue Coal Co.* v. *Ballard,* 65 F.3d 1189 (4th Cir. 1995). In that decision, the Court held that a miner who had totally-disabling lung cancer was not entitled to benefits because his pneumoconiosis, by definition, could not contribute to his disability. The Department believes a miner should not be denied benefits if the miner's pneumoconiosis causes further deterioration of a totally disabling (non-occupationally related) pulmonary or respiratory impairment. Although the effect is cumulative or additive, the pneumoconiosis nevertheless further diminishes the miner's already-compromised lung function. The Department stresses that this causation standard does not require an award of benefits simply because the miner has pneumoconiosis and the pneumoconiosis adversely affects his or her pulmonary condition. No award is permitted if there is not also present a totally disabling respiratory or pulmonary impairment. In such a case, the miner is entitled to benefits because (s)he is totally disabled and pneumoconiosis is a part of the overall disabling condition.

(h) Three comments contend generally that the disability causation standard promotes awards for smoking-induced disability. The Department has previously considered, and rejected, the same contention in the second notice of proposed rulemaking. 64 FR 54980 (Oct. 8, 1999). The BLBA, judicial precedent, and the program regulations do not permit an award based solely on smoking-induced disability. Because the commenters do not state any additional grounds for their contention, no further response is necessary.

(i) One comment suggests the role of smoking in causing disability undermines the regulatory presumptions by negating the validity of their factual premises. Specifically, the commenter argues that the rational connection between established and presumed facts is broken if the miner smoked. The Department disagrees with this analysis. The presumptions contained in §§ 718.302–718.306 are all derived from the BLBA. *See* 30 U.S.C. 921(c)(1) [implemented by § 718.302]; 921(c)(2) [implemented by § 718.303]; 921(c)(3) [implemented by § 718.304]; 921(c)(4) [implemented by § 718.305]; 921(c)(5) [implemented by § 718.306]. The regulatory presumptions are therefore authorized by the statute itself. The Supreme Court has upheld the constitutionality of 30 U.S.C. 921(c)(1)–(4) in *Usery* v. *Turner Elkhorn Mining Co.,* 428 U.S. 1, 22–31 (1976). In the 1981 amendments to the BLBA, Congress limited the applicability of 30 U.S.C. 921(c)(2) and (4) to claims filed before January 1, 1982, and 921(c)(5) to claims filed before June 30, 1982. Consequently, three of the statutory presumptions have little effect on the adjudication of black lung claims at this time. The Department also does not accept the commenter's premise that allegedly widespread cigarette smoking among miners has effectively destroyed the basis for the presumptions. If any individual miner's smoking is proven the sole cause of his or her disability, death or disease, the party opposing entitlement has rebutted the presumption (except with respect to § 718.304, which is irrebuttable). The presumption itself is not invalid if the presumed fact is disproved; rather, the evidence simply establishes that the presumed facts are not true in the particular case. Accordingly, the Department rejects the commenter's view that the incidence of smoking among miners necessarily causes constitutional infirmities in the regulatory presumptions.

(j) One comment urges the Department to join the lawsuit filed by the Department of Justice to recover money from the tobacco industry for benefits approved by the Department based on disability caused by cigarette smoking. The comment is not directed to any regulatory proposal, and no response is warranted.

(k) One comment supports the ''substantially contributing cause'' standard.

(l) No other comments have been received concerning this section, and no changes have been made in it.

20 CFR 718.205

(a) In the initial notice of proposed rulemaking, the Department proposed codifying its position, unanimously supported by circuit court precedent, that recognizes a causal relationship between a miner's death and pneumoconiosis if the disease hastened the miner's death. 62 FR 3345–46, 3378 (Jan. 22, 1997). The Department responded to the comments received when it issued the second notice of proposed rulemaking. 64 FR 54980 (Oct. 8, 1999). Several comments urged the Department to reinstate automatic entitlement for survivors of miners who were totally disabled by pneumoconiosis, but did not die from that disease (so-called ''unrelated death benefits''); one comment concluded the Department had effectuated that result by adopting the ''hastening death'' standard in § 718.205(c)(5). The Department rejected the first suggestion because the 1981 amendments to the Black Lung Benefits Act (BLBA) allow benefits in survivors' claims filed after January 1, 1982, only if the miner died due to pneumoconiosis. Similarly, the Department disagreed with the commenter's interpretation of the ''hastening death'' standard, citing its universal acceptance by the six circuits with jurisdiction over 90 percent of black lung claims litigation. The Department also rejected a recommendation that it make applicable to claims filed after January 1, 1982, a more lenient regulatory standard applicable to claims filed before 1982, since the standard was based on a statutory presumption (30 U.S.C. 921(c)(2)) repealed by Congress in the 1981 amendments. The Department did not propose any further changes to § 718.205 in the second notice of proposed rulemaking, although the regulation remained open for further comment. 64 FR 54971 (Oct. 8, 1999).

(b) One comment opposes the ''hastening death'' standard because it reinstates survivors' ''unrelated death benefits.'' The commenter states broadly that any lingering, non-traumatic, death will be affected by every disease process present in the individual. The Department disagrees. The commenter does not cite any medical support for its position, and it does not respond to the Department's explanation rejecting any similarity between the ''hastening death'' standard and ''unrelated death benefits'' in the second notice of proposed rulemaking. 64 FR 54980 (Oct. 8, 1999). Moreover, the commenter's premise overlooks the role of the claims adjudication process, which requires the claimant to submit credible medical evidence establishing a detectable hastening of the miner's death on account of pneumoconiosis. The party opposing entitlement has ample opportunity in each survivor's claim to submit evidence proving pneumoconiosis played no role in the miner's death.

(c) One comment argues that at least half of approved survivors' claims are based on deaths attributable to the adverse health effects of smoking. The commenter recommends reallocating the costs of these claims to the tobacco industry. The comment is not directed toward any regulatory proposal, and no response is warranted.

(d) Two comments generally assert the ''hastening death'' standard cannot be implemented by the Department because the regulation violates the notice and comment provisions of the Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.* The commenters do not indicate in what manner these APA requirements have been violated. Assuming the commenters are asserting the Department improperly adopted the ''hastening death'' standard in litigation rather than through rulemaking, the Department disagrees. The Department promulgated 20 CFR 718.205 in 1983, after complying with the APA's notice and comment provisions, in response to the 1981 amendments to the BLBA. 48 FR 24272 (May 31, 1983). Under those amendments, a deceased miner's survivor who filed a claim on or after January 1, 1982, is eligible for benefits only if the miner's death was due to pneumoconiosis. Based on the legislative history of the 1981 amendments, the Department provided that death will be considered ''due to pneumoconiosis'' where pneumoconiosis was at least ''a substantially contributing cause or factor.'' 20 CFR 718.205(c)(2) (1999). In later litigation, the Department set forth its interpretation of the regulatory phrase ''substantially contributing cause or factor,'' and consistently maintained that this standard is met by evidence proving pneumoconiosis actually hastened the miner's death. The ''hastening death'' standard gives practical meaning to the phrase ''substantially contributing cause.'' *See Bradberry* v. *Director, OWCP,* 117 F.3d 1361, 1365–66 (11 Cir. 1997) *and* cases cited therein. The Department is the administrator of the BLBA and, in that role, has the authority to interpret its own regulations. Indeed, because the Department's interpretation is reasonable and consistent with the regulatory language, every court of appeals to have considered the question has deferred to the Department's interpretation. *Bradberry,* 117 F.3d 1361, 1366–67; *Northern Coal Co.* v. *Director, OWCP,* 100 F.3d 871, 874 (10th Cir. 1996); *Brown* v. *Rock Creek Mining Co.,* 996 F.2d 812, 816 (6th Cir. 1993); *Peabody Coal Co.* v. *Director, OWCP,* 972 F.2d 178, 183 (7th Cir. 1992); *Shuff* v. *Cedar Creek Coal Co.,* 967 F.2d 977, 980 (4th Cir. 1992), *cert. den.* 506 U.S. 1050 (1993); *Lukosevicz* v. *Director, OWCP,* 888 F.3d 1001, 1006 (3d Cir. 1989). Accordingly, the ''hastening death'' standard is a permissible interpretation of § 718.205(c)(2), which was promulgated after public notice and comment in accordance with the APA.

(e) Two comments contend the Department cannot apply § 718.205(c)(5) to pending claims without violating a prohibition on retroactive rulemaking. (i) The Department previously addressed the retroactivity issue in the initial notice of proposed rulemaking. 62 FR 3347–48 (Jan. 22, 1997). The Department acknowledged the Supreme Court's holding in *Bowen* v. *Georgetown University Hospital,* 488 U.S. 204, 208 (1988), which limits the retroactive applicability of agency regulations unless Congress has expressly authorized such regulations. Although the Black Lung Benefits Act (BLBA) does not contain the express statutory authority required by *Bowen,* the Department concluded many of the proposed regulations could nevertheless apply to pending claims. These regulations, or revisions to regulations, principally clarify the Department's interpretation of the BLBA and the current program regulations. Revised regulations which could significantly change the regulated community's existing obligations and expectations, however, apply only prospectively to claims filed after the effective date of the final regulations. The Department reiterated this position in the second notice of proposed rulemaking. 64 FR 54981–82 (Oct. 8, 1999). It rejected recommendations to make all of the revisions either fully retroactive or entirely prospective. The Department adhered to its earlier explanation in the initial notice of proposed rulemaking: some regulations could apply to pending claims because they codify existing agency interpretations of the BLBA and regulations, while other regulations must be limited to prospective application because they involve significant changes to the existing program which could disrupt the parties' interests. The Department therefore declined to adopt a single approach for all of the revisions. Finally, the Department rejected arguments against retroactive

rulemaking premised on the Contract Clause of the United States Constitution, art. I, § 10, cl. 1, and the impairment of contracts. 64 FR 54981–82 (Oct. 8, 1999). (ii) The most recent comments do not cite any legal authority contradicting the Department's extensive analysis of the retroactivity issues in the initial and second notices of proposed rulemaking. In any event, the Department's analysis remains valid. An agency regulation does not run afoul of *Bowen* simply because it may operate retroactively. ''So long as a change in a regulation does not announce a new rule, but rather merely clarifies or codifies an existing policy, that regulation can apply retroactively. A rule clarifying an unsettled or confusing area of the law 'does not change the law, but restates what the law according to the agency is and has always been' * * * [.]'' *Orr* v. *Hawk,* 156 F.3d 651, 654 (6th Cir. 1998), *reh'g en banc den.,* 172 F.3d 411 (6th Cir. 1999), *quoting Pope* v. *Shalala,* 998 F.2d 473, 483 (7th Cir. 1993). *See also First National Bank of Chicago* v. *Standard Bank & Trust,* 172 F.3d 472, 478 (7th Cir. 1999) (noting *Bowen's* ban on retroactivity is inapplicable if rule is clarification rather than legislative change); *compare National Mining Assoc.* v. *U.S. Dept. of Interior,* 177 F.3d 1, 8 (D.C. Cir. 1999) (agency rule interpreting statute to impose liability for pre-rule acts gives retroactive effect which *Bowen* prohibits absent express statutory authority). As the Department explained in both the initial and second notices of proposed rulemaking, § 718.205(c)(5) simply codifies the Department's longstanding interpretation of the legal standard for proving a miner's pneumoconiosis was a ''substantially contributing cause'' of his or her death under the BLBA and part 718 regulations. 62 FR 3345–46 (Jan. 22, 1997); 64 FR 54980 (Oct. 8, 1999). Six circuit courts have adopted this interpretation while no court has disagreed. *Bradberry* v. *Director, OWCP,* 117 F.3d 1361, 1365–66 (11th Cir. 1997); *Northern Coal Co.* v. *Director, OWCP,* 100 F.3d 871, 874 (10th Cir. 1996); *Brown* v. *Rock Creek Mining Co.,* 996 F.2d 812, 816 (6th Cir. 1993); *Peabody Coal Co.* v. *Director, OWCP,* 972 F.2d 178, 183 (7th Cir. 1992); *Shuff* v. *Cedar Creek Coal Co.,* 967 F.2d 977, 980 (4th Cir. 1992), *cert. den.* 506 U.S. 1050 (1993); *Lukosevicz* v. *Director, OWCP,* 888 F.2d 1001, 1006 (3d Cir. 1989); *but see Tackett* v. *Armco, Inc.,* 16 Black Lung Rep. 1–88, 1–93 (1992), *vacated on remand* 17 Black Lung Rep. 1–103, 1–104 (1993) (rejecting ''hastening death'' standard, but vacating opinion on remand in light of controlling decision in *Shuff*). Section 718.205(c)(5) therefore represents a clarifying regulation which the Department may validly implement with retroactive effect for claims pending on the date the regulation becomes effective. (iii) Based on the foregoing analysis, the Department also rejects one commenter's position that the BLBA requires a ''direct cause and effect relationship'' between the miner's pneumoconiosis and death in order for a survivor to be entitled to benefits, at least insofar as the commenter would require that pneumoconiosis be the immediate, sole and proximate cause of the miner's death. Pneumoconiosis may be the direct, or proximate, cause of a miner's death (§ 718.205(c)(1)), but entitlement may also be premised on the lesser ''hastening death'' standard (§ 718.205(c)(2), (5)). The circuit court precedents cited above have unanimously upheld this interpretation. In both cases, a ''direct'' effect links the pneumoconiosis to the miner's death, *i.e.,* either as the leading, or contributing, cause of the miner's death. The Department's interpretation reflects Congressional intent that benefits be awarded if the survivor establishes that pneumoconiosis was a contributing cause of the miner's death, although not the sole and immediate cause. *See* 45 FR 13690 (Feb. 29, 1980); 48 FR 24276–78 (May 31, 1983).

(f) The Department received written comments and expert hearing testimony from physicians on the role pneumoconiosis may play in a miner's death. (i) *Expert Comments.* Drs. Ben V. Branscomb, Distinguished Professor Emeritus, University of Alabama (Birmingham), and William C. Bailey, Professor of Medicine and Eminent Scholar, Chair in Pulmonary Disease, University of Alabama (Birmingham), (Rulemaking Record Ex. 5–174, Appendix 8), comment that the medical literature does not substantiate any hastening effect of simple pneumoconiosis on the timing of a miner's death. They do acknowledge that severe complicated pneumoconiosis could have an additive effect in some instances, but only by reducing the miner's lifespan marginally. The physicians conclude that pneumoconiosis usually does not affect a miner's death from non-lung disease conditions, nor does mild or moderate stable pulmonary insufficiency affect other diseases leading to death. At the Department's Washington, D.C., public hearing, Dr. Branscomb also observed that simple pneumoconiosis has no effect on the common causes of death, and does not otherwise influence the course of a miner's death. Rulemaking Record (Ex. 35), Transcript, *Hearing on Proposed Changes to the Black Lung Program Regulations* (July 22, 1997), pp 47–48. At the same hearings, Dr. Robert Cohen, Chief, Division of Pulmonary Medicine, Cook County (IL) Hospital, generally described the means by which impairment of lung function from pneumoconiosis could weaken the body's defenses to infections and increase susceptibility to other disease processes. Rulemaking Record (Ex. 35), Transcript (July 23, 1997), pp 421–23. Dr. Gregory J. Fino, board-certified in Internal Medicine and in the subspecialty of Pulmonary Disease, (Rulemaking Record, Ex. 89–37, Appendix C), notes several studies which have shown that complicated pneumoconiosis is a cause of death, while other studies provide less authoritative evidence that simple pneumoconiosis may be a cause of death. This physician concludes that pneumoconiosis may be implicated in a miner's death provided the death is respiratory-related and the pneumoconiosis has caused respiratory dysfunction during the miner's life. With respect to non-respiratory deaths, Dr. Fino states that the medical literature does not document any contributory relationship between death and pneumoconiosis. (ii) *Scientific literature.* One of the principal scientific documents cited by the Department in both the initial and second notices of proposed rulemaking is the National Institute of Occupational Safety and Health's (NIOSH) *Criteria for a Recommended Standard, Occupational Exposure to Respirable Coal Mine Dust* (1995) (*Criteria*). 62 FR 3343 (Jan. 22, 1997); 64 FR 54978–79 (Oct. 8, 1999); Rulemaking Record, Exhibit 2–1. NIOSH cited studies from the United States and the United Kingdom which documented increases in mortality among miners from lung diseases related to respirable dust. *Criteria,* § 4.2.5.1, Rulemaking Record, Exhibit 2–1 at 63–64, *citing* Miller BG, Jacobsen M, ''Dust exposure, pneumoconiosis, and mortality of coal miners,'' Br J Ind Med 42:723–733 (1985), and Keumpel ED, *et al.,* ''An exposure-response analysis of mortality among U.S. miners,'' Am J Ind Med 28(2):167–184 (1995). Miller and Jacobson noted ''significant'' increases in mortality among U.K. miners with radiographic evidence of progressive massive fibrosis, and ''slightly decreased'' survival rates among miners with radiographic evidence of simple pneumoconiosis compared to miners without pneumoconiosis. Kuempel *et*

al. found increases in pneumoconiosis mortality among U.S. miners with progressive massive fibrosis, simple pneumoconiosis and exposure to dust of higher-rank coals. Based on these studies, NIOSH concluded: ''[M]iners with working lifetime exposures to respirable coal mine dust at a mean concentration of 2 mg/m^3 have an increased risk of dying from pneumoconiosis, chronic bronchitis, or emphysema.'' *Criteria,* § 4.2.5.1, Rulemaking Record, Exhibit 2–1 at 64. In the second notice of proposed rulemaking, the Department referenced another study which NIOSH had cited to the Department, Coggon D, *et al.,* ''Coal mining and chronic obstructive pulmonary disease: a review of the evidence,'' Thorax 53:398–407 (1998); *see also* 64 FR 54979 (Oct. 8. 1999). The authors reviewed studies on mortality in coal miners and reported that mortality attributed to chronic obstructive pulmonary disease was higher in miners than the general population. Among the studies submitted by one commenter is Green FHY, Vallyathan V, ''Coal Workers' Pneumoconiosis and Pneumoconiosis Due to Other Carbonaceous Dusts,'' in Chung A, Green FHY, eds., *Pathology of Occupational Lung Disease* (2d ed. 1998) 129; *see also* Rulemaking Record, Exhibit 89–21, attachment 2. Green and Vallyathan state that ''[a]pproximately 4% of coal miner deaths are directly attributable to pneumoconiosis,'' but note that the ''excess mortality rate from pneumoconiosis'' is primarily attributable to progressive massive fibrosis. (p. 137). The authors further note, however, that ''[d]eath from pneumoconiosis, chronic bronchitis, and emphysema has been related to cumulative dust exposure,'' citing Miller and Jacobson, and Kuempel *et al.* In contrast, Parker and Banks conclude, ''a series of mortality reports have not convincingly shown that simple [coal workers' pneumoconiosis] is associated with premature mortality, but that [progressive massive fibrosis] adversely affects survival * * *.'' Parker, Banks, ''Lung diseases in coal workers,'' *Occupational Lung Disease* (1998); *see also* Rulemaking Record, Exhibit 89–21, attachment 3. Parker and Banks also cite the results of the study by Kuempel *et al. See also* Morgan WKC, ''Dust, Disability, and Death,'' Am Rev Resp Dis 134:639, 641 (1986); Rulemaking Record, Exhibit 89–21, attachment 8 (concluding more emphasis should be placed on reducing cigarette smoking among miners than dust levels in mines to reduce mortality). (iii) By incorporating the ''hastening death'' standard into the regulation, the Department is clarifying the applicable statutory standard: a survivor is entitled to benefits if the miner's death was due to pneumoconiosis. This standard, in the Department's view as well as in the unanimous view of the circuit courts of appeals that have considered it, accords with Congress' intent to compensate survivors of miners whose deaths were in some way related to pneumoconiosis, as that term is broadly defined by the statute. The Department emphasizes, however, that the survivor must establish that the miner's death was hastened by pneumoconiosis in each case. The Rulemaking Record, including the variety of expert medical comments, studies and opinions on the potential contributory role of pneumoconiosis in the deaths of coal miners, does not demonstrate the necessity to depart from the hastening death legal standard. These views appear relatively consistent in stating that complicated pneumoconiosis (also called progressive massive fibrosis) may contribute to a miner's death given the severity of the disease. While opinions differ as to the possibility that simple pneumoconiosis can adversely affect the mortality process, the Department is persuaded by NIOSH's conclusion that the mortality studies it reviewed substantiate an increased risk of death from respiratory diseases which may be encompassed within the BLBA's definition of ''pneumoconiosis.'' NIOSH is the government agency charged with conducting research into occupationally-related health problems. In that capacity, the Department has previously consulted with NIOSH concerning issues related to the proposed definition of pneumoconiosis in § 718.201. 64 FR 54978–79 (Oct. 8, 1999); *see also* 30 U.S.C. 902(f)(1)(D) (Department to consult with NIOSH on criteria for tests which establish total disability in miners). The Department therefore considers NIOSH's view particularly significant in evaluating the conflicting medical opinions concerning the ''hastening death'' standard, especially since its views are consistent with other studies submitted into the record. To the extent the commenters express the view that simple pneumoconiosis can never cause death, such views are inconsistent with the BLBA. The statute contemplates an award of benefits based upon proof of pneumoconiosis as defined in the statute (which encompasses simple pneumoconiosis), and not just upon proof of complicated pneumoconiosis. *See, e.g., Penn Allegheny Coal Co.* v. *Mercatell,* 878 F.2d 106, 109–110 (3d Cir. 1989); *Wetherill* v. *Director, OWCP,* 812 F.2d 376, 382 (7th Cir. 1987). Similarly, regarding the connection between simple pneumoconiosis and non-respiratory deaths in particular, the comments from Drs. Bailey and Branscomb, along with those of Dr. Fino, focus on clinical pneumoconiosis as opposed to pneumoconiosis as more broadly defined by the statute; thus, they do not address whether, for instance, chronic obstructive pulmonary disease induced by coal mine dust exposure can, in certain circumstances, contribute to a non-respiratory death. Moreover, while Drs. Bailey and Branscomb indicate that a causal nexus between pneumoconiosis and a non-respiratory death would be unusual, they do not rule it out as a medical possibility. Dr. Cohen explained how such a cause and effect relationship could occur. Even though non-respiratory deaths hastened by pneumoconiosis may occur relatively infrequently, the survivor should nevertheless be given the opportunity to prove that pneumoconiosis had a tangible impact on the miner's death in those instances. Thus, the Department believes the ''hastening death'' standard sets a reasonable benchmark for proving, in any particular case, that pneumoconiosis contributed to the miner's death. Of course, the burden of persuasion remains with the survivor to prove that the miner's death was due to pneumoconiosis.

(g) One comment supports the ''hastening death'' standard.

(h) No other comments have been received concerning this section, and no changes have been made in it.

Subpart D

20 CFR 718.301

(a) In the initial notice of proposed rulemaking, the Department proposed deleting 20 CFR 718.301(b) (1999), which defined ''year'' for purposes of calculating the length of a miner's coal mine employment. 62 FR 3346 (Jan. 22, 1997). The Department proposed replacing subsection (b) and a separate provision in 20 CFR 725.493(b) (1999) (defining ''year'' of coal mine employment for identifying responsible operator) with a single definition of ''year'' in § 725.101(a)(32). The Department concluded that a single definition with general applicability was appropriate since the calculation of the length of a miner's employment is the same inquiry under both §§ 718.301 and 725.493(b). The Department proposed no additional changes to this regulation in the second notice of

proposed rulemaking. 64 FR 54971 (Oct. 8, 1999).

(b) No comments were received concerning this section, and no other changes have been made in it.

20 CFR 718.307

(a) In the initial notice of proposed rulemaking, the Department proposed moving the content of § 718.307(a) to § 725.103 to establish a regulation of general applicability concerning burdens of proof. 62 FR 3346 (Jan. 22, 1997). The Department also proposed deleting § 718.307(b) because it duplicated proposed § 725.103. The Department did not discuss § 718.307 in its second notice of proposed rulemaking, although the regulation remained open for public comment. 64 FR 54971 (Oct. 8, 1999).

(b) No comments were received concerning this section. It has therefore been removed.

20 CFR 718.401

(a) The Department proposed deleting 20 CFR 718.401 (1999) in the initial notice of proposed rulemaking because the provision duplicated material in proposed §§ 725.405 and 725.406. Former § 718.401 addressed each miner's statutory right to a complete pulmonary evaluation at no expense to the miner, a right outlined in proposed § 725.406. *See* 30 U.S.C. 923(b). Former § 718.401 also addressed the development of additional medical evidence necessary for the adjudication of a claim, subject matter that has been relocated to proposed § 725.405. Since both proposed § 725.405 and § 725.406 are regulations with program-wide applicability, the Department noted that no comparable regulation was necessary in part 718. 62 FR 3346 (Jan. 22, 1997). The Department proposed no additional changes to this regulation in the second notice of proposed rulemaking. 64 FR 54971 (Oct. 8, 1999).

(b) No comments were received concerning this section. It has therefore been removed.

20 CFR 718.402

(a) The Department proposed deleting 20 CFR 718.402 (1999) in the initial notice of proposed rulemaking because its content duplicated provisions of proposed § 725.414, which addressed a claimant's unreasonable refusal to cooperate in the medical development of his claim. 62 FR 3346 (Jan. 22, 1997). The Department proposed no additional changes to this regulation in the second notice of proposed rulemaking. 64 FR 54971 (Oct. 8, 1999).

(b) No comments were received concerning this section. It has therefore been removed.

20 CFR 718.403

(a) The Department proposed deleting 20 CFR 718.403 (1999) in the initial notice of proposed rulemaking and placing its provisions in part 725 as proposed § 725.103. Section 718.403 dealt with a party's burden of proof, and part 725 did not contain a comparable provision of program-wide applicability. 62 FR 3346 (Jan. 22, 1997). The Department proposed no additional changes to this regulation in the second notice of proposed rulemaking. 64 FR 54971 (Oct. 8, 1999).

(b) No comments were received concerning this section. It has therefore been removed.

20 CFR 718.404

(a) The Department proposed deleting 20 CFR 718.404 (1999) in the initial notice of proposed rulemaking and placing its provisions in part 725 as proposed § 725.203(c) and (d). Former § 718.404(a) addressed a miner's obligation to inform the Department if (s)he returns to coal mine employment; subsection (b) recognized the Department's authority to reopen a miner's final award during his or her lifetime and develop additional evidence if any issue arises concerning the continuing validity of the award. 62 FR 3346 (Jan. 22, 1997). The Department proposed no additional changes to this regulation in the second notice of proposed rulemaking. 64 FR 54971 (Oct. 8, 1999).

(b) No comments were received concerning this section. It has therefore been removed.

Appendix B to Part 718

(a) In the initial notice of proposed rulemaking, the Department proposed eliminating the option of taking an initial inspiration from the open air before commencing the pulmonary function maneuver. 62 FR 3346 (Jan. 22, 1997). The Department noted that open-air inspiration could not be recorded on the spirogram, which precluded any confirmation by a reviewing physician that the miner had taken a full breath. Thus, the test could yield spurious abnormal values. In the second notice of proposed rulemaking, the Department proposed Appendix changes to implement a requirement that physicians use the flow-volume loop in reporting pulmonary function test results. 64 FR 54981 (Oct. 8, 1999). The Department also responded to numerous comments. Some comments considered the requirement that the two highest FEV1 results vary by no more than 5 percent or 100 ml to be overly restrictive, and suggested either eliminating the requirement or liberalizing it to allow a variability limit of 10 percent or 200 ml. The Department was reluctant to eliminate the variation standard completely because it provided a baseline for ensuring the validity of the test. The Department acknowledged, however, that some individuals might be unable to provide pulmonary function results within the 5 percent variance standard. The Department therefore invited comment on alternative criteria which would guarantee reproducibility of the FEV1 and FVC values while permitting consideration of valid FEV1 results exceeding the 5 percent standard. Other comments criticized the disability table values as too stringent. The Department declined to consider any changes to the tables because it did not propose revising them in the initial notice of proposed rulemaking, and the commenters did not provide medical support for any revisions.

(b) Three comments oppose limiting the acceptable variation between the two largest FEV1's of the three acceptable tracings to 5 percent of the largest FEV1 or 100 ml, whichever is greater. *See* Appendix B(2)(ii)(G), of part 718. One comment urges the Department to raise the acceptable percentage of variability from 5 percent to 10 percent. A second comment states the 5 percent variation is too specific. This commenter recommends the physician reporting the study be allowed to use his judgment as to whether the test is acceptable. The third comment, submitted by the National Institute of Occupational Safety and Health (NIOSH), does not identify a specific percentage of increased acceptable variability, but recommends the Department include a provision permitting consideration of pulmonary function studies which exceed the 5 percent limit provided the failure of the test to comply with the standard is noted in the report. The Department agrees with the suggested revision recommended by NIOSH, and has amended Appendix B(2)(ii)(G) to adopt that suggestion with one addition. The Department has added the phrase ''by the physician conducting or reviewing the test.'' This language will ensure that a physician certifies the results of the pulmonary function test while recognizing that it does not meet the 5 percent variability requirement. The amended language will provide the adjudicator with greater flexibility in determining whether the pulmonary

function study actually substantiates the presence of a significant pulmonary impairment, despite the lack of reproducible spirometric curves within the 5 percent range.

(c) One comment recommends the Department revise the disability tables and adopt the more liberal pulmonary function disability criteria used by the Department of Justice for the Radiation Exposure Compensation Program. Although the Department received comments criticizing the table values as too stringent in response to its initial notice of proposed rulemaking, the Department did not propose any revisions to the tables in the second notice of proposed rulemaking, in part, because the commenters failed to provide any medical support for their recommendation that the tables be modified. 64 FR 54981, 55009 (Oct. 8, 1999). The Department does not consider the present comment to provide a sufficient basis for revision of these disability criteria. It constitutes the only comment the Department has received which included medical evidence suggesting alternate table values. Thus, the Department cannot determine whether the proffered evidence represents a consensus within the medical community about disability as measured by pulmonary function studies. The Department does not have an adequate record upon which to formulate a judgment about the validity of the current tables or the proposed changes. No change in the Appendix B table values is made.

(d) No other comments have been received concerning this section, and no other changes have been made in it.

Appendix C to Part 718

(a) The Department proposed amending Appendix C in the initial notice of proposed rulemaking to state that arterial blood gas studies should not be administered to a miner during, or soon after, an acute respiratory illness. 62 FR 3346, 3381 (Jan. 22, 1997). In the preamble to § 718.105 in the second notice of proposed rulemaking, the Department stated that one comment had noted the correct nomenclature for partial pressure of oxygen and carbon dioxide is an upper-case ''P,'' not the lower-case ''p'' then in use. The Department changed the references in § 718.105(c)(6) in the second proposal, but neglected to change the Appendix C table headings. Those changes have now been made. 64 FR 54971, 54977, 55012, 55017–18 (Oct. 8, 1999).

(b) No other comments were received concerning Appendix C, and no further changes have been made in it.

20 CFR Part 722—Criteria for Determining Whether State Workers' Compensation Laws Provide Adequate Coverage for Pneumoconiosis and Listing of Approved State Laws

20 CFR Part 722

(a) In its initial notice of proposed rulemaking, the Department proposed removing many of the regulations in 20 CFR Part 722 because they were obsolete. 62 FR 3346–47 (Jan. 22, 1997). Since 1973, Part 722 has set forth a procedure under which any state may request that the Secretary certify that its workers' compensation laws provide ''adequate coverage'' for occupational pneumoconiosis. Such a certification would prevent any claim for benefits arising in that state from being adjudicated under the Black Lung Benefits Act. 30 U.S.C. 931. In addition, Part 722 has provided a set of specific criteria that states were required to meet in order to obtain the requested certification. Because the Part 722 regulations had not been amended since 1973 although the statute had been amended in both 1978 and 1981, the Department proposed replacing the specific Part 722 criteria with a general statement of the statutory criteria for certification and the statement that in the future, the Department would review the workers' compensation laws of any state that applies for certification in light of the then-current statutory requirements. The Department stated that it would certify adequate coverage only if state law guaranteed at least the same compensation, to the same individuals, as is provided by the Act. The Department did not address Part 722 in its second notice of proposed rulemaking. *See* list of Changes in the Department's Second Proposal, 64 FR 54971 (Oct. 8, 1999).

(b) The Department has replaced a comma in the second sentence of § 722.3(a) with a semicolon to correct the punctuation of that sentence. In addition, the Department has added the word ''relevant'' to qualify the phrase ''administrative or court decision'' in the same sentence. This revision clarifies the Department's intent that states submit only relevant administrative or court decisions.

(c) One comment, in the context of setting forth alternatives for the Department to consider under the Regulatory Flexibility Act, urges the Department to establish specific criteria the Department will use to determine when a state black lung program provides adequate coverage for pneumoconiosis. This revision, the commenter suggests, would allow state legislatures to make reasoned decisions about whether to amend their workers' compensation laws in an attempt to provide the ''adequate coverage for pneumoconiosis'' the federal statute requires. In addition, the commenter suggests that the Department establish a formal, ongoing review of state workers' compensation laws to determine whether or not they provide adequate coverage.

Although no state has applied for certification in the 27 years that the Department has administered the program, the Department accepts the commenter's suggestion that the publication of specific criteria would be helpful to state legislators who wish to amend their state's laws in order to obtain Secretarial certification and thereby preclude the application of federal law to their state's coal mine operators. Publication of a current set of criteria, however, will require considerable study and additional drafting, and would needlessly delay final promulgation of the remaining regulations in the Department's proposal. Following completion of that work, the Department will issue a new notice of proposed rulemaking in order to ensure that interested parties have an opportunity to comment upon possible Secretarial certification criteria. The Department believes that in the interim the revised Part 722 will accommodate any state seeking certification.

The Department does not believe, however, that it would be productive to engage in a formal, ongoing review of each state's laws in order to determine whether they provide adequate coverage for occupational pneumoconiosis. States that revise their workers' compensation laws to meet the Department's criteria will do so in order to preempt the application of the Black Lung Benefits Act. Those states will have a clear incentive to submit an application to the Department for the appropriate certification. Relying on states to initiate the certification process thus makes the most efficient use of government resources at both the state and federal levels.

(d) The Department has not received any specific comments relevant to the individual regulations in Part 722, and no changes have been made in them.

20 CFR Part 725—Claims for Benefits Under Part C of Title IV of the Federal Mine Safety and Health Act, As Amended

Subpart A

20 CFR 725.1

(a) In its first notice of proposed rulemaking, the Department proposed adding subsection (k) to § 725.1 to

describe the incorporation into the Black Lung Benefits Act of a number of provisions of the Social Security Act. In addition, the new subsection noted the Department's authority to vary the application of the incorporated provisions. 62 FR 3347 (Jan. 22, 1997). The Department did not discuss section 725.1 in its second notice of proposed rulemaking, *see* list of Changes in the Department's Second Proposal, 64 FR 54971 (Oct. 8, 1999).

(b) One comment submitted in connection with the Department's first notice of proposed rulemaking and renewed in connection with the Department second notice of proposed rulemaking criticizes subsections (j) and (k) as confusing and inconsistent. The comment states that the subsections are confusing because they do not identify the individual instances in which the Department has altered the incorporated provisions of the Longshore and Harbor Workers' Compensation Act (LHWCA) and the Social Security Act (SSA). The comment also argues that the two subsections are inconsistent because subsection (j) limits the instances in which the BLBA departs from the LHWCA, while subsection (k) implies other departures may be contemplated. With respect to the first criticism, the Department believes that specific enumeration of the departures from incorporated LHWCA provisions is unnecessary. The objective of subsection (j) is simply to acknowledge that certain LHWCA provisions are incorporated into the Black Lung Benefits Act (BLBA) and that the BLBA confers specific authority on the Department to promulgate regulations which vary the terms of these incorporated provisions. *See* 30 U.S.C. § 932(a). Subsection (k) fulfills the same objective by acknowledging that there are also SSA provisions incorporated into the BLBA. Most of those provisions were incorporated into Part B of the BLBA, governing the adjudication of claims filed with the Social Security Administration prior to July 1, 1973, when Congress amended the BLBA in 1972 and 1977. *See, e.g.,* 30 U.S.C. 922(a)(5)(1)(B), incorporating the SSA definition of the term ''disability.'' These provisions are also incorporated into Part C, governing the adjudication of claims filed with the Labor Department, by 30 U.S.C. 940, but only ''to the extent appropriate.'' Subsection (k) recognizes the Department's authority to determine the extent to which the use of these incorporated provisions is appropriate. Furthermore, subsection (k) is consistent with subsection (j) because it notes that the Department may resolve conflicts which arise from the incorporation of inconsistent provisions of the two statutes. Thus, for example, the Department may choose to depart from an incorporated LHWCA provision (subsection (j)) because it has determined that a comparable but inconsistent SSA provision, which is also incorporated, better serves the interests of the program.

The Department acknowledges that, as originally proposed, subsection (k) did not contain any reference to the SSA excess earnings offset, 42 U.S.C. 403(b)–(1), incorporated into section 422(g). The Department's original explanation of subsection (k), 62 FR 3385 (Jan. 22, 1997), also inadvertently omitted specific mention of section 422(g). Section 430 gives the Department the authority to determine the extent to which application of incorporated SSA provisions into Part B of the Act is appropriate in the context of adjudicating claims under Part C. Section 422(g), however, provides no similar authority. It is located in Part C of the Act, and the Department applies the incorporated SSA offset provision as if it were a part of the BLBA. *See* 20 CFR 725.536 (1999). The Department has added an additional sentence to the end of subsection (k) to describe this incorporation. In addition, the Department has revised the first sentence of subsection (k) to recognize that section 402 of the BLBA is contained in Part A. The Department has also revised the fourth and seventh sentences of subsection (k) to clarify their meaning.

(c) No other comments were received concerning this section, and no other changes have been made in it.

20 CFR 725.2

(a) In its first notice of proposed rulemaking, the Department proposed revising section 725.2 in order to distinguish between revisions that would affect pending claims and revisions that would be applied prospectively only, *i.e.*, only to claims filed after the effective date of the revised regulations. The Department drew a distinction between revisions that merely clarified the Department's interpretation of the statute and existing regulations or were procedural regulations, and those that altered the obligations and expectations of the parties or could not easily be applied to pending claims. 62 FR 3347–48 (Jan. 22, 1997). The Department also explained the legal basis for its decision to apply certain regulations retroactively. In its second notice of proposed rulemaking, the Department added a regulation, § 725.351, to the list of revised regulations which would apply only prospectively. 64 FR 54981–82 (Oct. 8, 1999). In addition, the Department answered several comments, reiterating its belief that it lacked the statutory authority to make the final rule applicable, in its entirety, to all pending claims and rejecting the argument that the Department lacked the authority to apply any of the regulations to pending claims.

(b) One of the comments received in connection with section 725.367 contends that the Department's regulation governing the payment of attorneys' fees by responsible operators should not be applied retroactively. The Department agrees; section 725.367 was inadvertently omitted from the list of revised regulations in the Department's second notice of proposed rulemaking that should apply only to claims filed after the effective date of these revisions. As revised, the regulation significantly alters the attorneys' fees that are payable by the responsible coal mine operator. *See* 64 FR 54987 (Oct. 8, 1999) (discussing the Fourth Circuit's decision in *Clinchfield Coal Co.* v. *Harris*, 149 F.3d 407 (4th Cir. 1998)). In addition, because section 725.367 may increase the amount of attorneys' fees an operator has to pay in a contested case, it may influence the operator's decision to controvert the claimant's entitlement to benefits. In these circumstances, the Department agrees that the revised version of § 725.367 should not be applied to claims filed before the effective date of the Department's rulemaking. The Department also inadvertently omitted §§ 725.409, which governs denials of a claim by reason of abandonment, 725.416, which governs informal conference proceedings, and 725.458, which governs deposition testimony, from the list of revised regulations that should be applied prospectively only.

Similarly, section 725.465 was not open for comment in the Department's first notice of proposed rulemaking, 62 FR 3340–41 (Jan. 22, 1997). The Department proposed revising § 725.465 in its second notice of proposed rulemaking, 64 FR 54971, 54997 (Oct. 8, 1999), and has revised the regulation again in the final rule. As revised, § 725.465 prohibits the dismissal of the responsible operator finally designated by the district director from the adjudication of claims without the consent of the Director. The revision is an integral part of the new rules governing the identification, notification, and adjudication of which of the miner's former employers, if any, should be held liable for the payment of

his benefits (§§ 725.407–725.408, 725.415, 725.418, 725.491–725.495). The Department has also revised § 725.421(b), which governs the referral of a claim to the Office of Administrative Law Judges and the evidence to be transmitted to that Office for admission into the record at the hearing. The revisions to § 725.421(b) reflect the new rules governing the identification, notification and adjudication of the responsible operator. Because the revisions of those rules are prospective only, the revised version of sections 725.421(b) and 725.465 should be treated similarly. The Department has amended subsection (c) to add §§ 725.367, 725.409, 725.416, 725.421(b), 725.458, and 725.465 to the list of regulations which may be applied only prospectively.

(c) A number of comments continue to insist that the Department's regulations are impermissibly retroactive, and that the Department's proposal violates the Supreme Court's decisions in *Bowen* v. *Georgetown University Hospital*, 488 U.S. 204 (1988) and *Eastern Enterprises* v. *Apfel*, 524 U.S. 498 (1998). In *Bowen*, the Supreme Court held that, absent an explicit statutory grant of authority, administrative agencies could not promulgate retroactive rules. In its first notice of proposed rulemaking, the Department acknowledged that the Black Lung Benefits Act did not give the Department authority to promulgate regulations with a retroactive effect. 62 FR 3347 (Jan. 22, 1997). *Eastern Enterprises* did not involve the regulatory authority of administrative agencies; in that case, a majority of the Court held the Congress had violated the due process clause of the Fifth Amendment to the Constitution by improperly imposing retroactive burdens on coal mine operators in enacting certain provisions of the Coal Industry Retiree Health Benefit Act. For purposes of analyzing the Department's regulations, *Bowen* is the more restrictive decision. Because Congress did not grant the Department specific authority to engage in retroactive rulemaking under the Black Lung Benefits Act, the regulations will be permissible under *Bowen* only if they do not have a true retroactive effect. *Eastern Enterprises*, a case in which the retroactive effect of the legislation was clear, is inapposite to this analysis.

The Department addressed the retroactivity issue in its earlier notices of proposed rulemaking, 62 FR 3347–48 (Jan. 22, 1997) and 64 FR 54981–82 (Oct. 8, 1999). The Department observed that the issue of what constitutes a retroactive effect is complex. With respect to rules that clarify the Department's interpretation of former regulations, the Department quoted *Pope* v. *Shalala*, 998F.2d 473 (7th Cir. 1993), *overruled on other grounds, Johnson* v. *Apfel*, 189 F.3d 561, 563 (7th Cir. 1999), for the proposition that an agency's rules of clarification, in contrast to its rules of substantive law, may be given retroactive effect. The Sixth Circuit issued a similar holding in *Orr* v. *Hawk*, 156 F.3d 651, 654 (1994).

Underlying both the *Pope* and *Orr* decisions is the Supreme Court's opinion in *Manhattan General Equipment Co.* v. *Commissioner*, 297 U.S. 129 (1936). Both the Sixth and Seventh Circuits quote *Manhattan General* for the proposition that a rule clarifying an unsettled or confusing area of law ''is no more retroactive in its operation than is a judicial determination construing and applying a statute to a case in hand.'' 297 U.S. at 135, quoted at 998 F.2d at 483; 156 F.3d at 653. Both courts thus recognized that the Supreme Court's decision in *Bowen*, which was issued in 1988, did not overrule its 1936 decision in *Manhattan General* with respect to what constitutes a retroactive rule. *See First National Bank of Chicago* v. *Standard Bank & Trust*, 172 F.3d 472, 478 (7th Cir. 1999) (stating that if the regulation at issue ''was merely a clarification, rather than a legislative change, *Bowen*'s ban on retroactivity is inapplicable'').

The Department's rulemaking includes a number of such clarifications. For example, the revised versions of §§ 718.201 (definition of pneumoconiosis), 718.204 (criteria for establishing total disability due to pneumoconiosis) and 718.205 (criteria for establishing death due to pneumoconiosis) each represent a consensus of the federal courts of appeals that have considered how to interpret former regulations. *See* preamble to §§ 718.201 (citing cases recognizing an obstructive component to pneumoconiosis); 725.309 (citing cases recognizing the progressive nature of pneumoconiosis); 718.204; and 718.205. Moreover, none of the appellate decisions with respect to these regulations represents a change from prior administrative practice. Thus, a party litigating a case in which the court applied such an interpretation would not be entitled to have the case remanded to allow that party an opportunity to develop additional evidence. *See Betty B Coal Co.* v. *Director, OWCP*, 194 F.3d 491, 501 (4th Cir. 1999) (''* * * we are reluctant to compel reopening as a matter of constitutional law any time debatable questions of law are resolved by the BRB or the courts. When such open questions are answered, the law has been declared, not changed.''). Any party to litigation must assume the risk that a law or regulation will be interpreted in a manner other than that which it had hoped. The Department's embodiment of those decisions in regulatory form should not insulate the parties from their application to pending claims.

Similarly, the regulations in Part 725 that the Department intends to apply to pending claims represent clarifications of unsettled or confusing areas of the law. In particular, one commenter has objected to the application of §§ 725.502, 725.537, and 726.8 to pending claims. Section 725.502 provides parties to a claim with knowledge of when each benefit payment is due. In the first notice of proposed rulemaking, the Department observed that the revisions are consistent with the Department's current practice, and with appellate decisions interpreting section 21(a) of the Longshore and Harbor Workers' Compensation Act, 33 U.S.C. 921(a), as incorporated into the Black Lung Benefits Act by 30 U.S.C. 932(a). 62 FR 3365 (Jan. 22, 1997). Section 725.537 codifies the Department's position, upheld in litigation, with respect to the payment of benefits in cases in which the miner is survived by more than one surviving spouse. The revision ensures the proper implementation of 42 U.S.C. 416(d)(1) and (h)(1), Social Security Act provisions that are incorporated into the Black Lung Benefits Act by 30 U.S.C. 902(a)(2). As *Pope* and *Orr* recognize, *Bowen* does not prohibit the Department from promulgating regulations to codify its position with respect to these issues. Finally, the Department has responded to the contention that retroactive liability is imposed by § 726.8 in the preamble to § 726.8.

The same commenter has also argued that §§ 725.542–.544, 725.547, and 725.548 should not be retroactively applied to coal mine operators. Section 725.2, however, explicitly makes § 725.547 applicable to newly filed claims only. Sections 725.542 through 725.544 are applicable to operators only by operation of section 725.547; they are therefore also applicable only to claims filed after the effective date of these regulations. Finally, § 725.548 represents a renaming and renumbering of a part of the former regulation at § 725.547. 64 FR 55003 (Oct. 8, 1999). The Department does not believe that its decision to rename and renumber a previous regulation should be considered in any way retroactive.

By contrast, where the revision represents a clear change in the Department's interpretation, such as the regulation governing the payment of attorneys' fees by responsible operators, *see* 64 FR 54987 (Oct. 8, 1999) (discussing the Fourth Circuit's decision in *Clinchfield Coal Co.* v. *Harris,* 149 F.3d 407 (4th Cir. 1998)), the Department has made the change prospective only. Similarly, the revised procedures governing the processing and adjudication of claims, sections 725.351, 725.406 through 725.418, 725.423, 725.454 through 725.459, and 725.465, the regulations governing the identity of the responsible operator liable for the payment of benefits, sections 725.491 through 725.495, and the revised regulation governing operator overpayments, section 725.547, are expressly limited in their applicability to newly filed claims. In addition, the revisions of sections 725.309 and 725.310, governing additional claims and modification, respectively, are prospective only. The Department has thus taken considerable care to ensure that its revisions do not violate the Supreme Court's general prohibition against retroactive regulations.

(c) One commenter urges that the Department's prospective revisions not be made applicable to subsequent claims. Instead, the commenter suggests, they should be applied only to first-time claims filed by new claimants. The Department does not agree that a subsequent claim differs from a first-time claim for purposes of applying the revised regulations. In 1983, the Department considered a similar request when it promulgated regulations to implement the Black Lung Benefits Amendments of 1981, which transferred liability for certain claims from coal mine operators to the Black Lung Disability Trust Fund. A number of commenters suggested that a ''claim'' should be defined as a cause of action, so that an individual would only ever have one ''claim'' for benefits. The Department rejected the suggestion:

> The Department believes that the claims as cause of action analogy is misplaced. The more correct analogy would be to a complaint or other preliminary pleading which is filed to initiate an adjudication of the nature of the right or the validity of the cause of action which is being asserted. Throughout its various versions, the Act has been consistent in requiring that a claim must be filed before any determination of eligibility for benefits could be undertaken.

48 FR 24283 (May 31, 1983). Similarly, the Department has always required that a subsequent claim be adjudicated according to the standards in effect at the time the new application is filed. For example, a miner whose 1977 claim was adjudicated and denied under the interim presumption, 20 CFR § 727.203 (1999), is not entitled to have a 1987 claim adjudicated under the same criteria. Instead, that claim must be adjudicated under the more restrictive Part 718 criteria. *See Peabody Coal Co.* v. *Spese,* 117 F.3d 1001, 1007 (7th Cir. 1997). The Department does not believe that it should alter its consistent treatment of subsequent claims in order to exclude those claims from consideration under the Department's revised regulations.

(d) One commenter urges the Department to alter its definition of a ''pending'' claim, which allows a claim to be considered ''pending'' for up to one year after it is denied. The commenter suggests that the definition violates the jurisdictional rules governing finality set forth in 33 U.S.C. § 921. The Department does not agree that its definition violates any principles of finality. Currently, a claimant may file a request for modification at any time within one year after the denial of a claim. 20 CFR § 725.310 (1999). In fact, even a new claim filed during the one-year period will serve to reopen the existing claim. *See Betty B Coal Co.* v. *Director, OWCP,* 194 F3d 491, 497 (4th Cir. 1999). Consequently, an employer has no expectation that a denied claim has been fully and completely resolved until after the one-year period has passed.

The Department's definition of a ''pending claim'' is intended to prevent the application of certain regulatory revisions (those which will be applied only on a prospective basis) to any claim that was filed before the date on which those revisions take effect. The definition includes claims pending at various stages of adjudication (*i.e.,* before the district directors, the Office of Administrative Law Judges, the Benefits Review Board, or the federal courts). In addition, some claims that have been finally denied prior to the effective date of the revisions can be revived by a subsequent request for modification. For example, a claim may have been finally denied three months before the rules became effective, and the claimant may file a request for modification nine months later (or six months after the revised regulations took effect). The Department does not intend that the revised regulations that are prospective only (including, for example, the limitation on evidence) be used to adjudicate such a claim, and has drafted the definition of a ''pending claim'' to ensure that result.

20 CFR 725.4

(a) In its first notice of proposed rulemaking, the Department proposed revising subsection (d) to reflect the Department's decision to discontinue publication of the Part 727 regulations in the Code of Federal Regulations. 62 FR 3348 (Jan. 22, 1997). Subsection (d) therefore referred parties interested in reviewing the Part 727 regulations to the **Federal Register** or the most recent version of the Code of Federal Regulations containing the rules. The Department did not discuss § 725.4 in its second notice of proposed rulemaking. *See* list of Changes in the Department's Second Proposal, 64 FR 54971 (Oct. 8, 1999).

(b) Three comments urge the Department to continue publishing the Part 727 regulations because some claims governed by those regulations are still in litigation. It remains the Department's position, however, that future publication of Part 727 is unnecessary, in part because these regulations do not apply to any claim filed after March 31, 1980. Thus, more than twenty years have passed since claims were filed to which these regulations apply. In addition, the Code of Federal Regulations has printed these regulations annually for twenty years. Consequently, access to Part 727 is readily available in the public domain for the relatively few claims still subject to those regulations.

(c) No other comments were received concerning this section, and no changes have been made in it.

20 CFR 725.101

(a)(i) The Department proposed amending the definition of ''benefits'' (§ 725.101(a)(6)) in the initial notice of proposed rulemaking to include the cost of the initial complete pulmonary examination of the claimant authorized by the statute, 30 U.S.C. 923(b); § 725.406, and subsidized by the Trust Fund. 62 FR 3386 (Jan. 22, 1997). Several commenters opposed the change because they believed the revised definition would impose liability for the examination's cost on the claimant if the claim were ultimately denied or withdrawn. In response, the Department assured the commenters that the cost could not be shifted to the claimant despite its classification as a ''benefit.'' 64 FR 54982 (Oct. 8, 1999). The Department also proposed adding a reference to augmented benefits and a cross-reference to its definitional regulation (§ 725.520(c)). 64 FR 55023 (Oct. 8, 1999). The Department intended this change for the convenience of parties looking for a comprehensive

definition. 64 FR 54982 (Oct. 8, 1999). (ii) Citing the Department's representations concerning the exclusion of the complete pulmonary examination from costs recoverable from the claimant, two comments now support the amended definition. (iii) One comment opposes the change because it shifts the cost of the examination to the responsible operator if the claim is approved. The Department responded to this argument in the second notice of proposed rulemaking by noting its disagreement; since 1978, the regulations (20 CFR 725.406(c)) have required the operator found liable for the claimant's benefits to reimburse the Fund for the expenses associated with the initial pulmonary examination. 64 FR 54982 (Oct. 8, 1999). The present comment states the Department does not have the authority to shift the cost of the examination, citing *West Virginia University Hospitals, Inc.* v. *Casey,* 499 U.S. 83 (1991). At issue in *Casey* was the authority of a federal court to shift liability from one party to its opponent for the fees of experts retained to perform nontestimonial services. The Supreme Court held the fee shifting must be limited to the specific categories of expenses enumerated in the statute which authorized the trial court to award fees. Because nontestimonial expert services did not come within the ambit of any statutory category of reimbursable expenses, the Court held the district court could not reallocate fee liability. In so holding, the Court rejected the argument that such expenses could be considered part of an ''attorney's fee,'' liability for which did shift.

The Department considers *Casey* inapposite to the redefinition of ''benefits.'' That decision establishes only that fees for nontestimonial expert services cannot be considered ''attorney fees'' for purposes of a statute which shifts attorney fee liability to a prevailing party's opponent. *Casey* does not preclude the Department from defining a particular nontestimonial expert service—the § 725.406 medical examination—as a ''benefit,'' liability for which does shift to the responsible operator if the claim is ultimately approved. (iv) The Department has the statutory authority to define ''benefits'' to include the cost of the initial medical examination, and to require a responsible operator to pay for the examination in the event the claim is ultimately approved. The Black Lung Benefits Act (BLBA) incorporates section 7 of the Longshore and Harbor Workers' Compensation Act (LHWCA). 33 U.S.C 907, as incorporated by 30 U.S.C 932(a). Section 7(e) provides:

> In the event that medical questions are raised in any case, the Secretary shall have the power to cause the employee to be examined by a physician employed or selected by the Secretary and to obtain from such physician a report containing his estimate of the employee's physical impairment * * * The Secretary shall have the power in his discretion to charge the cost of examination or review under this subsection to the employer, if he is a self-insurer, or to the insurance company which is carrying the risk, in appropriate cases, or to the special fund * * *.

33 U.S.C. 907(e). Each miner's claim filed under the Black Lung Benefits Act (BLBA) raises ''medical questions'' because the status of the miner-claimant's pulmonary condition is the primary issue in every claim. Section 7(e) authorizes the Department to provide each miner-claimant with a complete pulmonary examination, and therefore address the ''medical questions'' raised by the claim. Thus, Section 7(e) provides the Department with the method for fulfilling its obligation under 30 U.S.C. 923(b) to provide each miner with the opportunity to substantiate his claim by undergoing a complete pulmonary evaluation. Section 7(e) also authorizes the Department, at its discretion, to charge the cost of the examination to the responsible operator. The Department's regulations have recognized this statutory authority since 1972, when section 7 was first incorporated into the BLBA, without regard to whether the claimant ultimately prevailed. 20 CFR 725.139, 37 FR 25466 (Nov. 30, 1972) (deputy commissioner has discretion to assess the operator or its insurer for the cost of a physician's examination conducted to resolve medical questions raised); 725.133 (1978) (deputy commissioner has the authority to assess a notified operator or its insurer for the cost of the miner-claimant's initial medical examination). The Department promulgated its current regulation implementing section 7(e) for BLBA purposes (20 CFR 725.406(c)) in 1978 after Congress amended section 413(b) to provide for complete pulmonary examinations. It requires the operator adjudged liable for the claimant's benefits to reimburse the Fund for the expenses associated with the examination. The Department has determined that such assessments are appropriate in those cases in which the award of benefits for which an individual operator is liable has become final. In the remaining cases, the Department believes the cost of the examinations should be absorbed by the coal mining industry as a whole by imposing the costs on the Trust Fund. 26 U.S.C. 9501(d)(1). As money payable under section 932(a), which incorporates section 7, the pulmonary examination cost is properly classified as a ''benefit'' and the liable operator must reimburse the Trust Fund for such cost under 30 U.S.C. 934. The responsible operator is required to secure the payment of benefits for which it is liable under section 932. 30 U.S.C. 933(a). The Department accordingly rejects the comment's position that it lacks the authority to define ''benefits'' to include the cost of the pulmonary examination required by 30 U.S.C. 923(b). (v) No other comments were received concerning this definition, and no changes were made in it.

(b)(i) In the initial notice of proposed rulemaking, the Department proposed amending § 725.101(a)(13), ''Coal Preparation,'' and (a)(19), ''Miner or Coal Miner,'' to specify that coke oven workers are excluded from coverage under the BLBA. 62 FR 3386, 3387 (Jan. 22, 1997). The Department received three comments supporting the proposed change, which were noted in the preamble to the second proposed rulemaking, 64 FR 54982 (Oct. 8, 1999). The Department further clarifies the intended scope of these definitions. In the initial notice of proposed rulemaking, the Department noted a long held position that ''the preparation activities undertaken at coke ovens are not covered by the BLBA.'' 62 FR 3348 (Jan. 22, 1997). The Department now believes this language may have been too broad, and accordingly amends the language of § 725.101(a)(19) to effectuate its intention that the definition of ''Miner'' exclude from coverage only those workers in the coke industry who are actually employed as coke-oven workers, *i.e.,* those at the coke-producing ovens. *See, e.g., Sexton* v. *Mathews,* 538 F.2d 88, 89 (4th Cir. 1975) (holding an individual who loaded coke ovens with coal, leveled the coal inside the oven, and shoveled finished coke for shipment, was not a ''coal miner'' under the BLBA). The Department, however, does not intend for the identity of the individual's employer as a coke manufacturer to be the determinative inquiry. In some cases, coke industry employees may be otherwise employed in activities which amount to custom coal preparation or come within the types of activities enumerated in § 725.101(a)(13). Those workers should not be excluded from BLBA coverage solely because they are employed by a coke producer. *See Hanna* v. *Director,*

OWCP, 860 F.2d 88, 92 (3d Cir. 1988) (stating: ''[T]he appropriate characterization of [the claimant's] work for purposes of entitlement under the Act is determined by evaluation of what he did, and not by who employed him''). The plain language of the statutory and regulatory definitions of ''miner'' focuses on what work the individual performed and where (s)he performed that work, and not who employed the individual. With respect to ''Coal preparation,'' the Department has deleted the reference to coke oven workers because the phrase is redundant in view of the language in ''Miner.'' (ii) No other comments were received concerning these definitions. (iii) The Department has changed § 725.101(a)(19) by substituting the words ''coal mine dust'' for ''coal dust.'' This change makes the regulation consistent with the Department's long-held position that the occupational dust exposure at issue under the BLBA is the total exposure arising from coal mining and not only exposure to coal dust itself. The Department previously explained this position in the second notice of proposed rulemaking. There the Department made the same change to § 725.491(d). 64 FR 54998 (Oct. 8, 1999). A comment responding to the initial notice of proposed rulemaking, 62 FR 3409 (Jan. 22, 1997), had identified an inconsistency between the reference to ''coal mine dust'' in the definition of a ''miner'' (§ 725.202) and the reference to ''coal dust'' in § 725.491. The Department agreed that a consistent reference to ''coal mine dust'' should be used throughout the regulations. ''Coal mine dust'' means any dust generated in the course of coal mining operations, including construction. The Department noted that this interpretation is consistent with Congressional intent to compensate for a broad array of dust-related lung diseases which can be linked to coal mining. 64 FR 54998 (Oct. 8, 1999). Finally, by making the change in § 725.101(a)(19), the Department expresses its disagreement with the result reached by the Tenth Circuit in *Bridger Coal Co./Pac. Minerals, Inc.* v. *Director, OWCP [Harrop],* 927 F.2d 1150 (10th Cir. 1991), which held that ''coal dust'' means only dust actually containing coal particulates. 927 F.2d at 1154. In the Department's view, *Harrop* represents too narrow a reading of Congress' intent. *See William Bros., Inc.* v. *Pate,* 833 F.2d 261, 264 (11th Cir. 1987); *Williamson Shaft Contracting Co.* v. *Phillips,* 794 F.2d 865, 870 (3d Cir. 1986) (both cases agreeing with the Department that ''coal mine dust'' is a permissible interpretation of BLBA).

(c) The Department proposed amending § 725.101(a)(16), ''District Director,'' in the initial notice of proposed rulemaking to substitute that title for ''Deputy Commissioner,'' and ensure that any actions taken by a district director would be afforded the same legal force as any action of a deputy commissioner. 62 FR 3348, 3386 (Jan. 22, 1997). No comments were received concerning this definition, and no changes were made in it.

(d) The Department proposed amending § 725.101(a)(17), ''Division or DCMWC,'' in the initial notice of proposed rulemaking to identify the agency within the Department which contains the Office of Workers' Compensation Programs and the Division of Coal Mine Workers' Compensation. 62 FR 3348, 3386 (Jan. 22, 1999). No comments were received concerning this definition, and no changes were made in it.

(e)(i) In the initial notice of proposed rulemaking, the Department proposed amending the definition of ''workers' compensation law'' (725.101(a)(31)) to exclude certain benefits paid from a state's general revenues. 62 FR 3387 (Jan. 22, 1997). The proposal responded to decisions from the Benefits Review Board and Third Circuit rejecting the Department's longstanding interpretation of the term. *O'Brockta* v. *Eastern Associated Coal Co.*, 18 Black Lung Rep.1–72, 1–79/1–80 (1994), *aff'd sub nom Director, OWCP* v. *Eastern Associated Coal Co.*, 54 F.3d 141, 148–150 (3d Cir. 1995). 62 FR 3348–49 (Jan. 22, 1997). The Department received comments to its initial proposal opposing the change and, in the second notice of proposed rulemaking, explained that the Third Circuit had suggested the Department alter the regulation to reflect accurately the Department's intended meaning. 64 FR 54982–83 (Oct. 8, 1999). (ii) Two new comments support the Department's change. (iii) One comment opposes the amended definition because it will adversely affect the Trust Fund financially by making certain state benefits unavailable for offset against corresponding federal benefits. The commenter notes the change will therefore indirectly affect the coal producers who finance the Fund. The comment, however, overlooks the fact that any adverse effect on operators is expected to be minimal because of the very small number of claims which would be affected by the exclusion of state-funded benefits. This effect is also spread across the entire industry since the industry as a whole pays the coal excise tax. Finally, using state benefits entirely funded by state general revenues to offset federal benefits would confer a windfall on responsible operators, at least in those few cases in which such state payments may be available concurrently with a period of federal entitlement. If such were the case, an individual operator would be able to offset its monthly federal benefits liability by an amount of money the state paid the claimant from its own general revenues. Thus, the operator would profit by using state benefits which it had not paid to reduce its federal liability. The proposed definition of ''workers' compensation law'' eliminates this windfall. (iv) One comment opposes the change because it codifies an alleged political agreement between the Department and one congressman, and favors only Pennsylvania residents. The commenter also states that the change will not affect pending or new claims from that state, but may have unintended consequences elsewhere. Neither point provides any basis for changing the Department's proposal, the purpose of which is to clarify long-standing policy. With respect to the first point, the comment fails to consider the historical basis of the Department's policy and its grounding in the legislative history of the BLBA. Part B of the BLBA contains a ''maintenance of effort'' provision, 30 U.S.C. 924(d), which states that no federal benefits shall be paid to the resident of any State which reduces the resident's state worker's compensation benefits because of a federal award. Both Parts B and C also each require federal benefits to be reduced by the amount of any payments received by a claimant under a state workers' compensation program for disability caused by pneumoconiosis. 30 U.S.C. 922(b), 932(g). On the eve of the BLBA's enactment in 1969, the House Managers of the bill explained in the joint conference report: ''Benefit payments made under State programs funded by general revenues are not included in the maintenance of effort provision in the House amendment for the reason that they are not to be considered workmen's compensation, unemployment compensation, disability insurance programs as such programs are generally understood, and as they are intended to be understood within the context of this benefit program.'' H.R. Rep. No. 761, 91st Cong., 1st Sess. (1969), *reprinted in* Senate Comm. on Labor and Public Welfare, *Legislative History of the Federal Coal Mine Health and Safety Act of 1969*, 1507, 1530 (1975). Congressman Dent of Pennsylvania

reinforced this understanding in his discussion of the offset provisions and which state benefits could be used to offset the federal benefits:

> We are not talking about State programs funded through general revenues. Any State that has such programs could reduce benefits payable to persons eligible to receive them under this provision. If the State did not so reduce the benefits, such benefits could not be offset or deducted from payments under this provision.

115 Cong. Rec. 39713 (1969). No contrary expression of understanding appears in the legislative history. Consequently, the Department fairly understood Congressional intent to exclude state-funded disability benefits being used to reduce federal benefits. The Third Circuit did not invalidate the Department's policy or contradict its understanding of Congressional intent; the Court merely held that the Department's regulation was inconsistent with its policy, and therefore the policy could not be sustained. As for the limited impact of proposed § 725.101(a)(31) on Pennsylvania residents, the Department acknowledges that Pennsylvania enacted legislation in 1970 to suspend state benefits paid from general revenues if the claimant received a federal award. 77 P.S. 1401(k). Those benefits therefore become unavailable for offset against federal payments in any event. The possibility remains that Pennsylvania may change its law in the future. Because the *O'Brockta* decision raises doubt concerning the Department's interpretation of ''workers' compensation law,'' the Department believes the regulation should be clarified to implement Congressional intent to exclude state benefits funded by general revenues. Finally, the potential impact of the change on states other than Pennsylvania is speculative at best, but all states, like the public as a whole, are entitled to a clear statement of governmental policy. In the event any other State enacts legislation comparable to the Pennsylvania program in the future, the legislature will have a clear understanding of the Department's position on the meaning of ''workers' compensation law.'' (v) No other comments were received concerning this definition, and no changes were made in it.

(f)(i) The Department initially proposed a uniform definition of ''year'' (§ 725.101(a)(32)) for computing the length of coal mine employment when required in the adjudication of claims. 62 FR 3387 (Jan. 22, 1997). Under the proposed definition, a ''year'' encompassed either a calendar year or partial periods totaling a year, during which the miner must have received pay for work as a miner for at least 125 days; computing a year included periods when the miner received pay while on an approved absence, *e.g.* vacation or sick leave. The Department proposed that, to the extent the evidence permitted, the beginning and ending dates of all periods of coal mine employment be ascertained. In the event the evidence was insufficient to establish such dates or if the miner's employment lasted less than a year, the Department proposed a formula for computing the length of coal mine employment based on the miner's annual earnings compared to average wage statistics for miners compiled by the Bureau of Labor Statistics (BLS). In response to a comment opposing the inclusion of approved absences from work in computing the length of coal mine employment, the Department cited judicial decisions upholding its position. 64 FR 54983 (Oct. 8, 1999). In the second notice of proposed rulemaking, the Department altered the regulation to account for leap years by adding ''366 days'' to the definition. 64 FR 55024 (Oct. 8, 1999). The Department now has amended the language of § 725.101(a)(32) to clarify that periods of approved absences count only towards the miner's ''year'' of employment, and not to the actual 125 ''working days'' during which the miner must have worked and received pay as a miner. Thus, in order to have one year of coal mine employment, the regulation contemplates an employment relationship totaling 365 days, within which 125 days were spent working and being exposed to coal mine dust, as opposed to being on vacation or sick leave. (ii) In response to the second notice of proposed rulemaking, two comments support the new definition because it does not afford definitive weight to Social Security Administration records. The Department emphasized in its second notice of proposed rulemaking that § 725.101(a)(32) does not place special weight on any particular type of evidence in determining how long an individual worked as a coal miner. 64 FR 54983 (Oct. 8, 1999). Rather, § 725.101(a)(32)(ii) recognizes that factual findings concerning a miner's work history should be based on all of the credible evidence available to the adjudicator. (iii) One comment opposes the proposed formula for computing a year because it may underestimate a miner's employment if the miner worked in a low-wage geographic area. The commenter urges crediting a Social Security earnings quarter of coverage as a calendar quarter of coal mine employment, particularly for periods of coal mine employment that occurred many years ago. Although this comment raises a legitimate concern, no change in the regulation is necessary. The proposed formula provides a default means of determining the length of time an individual worked as a coal miner. This method may be used when the beginning and ending dates of the miner's work cannot be ascertained from the existing evidence, or the miner worked less than a year as a miner. Moreover, the Department notes that the regulation allows a party to introduce any relevant evidence concerning the miner's employment. In any individual case, the miner may prove that the wages he received were below the industry average. (iv) One comment opposes the inclusion of non-work periods of employment when calculating a year of employment because the miner is not exposed to any occupational hazard during such periods. The Department disagrees, at least with respect to determining whether the miner worked a ''year.'' Judicial precedent has firmly established the legitimacy of counting periods of absence from the workplace for sickness or vacations as part of the miner's year(s) of employment. *See* 64 FR 54983 (Oct. 8, 1999). Despite the lack of actual exposure to coal mine dust during these periods, the employment relationship between the miner and his employer remains intact. Consequently, such periods of non-exposure may be included in the computation of the miner's work history. The Department agrees, however, that such absences should not be included when determining whether the miner actually worked at least 125 days during the year. The 125-day requirement means days of actual employment as a coal miner, and the regulation has been clarified to make the Department's position clear. *See generally Director, OWCP* v. *Gardner*, 882 F.2d 67, 69–70 (3d Cir. 1989) (noting ''[t]he 125 day limit [in 20 CFR 725.493(b)] relates to the minimum amount of time the miner may have been exposed to coal dust while in employment by [the] operator.''); *but see Thomas* v. *BethEnergy Mines, Inc.,* 21 Black Lung Rep. 1–10 (1997) (holding sick leave may be counted in determining whether miner worked 125 days during year). Thus, the periods of approved absence from the workplace may be counted only towards the miner's calendar year of work. (v) One comment generally opposes the definition contending it is based on outmoded concepts and

science. The commenter notes that miners today are exposed to less dust as a result of more hygienic working conditions. The Department, however, believes the definition provides a rational methodology for determining the length of a miner's employment relationship with an operator. The essential issues are the period(s) of time the coal mine operator employed the miner, and the number of days during a year of employment that the individual actually worked as a coal miner. If the miner actually worked at least 125 days during a calendar year or partial periods of different years totaling a 365-day period, then the miner has worked one year for purposes of the program regulations. Whether the miner was exposed to reduced levels of coal mine dust during the working days is irrelevant to this computation. Rather, such evidence may be relevant to an operator's attempt to rebut the presumption of regular and continuous exposure to coal mine dust found in § 725.491(d). With respect to the 125-working day issue, the Department notes its disagreement with *Landes* v. *Director, OWCP*, 997 F.2d 1192, 1197–98 (7th Cir. 1993), and *Yauk* v. *Director, OWCP*, 912 F.2d 192, 195 (8th Cir. 1989) (both cases decided under 20 CFR 718.301(b)). In both cases, the court held that a miner should receive credit for a full year of employment for each partial period of each calendar year during which the miner worked at least 125 days. The Department believes the partial periods must be aggregated until they amount to one year of coal mine employment comprising a 365-day period. Only then should the factfinder determine whether the miner spent at least 125 working days as a coal miner during the year. *See Croucher* v. *Director, OWCP*, 20 Black Lung Rep. 1–67 (1996) (holding ''year'' means calendar year or partial periods totaling calendar year; opposing party may establish irregular employment by showing miner worked fewer than 125 days during year). Consequently, no basis has been provided for abandoning the proposed definition of a ''year.'' (vi) No other comments were received concerning this definition, and no changes were made in it.

20 CFR 725.103

(a) In the initial notice of proposed rulemaking, the Department proposed § 725.103 as a regulation of general applicability to delineate the general burdens of proof for the parties to a claim. 62 FR 3388 (Jan. 22, 1997). The comments opposing this regulation challenged the Department's authority to adjust the burdens of proof among the parties. The Department responded with a detailed analysis of the relevant precedent and its own authority. 64 FR 54972–74 (Oct. 8, 1999). For a number of reasons, the Department concluded that the Administrative Procedure Act (APA), 5 U.S.C. 556(d), does not preclude it from incorporating presumptions into the regulations which reallocate the burden of proving certain facts. First, the statute itself places limitations on the operation of the APA while conferring on the Secretary broad regulatory authority. The Federal Mine Safety and Health Act (FMSHA), which includes the Black Lung Benefits Act (BLBA) as title IV, generally exempts its provisions from the APA. 30 U.S.C. 956. The BLBA, however, incorporates section 19 of the Longshore and Harbor Workers' Compensation Act (LHWCA), 33 U.S.C. 919(d), thereby making the APA applicable to the adjudication of claims. The incorporation of the APA is subject to one important constraint: Congress conferred on the Secretary the authority to vary the terms of the incorporated provisions by regulation. 30 U.S.C. 932(a) (provisions of LHWCA apply to BLBA ''except as otherwise provided * * * by regulations of the Secretary''). *See generally Director, OWCP* v. *National Mines Corp.,* 554 F.2d 1267, 1273–74 (4th Cir. 1977); *Patton* v. *Director, OWCP,* 763 F.2d 553, 559–60 (3d Cir. 1985). Second, the Department noted that the Supreme Court's decision in *Director, OWCP* v. *Greenwich Collieries,* 512 U.S. 267 (1994), did not address, much less restrict, the Department's statutory authority to alter the applicability of the APA. In *Greenwich Collieries,* the Supreme Court addressed only whether the Department had promulgated a regulatory presumption (20 CFR 718.3) that required a finding for the claimant if the evidence for and against a claimant on a particular issue was evenly balanced. The Court considered § 718.3(c) too ambiguous to operate as an exception to the APA's requirement that the party who bears the burden of persuasion must prevail by a preponderance of the evidence. Because the Court's interpretation of the regulation resolved the issue, the Court did not reach the Department's argument that it has statutory authority to override 5 U.S.C. 556(d) by regulation and shift the burden of persuasion as well. Furthermore, the Court did not decide which party bears the burden of persuasion; rather, it determined only what standard of proof must be met by the party bearing the burden of persuasion. The Department therefore concluded *Greenwich Collieries* does not prohibit the Department from assigning burdens of proof to parties other than the claimant if necessary to achieve the goals of the BLBA. 64 FR 54973 (Oct. 8, 1999). Finally, the Department surveyed other decisions which upheld the authority of an agency to allocate the burden of persuasion by means of factual presumptions. This caselaw lent additional support for the Department's conclusion that its general rulemaking authority permitted it to adjust the burdens of proof among the parties, provided a rational basis existed between the proven facts and those presumed.

(b) One comment contends the Department has no authority under the APA to allocate burdens of proof in a proceeding before an administrative law judge (ALJ). The comment cites no authority, statutory or otherwise, for this proposition. For purposes of responding to the comment, the Department assumes the reference to ALJ proceedings means a reference to a proceeding governed by the APA, including 5 U.S.C. 556(d) (allocating burden of persuasion to proponent of a rule or order). In the second notice of proposed rulemaking, the Department examined the statutory authority which permits it to vary the terms of the APA by regulation. 64 FR 54973 (Oct. 8, 1999). The comment provides no refutation of the conclusions drawn from this analysis. Because the Department has already responded to the substance of the comment's objection, no further response is warranted.

(c) One comment suggests the Supreme Court's decision in *Allentown Mack Sales & Service, Inc.* v. *NLRB,* 522 U.S. 359 (1998), prohibits the Department from reallocating burdens of proof absent statutory authority. As an initial matter, the Department addressed this decision in its second notice of proposed rulemaking. 64 FR 54973 (Oct. 8, 1999). The Department quoted *dicta* from the majority opinion which explicitly supports the authority of an agency to promulgate ''counterfactual evidentiary presumptions * * * as a way of furthering legal or policy goals[.]'' 522 U.S. at 378. The comment does not respond to this analysis, or explain in what manner the Department has erroneously interpreted the decision. In any event, the Department believes *Allentown Mack* provides no precedential basis for limiting the Department's authority to assign burdens of production and persuasion to parties other than the claimant. That case involved a dispute over the evidentiary showing a company must

make to deny recognition to an incumbent union. According to NLRB case law, the company must establish a ''reasonable doubt'' that the union enjoys the majority support of its members. The NLRB held that Allentown Mack had not established the existence of such doubt by a preponderance of the evidence. The Supreme Court ultimately overturned the Board's factual findings because the Court concluded the Board had applied in actuality a higher burden of proof than it had announced in its decisions. 522 U.S. at 378–80. Although the comment depicts this decision as an extension of *Greenwich Collieries, Allentown Mack* has no bearing on an agency's authority to vary the terms of the APA or reallocate the burden of persuasion to a party other than the proponent of a rule or order. *Allentown Mack* establishes only the proposition that an agency cannot announce one standard of proof in principle and apply a higher standard of proof in practice. The Department therefore rejects the comment's position.

(d) No other comments were received concerning this definition, and no changes were made in it.

Subpart B

20 CFR 725.202

(a) The Department proposed changing the definition of ''miner'' in the initial notice of proposed rulemaking. 62 FR 3388–89 (Jan. 22, 1997). Specifically, the Department proposed creating a rebuttable presumption that any individual working in or around a coal mine or coal preparation facility was a ''miner'' within the meaning of the Black Lung Benefits Act (BLBA). The party liable for benefits could rebut the presumption by proving the individual did not perform coal extraction, preparation or transportation work while at the mine site, or did not engage in mine maintenance or construction. The presumption could also be rebutted by demonstrating that the individual was not regularly employed around a coal mine or coal preparation facility. The Department also proposed restructuring the existing regulation (20 CFR 725.202) to differentiate special provisions applicable only to transportation and construction workers. *See generally* 64 FR 3349 (Jan. 22, 1997). The Department did not propose any further changes to this regulation in the second notice of proposed rulemaking. 64 FR 54971 (Oct. 8, 1999).

(b) Two comments generally object to the revised definition of ''miner,'' arguing that it forces operators to defend against claims from employees only peripherally involved in the coal mining process. The revisions primarily rearrange the component parts of 20 CFR 725.202(a), and segregate special provisions involving construction and transportation workers. The regulation does include a rebuttable presumption that any on-site worker at a coal mine or coal preparation facility is a ''miner.'' This presumption reflects the rational assumption that an individual working in or around a coal mine is involved in the extraction, preparation or transportation of coal, or in the construction of a mine site; these functions are enumerated by the statutory definition of a ''miner.'' The operator may rebut the presumption by disproving either the required nexus between the worker's duties and coal mining, or any regular employment at a coal mine facility. This burden is not onerous given the operator's access to information about the use and duties of the workers at its facilities.

(c) One comment objects to coverage for coal mine construction workers whose jobs are integral to the construction of a coal mine site or facility. The commenter argues that coverage should include only those construction workers whose jobs are integral to the extraction or preparation of coal, citing *William Bros., Inc.* v. *Pate,* 833 F.2d 261 (11th Cir. 1987), and *Bridger Coal Co./Pac. Minerals, Inc.* v. *Director, OWCP [Harrop],* 927 F.2d 1150 (10th Cir. 1991), and only if those individuals are also exposed to coal dust as a result of their work. The Department, however, believes the focus on mine construction, rather than coal extraction or preparation, is consistent with Congressional intent in extending coverage to construction workers. The Fourth Circuit has identified the flaw in using the traditional ''situs/function'' test for coal mine construction workers: ''Coal mine construction * * * involves neither the extraction nor preparation of coal. If, therefore, we apply the two-step test to coal mine construction workers, they would rarely, if ever, qualify as miners under the Act.'' *The Glem Co.* v. *McKinney,* 33 F.3d 340, 342 (4th Cir. 1994). The logical inquiry concerning the construction workers' activities must therefore look to coal mine construction, which inevitably (and generally) involves the pre-extraction work of building the mine facility itself. That such work is consistent with work at a coal mine is evident from the statutory definition of ''coal mine:'' ''an area of land and all structures, facilities, * * * shafts, slopes, tunnels * * * and other property, real or personal, * * * used in, *or to be used in,* the work of extracting'' coal. 30 U.S.C. 802(h)(2) (emphasis supplied); *see also* 20 CFR 725.101(a)(23) (renumbered as § 725.101(a)(12)). A construction worker who builds the ''coal mine'' is a ''miner'' to the extent work at the covered site exposes him or her to ''coal mine dust.'' Moreover, the fact that the claimant worked at non-operational mines is not, by itself, sufficient to establish a lack of coal mine dust exposure. The construction process itself may expose the miner to coal mine dust. In addition, a coal mine construction worker exposed to coal mine dust from an operating coal mine in the vicinity of the construction site is a ''miner'' under the Black Lung Benefits Act (BLBA). *R&H Steel Buildings* v. *Director, OWCP,* 146 F.3d 514, 516–17 (7th Cir. 1998).

Pate and *Harrop,* cited by the commenter, do not provide compelling authority to depart from the proposed regulation. In *Pate,* the Court stated that ''construction workers are covered only if they have been exposed to dust arising from the extraction or preparation of coal.'' 833 F.2d at 266 (footnote omitted). Limiting covered construction activities to work involving dust exposure from coal extraction and preparation, however, incorrectly combines two independent elements of the definition of ''miner'': the ''function'' requirement for qualifying as a miner under the BLBA, *i.e.,* working in the extraction or preparation or transportation of coal or in coal mine construction, and the exposure requirement for a construction worker. The two are unrelated. The only plausible explanation for separately including construction workers in the statutory definition of ''miner'' is Congress' recognition of their unique functional status. Construction workers generally perform their work before a mine becomes operational. Consequently, they generally will not be involved in the extraction or preparation of coal, or exposed to dust from such activities. While rejecting this position, the Court did acknowledge the Department's authority to implement its views through regulation: ''If the Secretary has a position he wishes to express, he can do it through the proper forum, i.e., the implementation of new, clarifying regulations.'' 833 F.2d at 265. Section 725.202 represents the exercise of that authority.

In *Harrop,* the Court held that the exposure to ''coal mine dust,'' required by 20 CFR 725.202(a) for coverage of a construction worker, involves exposure to ''dust containing coal.'' 927 F.2d at 1154, citing *Pate.* It interpreted the

statutory coverage of construction workers to reach only those individuals who are exposed to actual coal dust, despite acknowledging the variety of other (non-coal) dusts which may be inhaled at a mine construction site. The Department has consistently taken the position that ''coal mine dust'' means any dust generated at a coal mine site, and that exposure to coal mine dust is sufficient to meet the statutory definition of ''miner''for construction workers. 20 CFR 725.202(a); *see generally Williamson Shaft Contracting Co.* v. *Phillips,* 794 F.2d 865, 869 (3d Cir. 1986) (upholding validity of 20 CFR 725.202(a) because Congress understood ''coal dust'' to mean ''the various dusts around a coal mine''). The interpretation of coverage reached by the Court in *Harrop* would effectively exclude most, if not all, construction workers from the definition of ''miner'' after Congress explicitly changed the definition to include them. The Department declines to adopt the more restrictive standard suggested by the Tenth Circuit and the commenter.

(d) One comment objects to the application to construction workers of the rebuttable presumption that any on-site worker is a ''miner.'' For the reasons expressed in paragraph (b), the Department believes any individual whose employment requires him or her to perform work at a coal mine can logically be presumed to be involved in a covered coal mine function. The commenter has provided no reason to exclude construction workers from that presumption, and the Department declines to do so.

(e) One comment received after publication of the initial notice of proposed rulemaking and referenced again after publication of the second notice objects to subsection (d), which describes the elements of entitlement for a miner and references the specific regulatory criteria in Part 718 for establishing those elements. The comment links its objection to criticisms of the specific Part 718 regulations rather than any aspect of subsection (d). The Department's responses to those criticisms are discussed under the particular Part 718 sections. No further response in the context of this regulation is necessary.

(f) Two comments support the revised section 725.202.

(g) No other comments concerning this section have been received, and no changes have been made in it.

20 CFR 725.203

(a)(i) The Department proposed changing § 725.203 in the initial notice of proposed rulemaking to eliminate the filing of a claim as an element of entitlement for a miner. 62 FR 3389 (Jan. 22, 1997). This change clarified that a miner is entitled to benefits for all periods of compensable disability, including any period which occurred prior to the filing of the claim. 62 FR 3349 (Jan. 22, 1997). The Department also incorporated into § 725.203 provisions from 20 CFR 718.404, which was deleted. These provisions require an entitled miner to notify the Department if (s)he returns to coal mining or comparable work, and authorize the Department to reopen a final miner's award in appropriate circumstances for the development of additional evidence and the reevaluation of entitlement. 62 FR 3349, 3389 (Jan. 22, 1997). Finally, § 725.203(b)(2) now refers to § 725.504, which is the renumbered version of § 725.503A. 62 FR 3341 (Jan. 22, 1997). The Department proposed no further changes to § 725.203 in the second notice of proposed rulemaking. 64 FR 54971 (Oct. 8, 1999). (ii) The Department has now further amended § 725.203(d), however, to restore language requiring the beneficiary to submit ''medical reports and other evidence'' if the Office determines the evidence is necessary to resolve any question concerning the validity of the award. This phrase appears in 20 CFR 718.404(b), and was inadvertently omitted in the earlier proposal to change § 725.203. The Benefits Review Board has since interpreted the phrase in § 718.404(b) to involve discovery requests. *Stiltner* v. *Westmoreland Coal Co.,* Black Lung Rep., BRB No. 98–0337, slip op. at 5 (Jan. 31, 2000) (en banc). The Department did not intend the changes to § 725.203(d) to foreclose evidentiary development other than medical examinations of the miner. The Department therefore adds the language formerly in § 718.404(b) to § 725.203(d), and clarifies its intent that the miner may be required to submit to medical examinations, produce medical evidence and answer discovery requests when the circumstances raise any issue concerning the validity of the award after the award becomes final.

(b)(i) One comment suggests the revision of subsection (a) improperly extends the eligibility period. The Department rejects this interpretation. The change merely harmonizes that provision with § 725.503, and ensures the miner's entitlement to benefits for any period of eligibility which predates the filing of a claim. *See* 62 FR 3349 (Jan. 22, 1997). (ii) Two comments approve of the change to subsection (a).

(c) Three comments oppose subsection (d) because it permits the Department to reopen an approved claim if issues arise concerning its validity. Subsection (d) simply recognizes the Department's authority to investigate any finally approved miner's claim if circumstances raise an issue pertaining to the validity of the award. Such authority is necessary in order to monitor a miner's continuing eligibility and prevent the payment of benefits to any claimant whose eligibility ceases. The Department rejects the suggestion that this authority should be limited to cases involving fraud or the miner's return to coal mining. Limiting the reopening authority under subsection (d) in this manner would be inconsistent with the Department's statutory authority to modify an award based on a factual mistake or change in condition at any time within one year after the last payment of benefits. 33 U.S.C. 922, as incorporated by 30 U.S.C. 932(a); 20 CFR 725.310. Furthermore, such a limitation would impinge on the right of responsible operator to petition for modification and request a medical examination if circumstances call into question the entitlement of the miner. The Department emphasizes that the responsible operator does not have an absolute right to compel the claimant to submit to a medical examination for purposes of the modification petition. *Selak* v. *Wyoming Pocahantas Land Company,* 21 Black Lung Rep. 1–173, 1–178 (1999); *see also Stiltner* v. *Westmoreland Coal Co.,* Black Lung Rep., BRB No. 98–0337, slip op. at 5 (Jan. 31, 2000) (en banc) (holding operator does not have absolute right to compel claimant to respond to discovery request under 20 CFR 718.404(b) in connection with modification petition). Upon production of reasonable evidence justifying the request, however, the district director (or administrative law judge) may order the claimant to submit to a medical examination. *Selak,* 21 Black Lung Rep. at 1–179.

(d) One comment urges the Department to limit its authority to reopen awards under subsection (d) to the first year after the award becomes final. Such a limitation, however, is inconsistent with the Department's statutory authority to modify. 33 U.S.C. 922, as incorporated. In the case of an award, that authority extends to ''one year after the date of the last payment of compensation.'' Furthermore, the limitation would also adversely affect the responsible operator's right to request modification if it became aware of circumstances which call into question the validity of the award. *See* response to comments (c).

(e) In response to the initial notice of proposed rulemaking, one comment opposed subsection (d) because the provision did not expressly acknowledge that a claim may be reopened if the miner's condition improved. The Department previously rejected a similar suggestion when it promulgated the final version of 20 CFR 718.404 in 1980. The Department initially proposed § 718.404 with a requirement that an entitled individual contact the Office of Workers' Compensation Programs if ''[h]is or her respiratory or pulmonary condition improves[.]'' 43 FR 17727 (Apr. 25, 1978). The requirement was deleted in the final version ''in response to comments and testimony stating that pneumoconiosis does not, in fact, improve.'' 45 FR 13694 (Feb. 29, 1980). The same commenter submitted an additional response to the second notice of proposed rulemaking, and now approves of subsection (d) because it does not preclude the right of a liable party to challenge a final award at a later date. The Department therefore declines to incorporate any language affirmatively citing improvement in a miner's health as grounds for reopening an award.

(f) No other comments were received concerning this section, and no changes have been made in it.

20 CFR 725.204

(a) The Department proposed amending § 725.204 in the initial notice of proposed rulemaking to conform the regulatory criteria for marital relationships to intervening changes in the law since the regulation was issued in 1978. 62 FR 3349–50 (Jan. 22, 1997). The Department provided a detailed statutory analysis in the initial notice. To summarize: the Black Lung Benefits Act (BLBA) incorporates the definition of a dependent ''wife'' used by the Social Security Act (SSA), 42 U.S.C. 416(h)(1), as incorporated by 30 U.S.C. 902(a)(2), (e). The SSA recognizes both ''legal'' and ''deemed'' spouses; the latter is an individual who married the wage earner while ignorant that some legal impediment existed to deny validity to the marriage. Before 1990, § 416(h) contained a provision preventing a ''deemed spouse'' from receiving benefits if a ''legal'' spouse existed and was receiving benefits on the wage earner's account. 42 U.S.C. 416(h)(1)(B). The Department included this limitation in the dependency criteria when it promulgated § 725.204. 20 CFR 725.204(d)(1). In 1990, Congress amended the SSA to remove the prohibition on ''deemed spouse'' entitlement if a legal spouse existed and was receiving benefits. 104 Stat. 1388–278 to 1388–280 (1990). Legislative history clearly established Congressional intent to permit both the ''deemed'' spouse and the legal spouse to receive concurrent benefits. *See* H.R. Rep. No. 101–964, 1990 U.S.C.C. & A.N. 2649, 2650 (conference report). Accordingly, the Department proposed similar changes to § 725.204 to delete the regulatory bar to ''deemed'' spouse entitlement under the BLBA. The Department proposed no additional changes to this regulation in its second notice of proposed rulemaking. 64 FR 54971 (Oct. 8, 1999).

(b) Two comments approve of the change to this section acknowledging the eligibility of a spouse to receive benefits despite the existence of a legal impediment to the validity of the marriage to the miner unless the individual entered into the marriage with knowledge it was not valid.

(c) No other comments concerning this section were received, and no changes have been made in it.

20 CFR 725.209

(a) In the initial notice of proposed rulemaking, the Department erroneously proposed changing § 725.209(a)(2)(ii) to state that, in order to be considered a dependent, a child who is at least 18 and not a student must be under a disability that commenced before the age of 22. 62 FR 3390 (Jan. 22, 1997). The purpose of the change was to reflect in the regulation itself the age by which certain children's disabilities must commence, a requirement imposed by an incorporated provision of the Social Security Act. 42 U.S.C. 402(d)(1)(B)(ii), as incorporated into the BLBA by 30 U.S.C. 902(g). 62 FR 3350 (Jan. 22, 1997). After further consideration, however, the Department reproposed the regulation without the new language. 64 FR 55026 (Oct. 8, 1999). Eliminating the age by which the disability must have begun for a dependent child harmonizes § 725.209 with the statutory definition by preserving the distinction between a child/augmentee and a child/beneficiary (*see* § 725.221). A child who claims benefits in his or her own right based on personal disability (child/beneficiary) must prove the disability arose before age 22 as required by 30 U.S.C. 902(g). 30 U.S.C. 922(a)(3). A dependent child who is an augmentee of a beneficiary, however, is exempt from this requirement because the statutory definition of ''dependent'' explicitly exempts a ''child'' from the requirement that disability begin by a certain age. 30 U.S.C. 902(a)(1). *See generally* 64 FR 54983 (Oct. 8, 1999).

(b) Reference should be made to the Department's response to comments concerning § 725.219 to determine the effect of marriage on a child's dependency status under § 725.209(a)(1).

(c) No comments concerning changes to this section were received in response to either the initial notice of proposed rulemaking or the second notice of proposed rulemaking, and no further changes have been made in it.

20 CFR 725.212

(a) In the initial notice of proposed rulemaking, the Department proposed amending § 725.212 to codify the right of each surviving spouse of a deceased miner to receive a full monthly benefit without regard to the existence of any other entitled surviving spouse. 62 FR 3390 (Jan. 22, 1997). The Department concluded that both statutory analysis and Congress' intent compelled this result, and explained at length the reasoning behind the conclusion. 62 FR 3350–51 (Jan. 22, 1997). *See also* § 725.537, and response to comments. The Department proposed no further changes to this regulation in its second notice of proposed rulemaking. 64 FR 54971 (Oct. 8, 1999).

(b) Five comments object to subsection (b) because it permits each surviving spouse of a deceased miner to receive full monthly benefits if (s)he establishes eligibility regardless of the existence of any other entitled surviving spouse. The commenters assert that the change will increase the cost of paying survivors' benefits. Increased costs alone do not justify denying eligible individuals the benefits to which they are entitled by law.

(c) Two comments argue the change is not permitted by the relevant statutes; one comment disputes the Department's conclusion that its earlier procedure was adopted in error, citing undocumented representations by the Social Security Administration (SSA) to the Department in 1978. In the initial notice of proposed rulemaking, the Department provided a detailed legal analysis of the pertinent statutory authorities and legislative history, all of which support awarding full monthly benefits to more than one surviving spouse. *See* 62 FR 3350–51 (Jan. 22, 1997). Congress amended the Social Security Act in 1965 to allow benefits to a divorced surviving spouse as a ''widow'' of the miner. Pub. L. No. 89–97, § 308(b)(1), 79 Stat. 286 (1965). The legislative history of the amendment clearly established Congress' intent that payment of benefits to two (or more) ''widows'' would not reduce the benefits paid to either of the widows. S.

Rep. No. 404, 89th Cong., 1st Sess. (1965), *reprinted in* 1965 U.S.C.C. & A.N. 1943, 2047. In 1972, Congress amended the BLBA definition of ''widow'' to adopt the Social Security Act definition. 30 U.S.C. 902(e). The legislative history is equally clear that Congress intended to conform the BLBA definition to the Social Security Act definition. S. Rep. No. 743, 92nd Cong., 2d. Sess., *reprinted in* 1972 U.S.C.C. & A.N. 2305, 2332. The BLBA also reinforces this interpretation because it requires a ''widow'' to receive benefits at prescribed rates and makes no allowance for a reduction based on the existence of more than one widow. 30 U.S.C. 922(a)(2). To date, two courts of appeals and the Benefits Review Board have accepted the Department's position. *Peabody Coal Co.* v. *Director, OWCP [Ricker],* 182 F.3d 637, 642 (8th Cir. 1999); *Mays et al.* v. *Piney Mountain Coal Co.,* 21 Black Lung Rep. 1–59, 1–65/1–66 (1997), *aff'd* 176 F.3d 753, 764–765 (4th Cir. 1999). No court has reached a contrary result, and no comment has addressed the substance of this analysis. Consequently, the Department has no basis for changing the regulation. Finally, the Department cannot respond to the alleged communication between SSA and the Department because the comment provides no detailed evidence as to the nature or content of the communication. In any event, an undocumented assertion concerning another agency's intention cannot form the basis for displacing a proper interpretation of the pertinent statutes, especially when courts have unanimously upheld that interpretation.

(d) One comment states that the SSA regulations implementing part B of the BLBA do not permit more than one surviving spouse to receive full benefits. SSA's program regulations (20 CFR part 410) are silent on the entitlement of multiple surviving spouses. In any event, the Department has independent authority to issue regulations for part C of the BLBA, 30 U.S.C. 936(a), and § 725.212 is consistent with the applicable provisions of the BLBA and the SSA as incorporated.

(e) One comment states that the current Coal Mine (BLBA) Procedure Manual is consistent with the position that full monthly benefits cannot be paid to each surviving spouse when more than one spouse qualifies for one deceased miner. This statement is simply erroneous. Since at least 1994, the Procedure Manual has unequivocally provided that ''[w]hen a surviving spouse and a surviving divorced spouse both qualify as primary beneficiaries, each is entitled to full basic benefits plus full augmentation.'' Coal Mine (BLBA) Procedure Manual, ch. 2–900, ¶ 8.f (Sept. 1994).

(f) One comment contends the Department lacks the authority to require an operator to pay the same benefit twice. The Department rejects this contention. As discussed above, the BLBA unequivocally requires the payment of full monthly benefits to each surviving spouse who fulfills the eligibility criteria. The statute does not recognize any limitation on the liability for these benefits, or any reduction in the amount to which the eligible surviving spouse is entitled.

(g) Two comments support the change in subsection (b).

(h) No other comments were received concerning this section, and no changes have been made in it.

20 CFR 725.213

(a) The Department proposed amending § 725.213 in the initial notice of proposed rulemaking to harmonize that regulation with changes to § 725.204, which now recognizes the independent eligibility of a ''deemed'' spouse to receive benefits notwithstanding the existence of a legal spouse who is also receiving benefits. 62 FR 3351 (Jan. 22, 1997) The Department also proposed adding paragraph (c) to codify the right of a surviving beneficiary, who loses eligibility through some legal impediment, to resume eligibility upon the cessation of that impediment. The Department did not propose any further changes to the regulation in its second notice of proposed rulemaking. 64 FR 54971 (Oct. 8, 1999).

(b) Two comments object to reentitlement for a surviving spouse who loses eligibility, but later reestablishes all the requirements. The commenter states in general terms that the provision is contrary to the Social Security Act (SSA), represents an unwarranted increase in benefits liability, and should be abandoned. The commenter cites no specific authority for its argument. The legislative history of 30 U.S.C. 902(e), the statutory definition of ''widow'' which § 725.213 implements, establishes congressional intent to afford a miner's widow the same right to resumption of black lung benefits upon termination of a remarriage as exists for a widow receiving SSA benefits.

The Black Lung Benefits Act (BLBA), as enacted in 1969, defined ''widow'' to mean

> the wife living with or dependent for support on the decedent at the time of his death, or living apart for reasonable cause or because of his desertion, *who has not remarried.*

Pub. L. 91–173, § 402(e), 83 Stat. 793 (1969) (emphasis supplied). The emphasized language excluded from coverage any miner's survivor who later remarried, without regard to the subsequent termination of the marriage. In 1972, Congress amended the definition of 'widow' by enacting the current version. In pertinent part, the phrase ''who is not married'' replaced ''who has not remarried.'' The Senate report accompanying the proposed amendments states that ''[t]he term 'widow' in § 402(e) is likewise redefined to conform to the Social Security Act definition.'' S. Rep. No. 743, 92nd Cong., 2d. Sess. 30, *reprinted in* 2 Comm. On Labor and Pub. Welfare, 94th Cong., 1st Sess., *Legislative History of the Federal Coal Mine Health and Safety Act of 1969,* at 1974 (1975). The legislative history therefore unequivocally establishes congressional intent to define ''widow'' for purposes of the Black Lung Benefits Act and SSA in the same manner.

At the time of the 1972 amendments to the BLBA, the SSA defined a ''widow'' as an individual who ''is not married.'' 42 U.S.C. 403(e)(1)(A). Congress had previously amended the SSA definition in 1965 by replacing the phrase ''has not remarried'' with ''is not married.'' Pub. L. 89–97, § 308(b)(1), 79 Stat. 286, 376 (1965). The legislative history of the amendment indicates that Congress intended an aged divorced wife, widow or surviving divorced wife, who was not married at the age of eligibility, to retain ''whatever rights to benefits she has ever had, regardless of intervening marriages, which have ended in death, divorce or annulment.'' S. Rep. No. 404, 89th Cong., 1st Sess., *reprinted in* 1965 U.S.C.C. & A.N. 1943, 2048. The legislative history therefore underscores the congressional intention to permit restoration of SSA eligibility to a widow whose intervening marriage has terminated. The Social Security Administration regulations implementing Part B of the BLBA confirm this view:

> An individual is entitled to benefits as a widow, or as a surviving divorced wife, for each month beginning with the first month in which all of the conditions of entitlement * * * are satisfied. If such individual remarries, payment of benefits ends with the month before the month of remarriage * * *. Should the remarriage subsequently end, payment of benefits may be resumed * * *.

20 CFR 410.211(a). The Sixth Circuit and the Benefits Review Board have also adopted the Department's position, and no circuit has taken a contrary view. *Wolf Creek Collieries* v. *Robinson,* 872 F.2d 1264, 1266 (6th Cir. 1989); *Luchino* v. *Director, OWCP,* 8 Black Lung Rep. 1–

453, 1–456 (1986). The commenter's objection must be rejected.

In promulgating § 725.213, the Department recognizes that permitting reentitlement of surviving spouses and children (§ 725.219) treats these classes of beneficiaries more generously than surviving brothers and sisters of the deceased miner (§ 725.223). One comment notes it is appropriate to end benefit entitlement permanently when a brother or sister marries, and implies the same treatment should be accorded all other classes of beneficiaries and augmentees, including surviving spouses and children. The Department believes the difference in treatment is required by the BLBA. Section 412(a)(5) states that ''[n]o benefits to a sister or brother shall be payable under this paragraph for any month beginning with the month in which he or she * * * marries.'' 30 U.S.C. 922(a)(5). This provision terminates eligibility if a miner's brother or sister who is receiving benefits marries. Unlike the statutory definitions of ''widow'' and ''child,'' 30 U.S.C. 902(e), (g), section 412(a)(5) focuses on the occurrence of an event when ineligibility commences rather than the individual's status. The widow's or child's marriage status can change over time; once the event of marriage occurs for a brother or sister, ''no benefits shall be payable.'' The regulations therefore exclude brothers and sisters from reentitlement once they marry.

(c) One comment states that reentitling a surviving spouse after the termination of his or her intervening marriage is contrary to the SSA regulations implementing part B of the BLBA. The comment is incorrect. Section 410.211(a) provides that payment of benefits terminates if a surviving spouse or divorced wife remarries while receiving benefits; however, ''[s]hould the remarriage subsequently end, payment of benefits may be resumed * * * .'' 20 CFR 410.211(a). Sections 725.213 and 410.211 are therefore entirely consistent.

(d) Two comments support the new subsection (c).

(e) No other comments concerning this section were received, and no changes have been made in it.

20 CFR 725.214

(a) The Department proposed amending § 725.214 in the initial notice of proposed rulemaking to conform the regulatory criteria for marital relationships to intervening changes in the law since the regulation was issued in 1978. 62 FR 3349–50 (Jan. 22, 1997). Specifically, the Department intended this regulation (as well as § 725.204) to reflect statutory changes which now permit the surviving spouse of a miner, whose marriage is invalid due to a legal impediment, to receive benefits notwithstanding the existence of a legally-married spouse who also is receiving benefits. Consequently, the Department proposed eliminating language in 20 CFR 725.214(d) which required the termination of benefits for the surviving spouse whose marriage is invalid upon the entitlement of the legal spouse. The Department proposed no additional changes to this regulation in the second notice of proposed rulemaking. 64 FR 54971 (Oct. 8, 1999). For purposes of this rule, the Department has corrected one typographical error and made minor grammatical changes. The first and second notices of proposed rulemaking used the word ''interstate'' in § 725.214(c) to describe a miner's personal property. 62 FR 3391 (Jan. 22, 1997); 64 FR 55027 (Oct. 8, 1999). The correct word is ''intestate,'' and that word has been substituted in the regulation. In § 725.214(d), the Department has deleted the word ''and'' which immediately followed the phrase ''in a purported marriage between them,'' and added commas, as appropriate, to clarify the meaning of the provision.

(b) One comment objects to permitting a surviving spouse, whose marriage to the deceased miner may be invalid due to certain legal impediments, to maintain eligibility despite another person's eligibility as the miner's surviving spouse. The commenter states generally that the provision is contrary to the Social Security Act (SSA) and imposes an unwarranted increase in benefits liability. Neither objection demonstrates any basis for abandoning the revision. The Department proposed the same change in connection with § 725.204, and provided a detailed legal analysis of the reasons supporting the revision in its initial notice of proposed rulemaking. *See* 62 FR 3349–50 (Jan. 22, 1997). The Black Lung Benefits Act (BLBA) incorporates the definition of a dependent ''wife'' used by the SSA, 42 U.S.C. 416(h)(1), as incorporated by 30 U.S.C. 902(a)(2), (e). The SSA recognizes both ''legal'' and ''deemed'' spouses as potentially eligible for benefits on a single wage earner's record. The ''deemed'' spouse is an individual who married the wage earner while unaware that some legal impediment existed to the marriage. Before 1990, § 416(h) prohibited a ''deemed spouse'' from receiving benefits if a ''legal'' spouse existed and was receiving benefits on the wage earner's account. 42 U.S.C. 416(h)(1)(B). The Department imposed a similar limitation in the dependency criteria when it promulgated 20 CFR 725.204(d)(1). In 1990, Congress amended the SSA to remove the prohibition on ''deemed spouse'' entitlement if a legal spouse existed and was receiving benefits. 104 Stat. 1388–278 to 1388–280 (1990). Legislative history clearly established Congressional intent to permit both the ''deemed'' spouse and the legal spouse to receive concurrent benefits. *See* H.R. Rep. No. 101–964, 1990 U.S.C.C. & A.N. 2649, 2650 (conference report). Accordingly, the Department proposed similar changes to § 725.214 to delete the regulatory bar to ''deemed'' spouse entitlement under the BLBA. The comment does not respond to this analysis with any specific reasoning demonstrating the alleged inconsistency with the SSA or refuting the Department's authority to implement this change. Finally, increased benefits liability alone is not a legitimate basis for denying benefits to eligible claimants under the BLBA.

(c) No other comments concerning this section were received, and no other changes have been made in it.

20 CFR 725.215

(a) In the initial notice of proposed rulemaking, the Department proposed clarifying the intended operation of § 725.215(g)(3) by changing a reference in that regulation from ''section'' to ''paragraph.'' 62 FR 3391 (Jan. 22, 1997). The change ensures that the exception to the nine-month marriage rule is confined to subsection (g) rather than applicable to the entire regulation. 62 FR 3351 (Jan. 22, 1997). The Department proposed no additional changes to this regulation in the second notice of proposed rulemaking. 64 FR 54971 (Oct. 8, 1999).

(b) No comments concerning this section were received, and no changes have been made in it.

20 CFR 725.219

(a) In the initial notice of proposed rulemaking, the Department proposed changing § 725.219 to account for a change in the age of onset of disability in the Social Security Act (SSA), 42 U.S.C. 402(d)(1)(B), which is incorporated into the Black Lung Benefits Act's (BLBA) definition of ''child,'' 30 U.S.C. 902(g). 62 FR 3350 (Jan. 22, 1997). The Department did not propose any additional changes in the second notice of proposed rulemaking. 64 FR 54971 (Oct. 8, 1999). The Department, however, did assert in general terms that marriage is a

permanent bar to future entitlement for any individual other than a miner's surviving spouse or surviving divorced spouse. 64 FR 54983–84 (Oct. 8, 1999). Based on this position, the Department withdrew a proposed change to § 725.223 which extended reentitlement to a miner's surviving dependent brother or sister if the sibling married while receiving benefits, but the marriage later ended.

(b) Two comments recommend adopting a provision (analogous to § 725.213(c)) which would allow a deceased miner's surviving disabled child, whose entitlement terminates upon marriage, to regain eligibility when that marriage ends. Formerly, the regulations permitted a child whose entitlement terminated at age 18 to apply for reinstatement if the child was a student, younger than age 23, and was not married. 20 CFR 725.219(c). The regulations did not make any provision for reentitling a disabled child whose entitlement is terminated by marriage. The Department agrees with the comments that such a provision is appropriate, and therefore has added subsection (d). This provision enables a child whose entitlement terminates upon marriage to apply for reinstatement of benefits once the marriage terminates. Subsection (d) also excuses the child-beneficiary from any requirement to reestablish the deceased miner's total disability or death due to pneumoconiosis.

The BLBA provides that survivor's benefits ''shall only be paid to a child for so long as he meets the criteria for the term 'child' contained in section 402(g).'' 30 U.S.C. 922(a)(3). Section 402(g) defines ''child'' to mean a:

child or a stepchild who is—

(1) unmarried; and

(2)(A) under eighteen years of age, or

(B)(i) under a disability as defined in section 423(d) of title 42

(ii) which began before the age specified in section 402(d)(1)(B)(ii) of title 42, or, in the case of a student, before he ceased to be a student; or

(C) a student.

30 U.S.C. 902(g). The literal language of the statute does not preclude a child's eligibility for all time based upon the existence of a marriage. Rather, the two statutory provisions authorize the payment of benefits to an eligible child survivor ''for so long as'' (s)he ''is unmarried.'' If a marriage terminates prior to any period of eligibility, the child is nevertheless unmarried when (s)he becomes entitled to benefits. *See Adler* v. *Peabody Coal Co.,* Black Lung Rep., BRB No. 98–1513 BLA (Feb. 4, 2000). If the child marries while receiving benefits, (s)he cannot continue as an eligible survivor for the duration of the marriage. *Sullenberger* v. *Director, OWCP,* Black Lung Rep., BRB No. 99–0449 BLA (March 8, 2000) Upon cessation of the marital relationship, however, the child again ''is unmarried,'' which complies with the statutory requirement. Assuming all other conditions for eligibility are met, an ''unmarried'' child retains his or her status as a ''child'' under the plain language of the statute notwithstanding the occurrence of the marriage. In this regard, the Department disagrees with the broad statement in *Reigh* v. *Director, OWCP,* 20 Black Lung Rep. 1–44 (1996), that a surviving child of a miner cannot revive her status as the unmarried dependent of her parents upon the death of her husband. 20 Black Lung Rep. at 1–48.

The Department's interpretation of the plain language of § 402(g) gains support from Congress' decision to omit certain provisions of 42 U.S.C. 402(d) (the Social Security Act) from the BLBA. Significantly, Congress did not incorporate § 402(d)(6), which permits a child to become reentitled to benefits after turning 18 if the child is a student under age 22 or disabled, ''provided no event specified in paragraph (1)(D) has occurred.'' 42 U.S.C. 402(d)(6). Section 402(d)(1)(D) states that a child's benefits terminate ''the month preceding * * * the month in which such child dies or marries[.]'' In *McMahon* v. *Califano,* 605 F.2d 49 (2d Cir. 1979), *cert. den.* 444 U.S. 847 the Court held that ''the only reasonable interpretation of [§ 402(d)(6) and (d)(1)(D)] is that any marriage occurring subsequent to a child's initial entitlement to benefits terminates those benefits and prevents re-entitlement in the future.'' 605 F.2d at 53; *see also Downs* v. *D.C. Police & Firefighters Retirement and Relief Bd.,* 666 A.2d 860 (D.C.C.A. 1995) (holding disabled child's annuity permanently terminated when child married and later divorced). Otherwise, the Court concluded, the proviso language of § 402(d)(6) would be superfluous because no other interpretation would afford it any meaning. Congress therefore has implemented a policy determination that a disabled child receiving SSA benefits should become permanently ineligible if the child marries, regardless of the subsequent termination of the marriage. By omitting the incorporation of these provisions into the BLBA definition of ''child,'' however, the Department concludes that Congress did not intend to adopt the same policy for the BLBA.

The legislative history of the definition of ''child'' does not support a contrary interpretation. The BLBA originally defined ''dependent'' to mean a dependent wife or child within the meaning of 5 U.S.C. 8110; ''wife'' and ''child'' were not defined separately. 30 U.S.C. 902(a) (1969). Section 8110 defined a dependent child as an ''unmarried child'' living with, or receiving regular contributions from, the employee if the child is under 18 years of age; over that age but incapable of self-support because of a physical or mental impairment; or a student. 5 U.S.C. 8110(a)(3). In 1972, Congress amended the BLBA to include a new definition of ''dependent'' and separate definitions of ''child'' and ''widow.'' 30 U.S.C. 902(a), (g), (e) (1972). The legislative history of the 1972 amendments simply states that the statutory definition of ''child'' conformed to the SSA definition. S. Rep. No. 743, 92nd Cong., 2nd Sess. (1972), *reprinted in* Senate Subcommittee on Labor, Committee on Labor and Public Welfare, 94th Cong., 1st Sess., *History of the Federal Coal Mine Health and Safety Act of 1969,* as amended through 1974, Part 2—Appendix at 1946, 1974 (1975). That conformance extended only to the specific adoption of SSA eligibility criteria for age, disability, and student requirements, but did not include provisions such as the permanent ban on reentitlement for a child who marries in § 402(d)(6). Consequently, the Department is free to depart from the SSA eligibility scheme contained in § 402(d)(6) by permitting reentitlement.

The effect of marriage on a claimant's eligibility has also arisen in connection with a miner's surviving spouse. 30 U.S.C. 902(e). Since the 1972 amendments, the statutory definition of ''widow'' has limited eligibility to a miner's surviving spouse or surviving divorced spouse ''who is not married.'' Legislative history linking the 1972 amendment of 30 U.S.C. 902(e) to changes in the parallel SSA definition clearly establish Congress' intention to permit reentitlement for a widow who remarried after the beneficiary's death and later became unmarried. *See generally Wolf Creek Collieries* v. *Robinson,* 872 F.2d 1264, 1266 (6th Cir. 1989); *Luchino* v. *Director,* OWCP, 8 Black Lung Rep. 1–453, 1–456 (1986). The statutory definitions of ''widow'' and ''child'' are alike in that both require the individual to be unmarried as a condition of eligibility. The legislative history of the Black Lung Benefits Act's 1972 amendments strongly supports limiting the effect of an intervening marriage on a surviving spouse's eligibility, and does not contradict affording the same treatment

to a child. In the absence of such contradictory evidence of Congress' intentions, both statutory definitions should be construed alike given the similarities in their language. Accordingly, a presently unmarried child of a miner is eligible for benefits notwithstanding any prior marriage. The marriage merely suspends the child's eligibility for benefits for the duration of the marriage if the child marries during a period of entitlement. Eligibility then resumes upon termination of the marriage, assuming all other conditions of eligibility can be satisfied. If the child's marriage terminates prior to any period of entitlement, the marriage has no effect upon the child's eligibility.

(c) No other comments concerning this section were received, and no other changes have been made in it.

20 CFR 725.221

(a) The Department proposed changing the date of onset of disability in § 725.221 from 18 to 22 years of age to conform the regulation to the same change in 42 U.S.C. 423(d). 62 FR 3350, 3392 (Jan. 22, 1997). The Department proposed no additional changes in the second notice of proposed rulemaking. 64 FR 54791 (Oct. 8, 1999).

(b) One comment supported the change in the age by which disability must commence.

(c) No other comments were received concerning this section, and no changes have been made in it.

20 CFR 725.222

(a) The Department proposed changing the date of onset of disability in § 725.222 from 18 to 22 years of age to conform the regulation to the same change in 42 U.S.C. 423(d). 62 FR 3350, 3392 (Jan. 22, 1997). The Department proposed no additional changes in the second notice of proposed rulemaking. 64 FR 54791 (Oct. 8, 1999).

(b) One comment recommends that subsection (b) allow a deceased miner's parent, brother or sister to claim benefits unless the miner's surviving spouse or child has established entitlement. The Department rejects this change because it is inconsistent with the Black Lung Benefits Act. Section 412 of the Act provides guidelines for the payment of benefits to eligible beneficiaries. 30 U.S.C. 922. Section 412(a)(5) states, in pertinent part, that a dependent parent of a deceased miner ''who is not survived at the time of [the miner's] death by a widow or a child'' is eligible for benefits. 30 U.S.C. 922(a)(5). The same provision also states that a dependent surviving sibling of the deceased miner ''who is not survived at the time of [the miner's] death by a widow, child, or parent'' is eligible for benefits. The current language in 20 CFR 725.222(b) follows the statutory language, and no change in that subsection is appropriate. The statutory provisions are unequivocal: the existence of a surviving spouse or child is sufficient to preclude entitlement for other survivors even if the spouse or child is not receiving benefits.

This interpretation is further supported by another provision of section 412. Paragraph (a)(3) states that ''no entitlement to benefits as a child shall be established under this paragraph (3) for any month for which entitlement to benefits as a widow is established under paragraph (2).'' 30 U.S.C. 922(a)(3). Under this provision, a child may receive benefits even if a surviving spouse exists unless (or until) the spouse establishes his or her own entitlement and supersedes the child as the primary beneficiary. By using different eligibility criteria within the same statutory provision, Congress drew a clear distinction between the circumstances in which the existence of an eligible surviving spouse could preclude any potential beneficiary with lesser standing from obtaining benefits. The child may therefore constitute a primary beneficiary until such time as the spouse asserts (and proves) his or her own entitlement; at that time, the spouse replaces the child as the beneficiary. The mere existence of a surviving spouse or child, however, does preclude an otherwise eligible parent or sibling from claiming benefits. The commenter's recommended change would violate the distinction between classes of eligible beneficiaries which Congress has drawn. The recommendation must be rejected.

(c) One comment supported the change in age, from 18 to 22, by which disability must commence.

(d) No other comments concerning this section were received, and no changes have been made in it.

20 CFR 725.223

(a) In the initial notice of proposed rulemaking, the Department proposed revising § 725.223 to adopt the change in age limits for disability specified by 42 U.S.C. 402(d)(1)(B), as incorporated by the Black Lung Benefits Act (BLBA), 30 U.S.C. 922(a)(5). 62 FR 3351, 3393 (Jan. 22, 1997). The Department also proposed adding subsection (d) to permit reentitlement for a miner's dependent brother or sister whose eligibility had terminated upon marriage, provided the marriage ended and the individual again fulfilled all the eligibility criteria. The Department thereafter reconsidered this proposal, and suggested its removal in the second notice of proposed rulemaking. 64 FR 55029 (Oct. 8, 1999). The Department concluded that the proposed subsection (d) contradicted longstanding agency policy, which permitted reentitlement upon cessation of marriage only in the case of a surviving spouse. Because the Department stated it considered a miner's children permanently barred from reentitlement upon the cessation of marriage, it declined to afford preferential treatment to the miner's siblings. In the case of a married sibling who becomes the miner's dependent, the Department concluded that eligibility should not be precluded by the existence of the marriage if the sibling's spouse provided no support. Once a married sibling received support or an unmarried dependent married, however, the Department relied on the assumption that the married sibling would receive support from the spouse and a sibling whose marriage terminated would rely on savings or property from the marriage, etc. 64 FR 54983–84 (Oct. 8, 1999).

(b) The Department has changed its position that reentitlement for beneficiaries after resumption of unmarried status must be confined to surviving spouses and surviving divorced spouses. *See* § 725.219(d) above, with respect to children. Although the Department recognizes reentitlement for children as well as spouses, the Department has not changed its views about the effect of marriage as a permanent bar to reentitlement for a miner's brother or sister. The BLBA supports this policy. Section 412(a)(5) states that ''[n]o benefits to a sister or brother shall be payable under this paragraph for any month beginning with the month in which he or she * * * marries.'' 30 U.S.C. 922(a)(5). This provision is unequivocal. Once a brother or sister who is receiving benefits marries, eligibility terminates. That the termination is permanent may be inferred from the phrasing of the provision: upon marriage, no benefits are payable to the sibling ''for *any* month'' starting with the month of the marriage. Section 412(a)(5) does not include any qualifying language which would suggest that benefits are not payable simply for the duration of the marriage. Rather, it identifies a point when ineligibility commences, with no provision for restoring eligibility. In this regard, section 412(a)(5) differs from the statutory definitions of ''widow'' and ''child,'' 30 U.S.C. 902(e), (g). Section 412(a)(5) links the occurrence of an event to the termination of eligibility

while the ''widow'' and ''child'' definitions focus on the individual's status. The widow's or child's marriage status can change; consequently these individuals can move in or out of eligibility. Once a brother or sister marries, ''no benefits shall be payable * * *.'' The BLBA therefore requires that a miner's brothers and sisters be excluded from reentitlement upon the dissolution of marriage.

(c) One comment endorses the withdrawal of proposed subsection (d), and a return to current practice with respect to the marriage of a miner's brothers and sisters.

(d) No other comments concerning this section were received, and no changes have been made in it.

Subpart C

20 CFR 725.306

(a) In its first notice of proposed rulemaking, the Department proposed revising § 725.306(a)(3) by cross-referencing § 725.522 so that an unrelated revision of the term ''benefits'' in section 725.101(a)(6) would not adversely affect a claimant's ability to withdraw his claim for benefits. The Department specifically noted its intention not to require reimbursement of the amount spent on the claimant's complete pulmonary evaluation as a condition for withdrawal of a claim, notwithstanding its proposal to include the complete pulmonary evaluation within the definition of ''benefits.'' 62 FR 3351 (Jan. 22, 1997). The Department did not discuss section 725.306 in its second notice of proposed rulemaking. *See* list of changes in the Department's second proposal, 64 FR 54971 (Oct. 8, 1999).

(b) Several comments opposed the revised definition of ''benefits,'' § 725.101(a)(6), because it includes the cost of the miner's complete pulmonary examination for which the Department is liable in the absence of a final award of benefits. The commenters believe the revised definition will impose liability on the miner under § 725.306 for repayment of the cost of the examination if he should decide to withdraw his claim. For the reasons stated in the Department's initial notice of proposed rulemaking, 62 FR 3351 (Jan. 22, 1997), and in response to comments received in connection with § 725.101(a)(6), 64 FR 54982 (Oct. 8, 1999), the Department has not made reimbursement of the examination ''benefit'' a price for withdrawing a claim. No other comments were received concerning this section, and no changes have been made in it.

20 CFR 725.308

Although the Department received comments relevant to this section, the regulation was not open for comment, *see* 62 Fed. Reg. 3341 (Jan. 22, 1997); 64 Fed. Reg. 54971 (Oct. 8, 1999). It was repromulgated only for the convenience of readers. Accordingly, no changes are being made in this section.

20 CFR 725.309

(a) In its first notice of proposed rulemaking, the Department proposed revising § 725.309 to clarify the rule governing subsequent claims. 62 FR 3351 (Jan. 22, 1997). A subsequent claim is an application filed by the same individual after final denial of a prior claim. The Department observed that a majority of the federal appellate courts that had considered the issue had deferred to the Department's interpretation of the former regulation governing such claims. That regulation required a claimant to establish that he had suffered a material change in condition since the denial of his earlier claim in order to escape the denial of the later claim on the grounds of the prior denial. 20 CFR 725.309 (1999). The Department's interpretation of that rule allowed miners to establish the necessary material change in condition by introducing new evidence that demonstrated a change in one of the necessary elements of entitlement, such as the existence of pneumoconiosis. The Department proposed to codify its interpretation by creating a rebuttable presumption that the miner's condition had changed if new evidence established one of the elements of entitlement previously resolved against the miner. An operator could rebut the presumption by establishing that the earlier denial was erroneous, *i.e.*, that the new evidence submitted by the claimant did not demonstrate a change in his condition but simply that the earlier determination was mistaken. If the presumption was not rebutted, the factfinder would weigh all of the evidence on the remaining elements of entitlement to determine whether the claimant was entitled to benefits. The original proposal also provided that the remaining issues of entitlement were subject to *de novo* adjudication unless the parties had stipulated to, or waived their right to contest, those issues in the earlier proceeding. Thus, once the claimant established a change in his condition, no parties to the claim were entitled to rely on findings made in connection with the denial of the prior claim.

The Department substantially revised its proposal in its second notice of proposed rulemaking. 64 FR 54984–85 (Oct. 8, 1999). The Department deleted the rebuttable presumption and substituted a threshold test which allowed the miner to litigate his entitlement to benefits without regard to any previous findings by producing new evidence that established any of the elements of entitlement previously resolved against him. The Department explained that this test effectuated the Fourth Circuit's decision in *Lisa Lee Mines* v. *Director, OWCP,* 86 F.3d 1358 (4th Cir. 1996), *cert. denied,* 117 S. Ct. 763 (1997), by accepting the correctness of the earlier denial of benefits. In addition, in response to several comments, the Department restored a provision requiring the denial of an additional survivor's claim, but limited the circumstances in which such a denial was appropriate. The Department proposed the automatic denial of an additional survivor's claim in cases in which the denial of the previous claim was based solely on a finding or findings that were not subject to change. For example, if the earlier claim was denied solely because the miner did not die due to pneumoconiosis, the regulation would require the denial of any additional claim as well. The Department responded to other comments, rejecting the suggestion that the revised regulation was inconsistent with § 22 of the Longshore and Harbor Workers' Compensation Act, 33 U.S.C. 922, as incorporated by 30 U.S.C. 932(a), and § 413(d) of the Black Lung Benefits Act, 30 U.S.C. 923(d). Finally, the Department discussed why findings favorable to the claimant that were made in the previous denial of benefits should not be given preclusive effect, and clarified the date from which benefits were payable in the event an additional claim was awarded.

(b) Two comments object to the Department's rule allowing subsequent claims on the basis that the record lacks adequate justification of the latency and progressivity of pneumoconiosis. In its first notice of proposed rulemaking, the Department proposed revising the definition of the term ''pneumoconiosis'' in § 718.201 to, among other things, explicitly recognize that it referred to a progressive disease. 62 FR 3343–44 (Jan. 22, 1997). Several commenters argued that the Department's proposed definition was scientifically unsound, and presented testimony from a panel of physicians with expertise in pulmonary medicine at the Department's July 22, 1997 hearing in Washington, D.C. The Department also received comments and testimony in support of its proposal.