Resolution Trust Corporation.

William J. Tricarico,

Assistant Secretary.

[FR Doc. 93–24608 Filed 10–6–93; 8:45 am]

BILLING CODE 6714–01–M

SECURITIES AND EXCHANGE COMMISSION

Self-Regulatory Organizations; Applications for Unlisted Trading Privileges; Notice and Opportunity for Hearing; Chicago Stock Exchange, Inc.

October 1, 1993.

The above named national securities exchange has filed applications with the Securities and Exchange Commission ("Commission") pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f–1 thereunder for unlisted trading privileges in the following securities:

Northern Technologies International Corp.
Common Stock, $.02 Par Value (File No. 7–11326)
Intercapital California Quality Municipal Securities
Common Stock, $.01 Par Value (File No. 7–11327)
Intercapital New York Quality Municipal Securities
Common Stock, $.01 Par Value (File No. 7–11328)
PanAmerican Beverages, Inc.
Class A Common Stock, $.01 Par Value (File No. 7–11329)
Colonial Properties Trust
Common Stock, $.01 Par Value (File No. 7–11330)
Northern Border Partners L/PL
Common Stock, $.01 Par Value (File No. 7–11331)
Fortune Petroleum Corporation
Common Stock, $.001 Par Value (File No. 7–11332)
Integrated Health Services, Inc.
Common Stock, $.001 Par Value (File No. 7–11333)
Belden, Inc.
Common Stock, $.01 Par Value (File No. 7–11334)
Capital Guaranty Corporation
Common Stock, $.10 Par Value (File No. 7–11335)
Corrpro Companies, Inc.
Common Stock, No Par Value (File No. 7–11336)
Rex Stores Corporation
Common Stock, $.01 Par Value (File No. 7–11337)
Chemical & Mining Co. of Chile, Inc.
American Depositary Shares, rep. 8 Ser. B Share, No Par Value (File No. 7–11338)
Trinitech Systems, Inc.
Common Stock, $.001 Par Value (File No. 7–11339)
Northern Border Partners L.P.
Common Stock, $.01 Par Value (File No. 7–11340)
Ballard Medical Products
Common Stock, $.10 Par Value (File No. 7–11341)
Templeton Emerging Markets Income Fund, Inc.
Common Stock, $.01 Par Value (File No. 7–11342)
DVI, Inc.
Common Stock, $.005 Par Value (File No. 7–11343)

These securities are listed and registered on one or more other national securities exchange and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before October 1, 1993, written data, views and arguments concerning the above-referenced application. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the application if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such application is consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 93–24673 Filed 10–6–93; 8:45 am]

BILLING CODE 8010–01–M

Self-Regulatory Organizations; Applications for Unlisted Trading Privileges; Notice and Opportunity for Hearing; Cincinnati Stock Exchange, Inc.

October 1, 1993.

The above named national securities exchange has filed applications with the Securities and Exchange Commission ("Commission") pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f–1 thereunder for unlisted trading privileges in the following securities:

American Select Portfolio, Inc.
Common Stock, $.01 Par Value (File No. 7–11344)
Coca-Cola FEMSA, S.A. de C.V.
American Depositary Shares (rep. 10 sh. Ser. L Comm. Stk., 1 new Peso Par Value (File No. 7–11345)
Cohen & Steers Total Return Realty Fund, Inc.
Common Stock, $.001 Par Value (File No. 7–11346)
International Technology Corp.
Depositary Shares (rep. 1/100 sh. Cum. Conv. Exch. Pfd. Stk., $100.00 Par Value) (File No. 7–11347)
Kimco Realty Corp
Depositary Shares (rep. 1/10 sh. 7.75% Ser. A Cum. Red. Pfd. Stk., $1.00 Par Value) (File No. 7–11348)
Morgan Stanley Group, Inc.
Common Stock, $.01 Par Value (File No. 7–11349)
Nuveen Premium Income Municipal Fund 6
Shares of Beneficial Interest, $.01 Par Value (File No. 7–11350)
Sterling Electronics
Common Stock, $.50 Par Value (File No. 7–11351)
Newscorp Overseas Ltd.
8⅝% Cum. Gtd. Pref. shares, Ser. A, $25.00 Par Value (File No. 7–11352)
Ballard Medical Products
Common Stock, $.10 Par Value (File No. 7–11353)
Templeton Emerging Markets Income Fund, Inc.
Common Stock, $.01 Par Value (File No. 7–11354)

These securities are listed and registered on one or more other national securities exchange and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before October 25, 1993, written data, views and arguments concerning the above-referenced applications. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the applications if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such applications are consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 93–24674 Filed 10–6–93; 8:45 am]

BILLING CODE 8010–01–M

Self-Regulatory Organizations; Applications for Unlisted Trading Privileges; Notice and Opportunity for Hearing; Philadelphia Stock Exchange, Inc.

October 1, 1993.

The above named national securities exchange has filed applications with the Securities and Exchange Commission ("Commission") pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f–1 thereunder

for unlisted trading privileges in the following securities:

Buenos Aires Embotelladora S.A.
American Depository Shares (File No. 7–11312)
Templeton Emerging Markets Income Fund, Inc.
Common Stock, $.01 Par Value (File No. 7–11313)
Intercapital Quality Municipal Securities
Common Shares of Beneficial Interest, $.01 Par Value (File No. 7–11314)
Intercapital California Quality Municipal Securities
Common Shares of Beneficial Interest, $.01 Par Value (File No. 7–11315)
Intercapital New York Quality Municipal Securities
Common Shares of Beneficial Interest, $.01 Par Value (File No. 7–11316)
PanAmerican Beverages, Inc.
Class A Common Stock, $.01 Par Value (File No. 7–11317)
Cohen & Steers Total Return Realty Fund, Inc.
Common Stock, $.001 Par Value (File No. 7–11318)
Margaretten Financial Corporation
Depository Shares each representing ¼ of a Share of Cum. Pfd Stock (File No. 7–11319)
Boise Cascade Corporation
$1.58 Depository Shares (File No. 7–11320)
Northern Border Partners L.P.
Common Units Representing Ltd. Partner Interest, $.01 Par Value (File No. 7–11321)
Integrated Health Services, Inc.
Common Stock, $.001 Par Value (File No. 7–11322)
Serenpet, Inc.
Common Stock, No Par Value (File No. 7–11323)
Van Kampen Florida Municipal Opportunity Trust
Sahres Beneficial Interest (File No. 7–11324)
Ballard Medical Products
Common Stock, $.10 Par Value (File No. 7–11325)

These securities are listed and registered on one or more other national securities exchange and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before October 25, 1993, written data, views and arguments concerning the above-referenced application. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the application if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such applications are consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 93–24672 Filed 10–6–93; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–32991; File No. SR–PHLX–92–31]

Self-Regulatory Organizations; Filing and Order Granting Accelerated Approval to a Proposed Rule Change by Philadelphia Stock Exchange, Inc., Relating to an Extension of the Deadlines for Submission of Exercise Advice Memoranda and Notices for Index Option Contracts

September 30, 1993.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on December 14, 1992, the Philadelphia Stock Exchange, Inc. ("PHLX" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization.[1] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The PHLX proposes to amend Exchange Rule 1042A, "Exercise of Option Contracts," to provide that, for American-style industry (narrow-based) index options, the deadline for submitting exercise advices and memoranda to exercise shall be 4:15 p.m. Eastern Time ("ET") or five minutes after the close of trading, and that the deadline for submitting exercise advices and memoranda to exercise National Over-the-Counter Index ("XOC") options shall be 4:20 p.m. ET or five minutes after the close of trading. In addition, the PHLX proposes to amend Floor Procedure Advice ("Advice") G–1, "Exercise Requirement," to extend the daily cut-off time for submitting exercise advice forms for 25 or more American-style stock index options to the Exchange's Surveillance Post to 4:20 p.m. ET or five minutes after the close of trading on the day of the exercise. The Advice, as amended, also requires firms utilizing the electronic Clearing Management and Control System (C/MACS) to transmit index exercise instructions to the Options Clearing Corporation ("OCC") according to the time frames established by the Advice.

The text of the proposal is available at the Office of the Secretary, the PHLX, and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

Currently, Exchange Rule 1042A requires PHLX member organizations to submit a memorandum to exercise any stock index option contract, other than Value Line Index ("VLE") and XOC option contracts, by 4:10 p.m. ET. In addition, for any account exercising 25 or more contracts in the same series on the same business day on behalf of an individual customer, specialist, ROT, or firm, the firm must submit an exercise advice form to the Exchange by 4:10 p.m. ET. Exchange Rule 1042A also requires PHLX members to prepare or

[1] On January 15, 1993, the PHLX amended its proposal to establish a 4:20 p.m. Eastern Time ("ET") deadline for the submission of index option exercise advice forms for American-style index options. See File No. SR–PHLX–92–31, Amendment No. 1. On July 12, 1993, the PHLX deleted Amendment No. 1 and filed Amendment No. 2, which replaces Amendment No. 1 and amends Exchange Rule 1042A, "Exercise of Option Contracts," and Floor Procedure Advice ("Advice") G–1, "Exercise Requirements," to establish the deadlines for submitting memoranda to exercise and exercise advice forms to the Exchange as 4:15 p.m. ET or five minutes after the close of trading for American-style industry (narrow-based) index options, and 4:20 p.m. or five minutes after the close of trading for options on the National Over-the-Counter Index ("XOC"). See File No. SR–PHLX–92–31. The PHLX also amended its proposal to delete references in the filing to the Utility Index ("UTY") and the PHLX/KBW Bank Index ("BKX"). See Letter from Edith Hallahan, Attorney, Market Surveillance, PHLX, to Yvonne Fraticelli, Staff Attorney, Options Branch, Division of Market Regulation ("Division") Commission, dated January 20, 1993. Finally, the Exchange amended its proposal to make clear that paragraph (i) and (ii) of Exchange Rule 1042A, as amended, apply to narrow-based indexes, and that paragraph (iii) applies to the XOC. See Letter from Edith Hallahan, Special Counsel, Regulatory Services, PHLX, to Richard Zack, Branch Chief, Options Branch, Division, Commission, dated September 1, 1993.

receive a memorandum to exercise any American-style index option contract before the deadline stated in Exchange Rule 1042A and to time-stamp the exercise instructions to confirm the time of receipt or preparation.

The PHLX's exercise advice forms identify the entity exercising, the option series and the number of contracts being exercised. Pursuant to Exchange Rule 1042A(b), index exercise advice forms are not used on the last day of trading prior to the expiration date of that option ("expiration Friday"). On an expiration Friday, paragraph (b) of PHLX Rule 1042A governs.

Currently, the PHLX lists one narrow-based American-style stock index option on the Gold/Silver Index ("XAU") which trades until 4:10 p.m. ET, the same time as the deadline for member firms to (i) receive or prepare memoranda to exercise such options and (ii) submit exercise advice forms to the Exchange (if the account is exercising 25 or more contracts in the same series).[2] Similarly, the PHLX lists options on the XOC, a broad-based index which trades until 4:15 p.m. ET, reflecting an additional five minutes of trading in the corresponding futures. For XOC options, the deadline for receiving or preparing memoranda to exercise and for submitting exercise advice forms (for accounts exercising 25 or more contracts in the same series) is 4:15 p.m. ET.

The Exchange proposes to amend PHLX Rule 1042A to extend the deadline for submitting exercise advice forms and memoranda to exercise PHLX narrow-based American-style index options to 4:15 p.m. ET or five minutes after the close of trading.[3] In addition, the PHLX proposes to amend Exchange Rule 1042A to provide that the deadline for submitting exercise advice forms and memoranda for XOC options shall be 4:20 p.m. ET or five minutes after the close of trading.

The PHLX proposes corresponding changes to Advice G–1. Specifically, the PHLX proposes to amend Advice G–1 to provide that specialists, registered options traders ("ROTs"), customers and firms must submit exercise advice forms for 25 or more American-style index options to the Exchange's Surveillance Post by 4:20 p.m. ET or five minutes after the close of trading on the day of the exercise. In addition, the proposal provides that firms utilizing C/MACS must transmit index exercise instructions to the OCC according to the time frames established by the Advice.

The PHLX believes that extending the exercise notice cutoffs should ensure that market participants are afforded adequate time to make accurate investment decisions, including time to evaluate their final position after closing prices in the various markets have been disseminated. For example, the PHLX notes that execution reports for hedge orders and stocks comprising an index may not be available immediately after the close of trading. In addition, the Exchange believes that the proposal may help to increase liquidity near the close of trading, as market participants will be able to remain in the crowd, focusing on making quality markets in lieu of preparing exercise forms for submission by the close of trading.

The PHLX also believes that allowing an additional five minutes for the submission of exercise advice forms and memoranda is reasonable and should provide the advantages cited above.

Finally, the PHLX proposes several nonsubstantive changes to clarify exchange Rule 1042A. Specifically, the PHLX proposes to delete current paragraph (ii) of Exchange Rule 1042A(a) and incorporate that provision into paragraph (i) for clarity, and to delete paragraph (c) from Exchange Rule 1042A because paragraph (c) repeats the provisions of current paragraph (a)(iii) (proposed paragraph (a)(ii)).

Finally, the PHLX notes that the Chicago Board Options Exchange, Inc. ("CBOE"), the Pacific Stock Exchange, Inc. ("PSE"), and the American Stock Exchange ("Amex") have similarly extended exercise notice cut-offs for index options.[4]

For the above reasons, the PHLX believes that the proposed rule change to establish a 4:15 p.m. ET deadline for the submission of index option exercise advice forms and memoranda for narrow-based American-style index options, and a 4:20 p.m. ET deadline for XOC options, is consistent with section 6 of the Act, in general, and, in particular, with section 6(b)(5), in that the proposal is designed to promote just and equitable principles of trade, and to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The PHLX does not believe that the proposed rule change will impose any inappropriate burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has requested that the proposed rule change be given accelerated effectiveness pursuant to section 19(b)(2) of the Act in order to conform the PHLX's rules to the rules of the Amex, CBOE, PSE, and the Chicago Mercantile Exchange ("CME").[5]

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, the requirements of section 6(b)(5) thereunder.[6] Specifically, the Commission believes that the amendments to Exchange Rule 1042A and Advice G–1 which extend the deadline for submitting exercise advice forms and memoranda will benefit market participants by allowing them to make investment decisions based upon the evaluation of their final positions after having completed trading for the day.

The Commission also believes that the proposal will benefit the market in general by fostering higher quality markets at the close of the trading day. First, market makers will not be preoccupied with the process of submitting exercise advice forms prior to the actual close of the market and, therefore, can concentrate more fully on providing a quality market at the close. Second, market participants will be able to determine whether or not their orders

[2] The PHLX also trades the following index options, which are European-style and, thus, not subject to the exercise advice procedure of Exchange Rule 1024A: options on the VLE, a broad-based or market index, and options on two industry (narrow-based) indexes, the BKX and the UTY.

[3] The Exchange proposes to add the language "or five minutes after the close of trading," in the event trading does not begin and end pursuant to ordinary procedures and time frames. See e.g., CBOE Rule 11.1 (.03) and Securities Exchange Act Release No. 29860 (October 25, 1991), 56 FR 5625 (November 1, 1991) (order approving File No. SR–CBOE–91–28).

[4] See Securities Exchange Act Release Nos. 29860 (October 25, 1991), 56 FR 56254 (order approving File No. SR–CBOE–91–28); 30152 (January 6, 1992), 57 FR 1778 (order approving File No. SR–PSE–91–46); and 31057 (August 19, 1992), 57 FR 38894 (order approving File No. SR-Amex–92–33).

[5] See Amex Rule 980C (establishing a deadline of 4:15 p.m. EST, or five minutes after the close of trading); CBOE Rule 11.1, Interpretations and Policies .03 (establishing a deadline of 3:20 p.m., Central Time ("CT") or five minutes after the close of trading); PSE Rule 7.15 (establishing a deadline of 1:20 p.m., Pacific Time, or five minutes after the close of trading); and CME Rule 550. Under the CME's rules, market participants have an additional five minutes to settle trades after 3:15 p.m. CT.

[6] 15 U.S.C. 78f(6)(5) (1988).

on other related markets were executed, such as orders intended to hedge their options positions. If their hedging transactions in other markets are not executed by 4:15 p.m. ET, for narrow-based American-style index options, or 4:20 p.m. ET, for XOC options, then, under the proposal, market participants will still be able to exercise their options positions and not remain in an unhedged position after the close of trading. Third, the proposal will give market participants additional time to evaluate the closing prices of the stocks that are used to calculate the indexes and determine whether or not to exercise their positions.

In addition, the Commission believes that the proposal to delete current paragraph (ii) of Exchange Rule 1042A(a) and to incorporate that provision into paragraph (i), and to delete paragraph (c) from Exchange Rule 1042A because it repeats existing provisions of the rule will help to clarify the application of the rule.

The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the date of publication of notice of filing thereof in the **Federal Register**. The Commission finds that the PHLX's proposal to extend the deadline for submitting exercise advice forms and preparing exercise memoranda is similar to the Amex, CBOE, and PSE proposals previously approved by the Commission and raises no new issues.[7] The Commission notes that it received no comments on the previously approved CBOE, Amex, and PSE proposals. In addition, as discussed above, the change will provide a variety of benefits to market participants. Accordingly, the Commission believes that granting accelerated approval of the proposed rule change is appropriate and consistent with Section 6 of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by October 28, 1993.

It is therefore ordered, Pursuant to Section 19(b)(2) of the Act,[8] that the proposed rule change (SR–PHLX–92–31) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[9]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–24590 Filed 10–6–93; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–32990; International Series Release No. 586; File No. SR–PHLX–92–10]

Self-Regulatory Organizations; Order Approving Proposed Rule Change and Notice of Filing and Order Granting Accelerated Approval to Amendment Nos. 1 and 2 to the Proposed Rule Change by the Philadelphia Stock Exchange, Inc., Relating to the Eligibility of Registered Representatives To Sell Foreign Currency Options

September 30, 1993.

On April 10, 1992, as amended on September 14, 1993, and September 28, 1993, the Philadelphia Stock Exchange, Inc. ("PHLX" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission"), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b-4 thereunder,[2] a proposal to amend Exchange Rule 1024(a)(ii) to allow registered representatives who passed the Series 7 General Securities Representative Examination ("Series 7 Examination") prior to June 1986 to sell PHLX foreign currency options.

The proposed rule change was published for comment in Securities Exchange Act Release No. 30705 (May 14, 1992), 57 FR 21688. No comments were received on the proposed rule change.[3]

Since June 1986, the Series 7 Examination has included questions regarding the trading of listed foreign currency options. For that reason, registered representatives who passed the Series 7 Examination after June 1986 have been eligible to sell foreign currency options on the PHLX. The PHLX proposes to amend Exchange Rule 1024(a)(ii) to establish a procedure which will allow registered representatives who passed the Series 7 Examination prior to June 1986 to sell PHLX foreign currency options. The proposal will apply solely to registered representatives who are associated with PHLX member firms or participant organizations of the PHLX.[4]

The purpose of the proposal is to permit registered representatives qualified by the length and depth of their industry experience to sell foreign currency options without having to pass a separate examination, such as the Series 15 Examination, that relates solely to foreign currency options. The PHLX states that its members and participant organizations have urged the PHLX to increase accessibility to selling foreign currency options because, aside from "housekeeping idiosyncracies," the foreign currency options program is

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[7] See note 5, supra.

[8] 15 U.S.C. 78s(b)(2) (1982).

[9] 17 CFR 200.30–3(a)(12) (1992).

[1] 15 U.S.C. 78s(b)(1) (1982).

[2] 17 CFR 240.19b-4 (1992).

[3] On September 14, 1993, the PHLX amended its proposal to establish an application procedure through which registered representatives who passed the Series 7 Examination prior to 1986 may become eligible to sell foreign currency options on the PHLX without passing the Series 15 Examination. Specifically, a registered representative who passed the Series 7 Examination prior to 1986 may submit to the Exchange's Director of Examinations an Exchange-approved form, "Application for Waiver of Series 15 Examination," which requires a description of the registered representative's options experience and certification of that experience by a current or former supervisor with knowledge of the registered representative's options experience. The supervisor must certify that the applicant understands options and has applied his knowledge in the course of trading and monitoring options positions over a period of no less than six months. The Exchange will review the applications and, based on the information provided in the application, the Director of Examinations will determine whether the registered representative demonstrates sufficient knowledge of foreign currency options and the underlying markets to allow the registered representative to sell foreign currency options without taking the Series 15 Examination. See Letter from Gerald D. O'Connell, Vice President, Market Surveillance, PHLX, to Richard Zack, Branch Chief, Options Branch, Division of Market Regulation ("Division"), Commission, dated September 2, 1993 ("Amendment No. 1"). In addition, the PHLX modified the text of proposed Commentary .06 to clarify that the waiver of the Series 15 Examination is not automatic, but is subject to approval based on the information contained in the application. See Letter from Gerald D. O'Connell, Vice President, Market Surveillance, PHLX, to Richard Zack, Branch Chief, Options Regulation, Division, Commission, dated September 28, 1993 ("Amendment No. 2").

[4] See Letter from William W. Uchimoto, General Counsel, PHLX, to Richard Zack, Branch Chief, Options Branch, Division, Commission, dated may 27, 1993.

similar to the equity options program. In this regard, the PHLX notes that foreign currency options trade pursuant to the same auction market regimen and have the same underlying characteristics as equity options with regard to their issuer, clearing guarantees, uniform margin requirements, suitability standards, and the existence of position and exercise limits. While the actual margin requirements and position and exercise limits may differ, the PHLX believes that such differences are easily discernible specification differences rather than core substantive differences.

The PHLX explains that its foreign currency options market has matured to the point that it is now an essential and integral part of the securities business. The PHLX has determined that registered representatives who passed the Series 7 Examination prior to June 1986 are at least as qualified to trade foreign currency options as registered representatives who passed the Series 7 Examination after June 1986.

The PHLX notes that firms will continue to determine the segment of their sales force that will sell foreign currency options and, likewise, that firms will continue to bear the responsibility of assuring that their sales forces are supervised properly by appropriate personnel. In addition, the PHLX has developed an application procedure through which registered representatives who passed the Series 7 Examination prior to 1986 may become eligible to sell foreign currency options on the PHLX without passing the Series 15 Examination. Specifically, a registered representative who passed the Series 7 Examination prior to 1986 may submit to the Exchange's Director of Examinations an Exchange-approved form, "Application for Waiver of Series 15 Examination," which describes the registered representative's options experience and contains the certification of a current or former supervisor with knowledge of the registered representative's options experience which states that the applicant understands options and has applied his knowledge in the course of trading and monitoring options positions over a period of no less than six months. The Exchange will review the applications and, based on the information provided in the application, the Director of Examinations will determine whether the registered representative demonstrates sufficient knowledge of foreign currency options and the underlying markets to allow the registered representative to sell foreign currency options without taking the Series 15 Examination.[5]

The Series 15 Examination will continue to be a prerequisite for registered representatives whose exclusive sales focus is foreign currency options and who have not passed the Series 7 Examination.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, with the requirements of section 6(b)(5) in that the proposal is designed to protect investors and the public interest.

PHLX Rule 1024, "Conduct of Accounts for Options Trading," provides that, prior to soliciting or accepting customers' orders in foreign currency options, account executives of member organizations must complete an examination "prescribed by the Exchange for the purpose of demonstrating an adequate knowledge of foreign currency options and of the markets for the underlying foreign currencies."[6] The Commission agrees with the PHLX's determination that registered representatives who passed the Series 7 Examination prior to June 1986 may be adequately qualified to trade foreign currency options on the PHLX. In this regard, the Commission shares the PHLX's conclusion concerning the common characteristics of foreign currency options and equity options. In particular, foreign currency options trade pursuant to the same auction market regimen and have the same underlying characteristics as equity options with regard to their issuer, applicable clearing guarantees, uniform margin requirements, suitability standards, and the existence of position and exercise limits. Thus, despite the unique nature of the foreign currency options market, the Commission believes that it is reasonable for the PHLX to conclude that registered representatives who passed the Series 7 Examination prior to June 1986 may be qualified to trade foreign currency options.

In this regard, the Commission believes that the application procedure developed by the PHLX should help to ensure that only registered representatives with adequate experience in options trading and knowledge of foreign currency options and the underlying markets will be permitted to waive the Series 15 Examination. The Commission notes, in addition, that under the rules of the National Association of Securities Dealers, Inc. ("NASD"), a registered representative whose employment as a representative or principal has been terminated for a period of two years or more would be required to retake the current Series 7 Examination, which includes questions on foreign currency options.[7] Thus, a registered representative who passed the Series 7 prior to June 1986 and left the industry for a period of two years or more would be required to retake the Series 7 Examination.

In summary, the Commission believes that the procedures for waiver approval, along with the NASD's two-year requirement, will ensure that registered representatives who passed the Series 7 Examination prior to 1986 and who are approved by the Exchange for waiver of the Series 15 Examination should have the knowledge, skills, and abilities to trade foreign currency options. Moreover, the Commission notes that the proposal retains the requirement that registered representatives take the Series 15 examinations if their exclusive sales focus is on foreign currency options, and they have not passed the Series 7 Examination. By enabling additional qualified representatives to trade foreign currency options, the Commission believes that the PHLX's proposal should help the PHLX to maintain the depth and liquidity of its foreign currency options markets, which will benefit market participants.

The Commission finds good cause for approving Amendment Nos. 1 and 2 to the proposed rule change prior to the thirtieth day after the date of publication of notice of filing thereof in the Federal Register because the amendments strengthen and clarify the Exchange's proposal. Amendment No. 1 sets forth the specific conditions under which a waiver will be granted. Amendment No. 2 clarifies the text of Commentary .06 by stating specifically that a waiver is not automatic, but is subject to the Exchange's approval based on the information contained in the application. Accordingly, the Commission believes that it is consistent with section 6(b)(5) of the Act to approve Amendment Nos. 1 and 2 to the PHLX's proposal on an accelerated basis.

Interested persons are invited to submit written data, views and arguments concerning Amendment Nos. 1 and 2. Persons making written

[5] See Amendment No. 1, *supra* note 3.

[6] See PHLX Rule 1024(a)(ii).

[7] See NASD Manual, Schedule C, Part III(1)(c), "Requirement for Examination on Lapse of Registration." See also Letter from Edith Hallahan, Attorney, Market Surveillance, PHLX, to Sharon Lawson, Assistant Director, Division, Commission, dated April 22, 1993.

submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by October 28, 1993.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the proposed rule change (File No. SR–PHLX–92–10) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[8]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–24591 Filed 10–6–93; 8:45 am]

BILLING CODE 8010–01–M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Research and Development Programs Meeting

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice.

SUMMARY: This notice announces a public meeting at which NHTSA will describe and discuss specific research and development projects and requests suggestions for agenda topics.

DATES AND TIMES: The National Highway Traffic Safety Administration will hold a public meeting devoted primarily to presentations of specific research and development projects on October 12, 1993, beginning at 1:30 p.m. and ending at approximately 5 p.m. The deadline for interested parties to suggest agenda topics is 4:15 p.m. on September 17, 1993. Questions may be submitted in advance regarding the Agency's research and development projects. They must be submitted in writing by October 4, 1993 to the address given below. If sufficient time is available, questions received after the October 4 date will be answered at the meeting in the discussion period. The individual, group or company asking a question does not have to be present for the question to be answered. A consolidated list of the questions submitted by October 4 will be mailed to interested personnel by October 6 and will be available at the meeting.

ADDRESSES: The meeting will be held at the Ramada Inn, near Detroit Metro, 8270 Wickham Rd., Romulus, MI 48174. Suggestions for specific R&D topics as described below and questions for the October 12, 1993 meeting relating to the Agency's research and development programs should be submitted to George L. Parker, Associate Administrator for Research and Development, NRD–01, National Highway Traffic Safety Administration, room 6206, 400 Seventh St. SW., Washington, DC 20590. The fax number is 202–366–5930.

SUPPLEMENTARY INFORMATION: NHTSA intends to provide detailed presentations about its research and development programs in a series of quarterly public meetings. The purpose is to make available more complete and timely information regarding the Agency's research and development programs. At the first meeting, on April 6, 1993, NHTSA officials from the Office of Research and Development provided a summary overview of research and development projects in the areas of crashworthiness and crash avoidance. At the second meeting, held on June 23, 1993, NHTSA staff gave detailed presentations about the agency frontal and rollover crash protection research projects, including the topics of structural integrity, door latch integrity, and glass-plastic glazing. The next meeting in this series will be held on October 12, 1993.

NHTSA requests suggestions from interested parties on the specific agenda topics. NHTSA will base its decisions about the agenda on the suggestions it receives by September 17, 1993. Before the meeting, it will publish a notice listing the research and development topics to be discussed. NHTSA asks that the suggestions be taken from the list below and that they be limited to five, in priority order, so that the presentations at the October 12 R&D meeting can be most useful to the audience. The list does not include the topics discussed at the previous meeting on June 23, 1993.

Specific Crashworthiness R&D topics are:
- Dynamic side impact—LTVs
- Hybrid III chest deflection
- Improved safety belt design
- Upgrade fuel system integrity
- Highway traffic injury studies
- Head and neck injury research
- Thorax injury research
- Human injury simulation and analysis
- Crash test dummy component development
- Vehicle aggressivity and fleet compatibility
- Upgrade side crash protection
- Upgrade seat and occupant protection system
- Child safety research
- Electric vehicle safety

Specific Crash Avoidance R&D topics are:
- Vehicle motion environment
- Crash causal analysis
- Heavy truck antilock brake systems
- Long combination vehicle safety
- Drowsy driver monitoring
- Driver workload assessment

Specific topics from the National Center for Statistics and Analysis are:
- New data elements for FARS and NASS
- Special crash investigations program regarding air bag performance
- Pedestrian special NASS data collection project
- Critical Outcome Data Evaluation System (CODES)—Linkage of databases on police accident reporting and medical outcomes.

This meeting is followed on the next day by the regular quarterly NHTSA Technical Industry Meeting, which was announced on August 19, 1993 (58 FR 44206).

Questions regarding research projects that have been submitted in writing in advance will be answered as time permits. A transcript of the meeting, copies of materials handed out at the meeting, and copies of the suggestions offered by commenters will be available for public inspection in the NHTSA Technical Reference Section, room 5108, 400 Seventh Street SW., Washington, DC 20590. Copies of the transcript will then be available at 10 cents a page, upon request to NHTSA Technical Reference Section. The Technical Reference Section is open to the public from 9:30 a.m. to 4 p.m.

NHTSA will provide technical aids to participants as necessary, during the NHTSA Industry Research and Development Meeting. Thus any person desiring assistance of "auxiliary aids" (e.g. sign-language interpreter, telecommunication devices for deaf persons (TTDs), readers, taped texts,

[8] 17 CFR 200.30–3(a)(12) (1992).

braille materials, or large print materials and/or a magnifying device), please contact Barbara Coleman on 202/366–1537 by COB October 4, 1993.

FOR FURTHER INFORMATION CONTACT: Dr. Richard L. Strombotne, Special Assistant for Technology Transfer Policy and Programs, Office of Research and Development, 400 Seventh Street SW., Washington, DC 20590. Telephone: 202–366–4730. Fax number: 202–366–5930.

Issued: September 7, 1993.

George L. Parker,

Associate Administrator for Research and Development.

[FR Doc. 93–24698 Filed 10–6–93; 8:45 am]

BILLING CODE 4910–59–M

Sunshine Act Meetings

Federal Register
Vol. 58, No. 193
Thursday, October 7, 1993

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

TIME AND DATE: 10:00 a.m., Wednesday, October 13, 1993.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204. You may call (202) 452–3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: October 5, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93–24859 Filed 10–5–93; 3:10 pm]

BILLING CODE 6210–01–P

NATIONAL SCIENCE FOUNDATION

National Science Board

DATE AND TIME:

October 14, 1993, 2:00 p.m. Closed Session
October 15, 1993, 8:30 a.m. Closed Session
October 15, 1993, 9:00 a.m. Open Session

PLACE: National Science Foundation, 1800 G Street, NW., Room 540, Washington, DC 20550.

STATUS:

Part of this meeting will be open to the public.

Part of this meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

Thursday, October 14, 1993

Closed Session (2:00 p.m.–3:30 p.m.)

1. Minutes of August 1993 Meeting
2. FY 1995 Budget

Friday, October 15, 1993

Closed Session (8:30 a.m.–9:00 a.m.)

3. Grants and Contracts

Open Session (9:00 a.m.–11:00 p.m.)

4. Minutes from August Meeting
5. Acting Director's Report
6. Reports from Committees
7. Astronomy Review
8. Other Business

Marta Cehelsky,

Executive Officer.

[FR Doc. 93–24842 Filed 10–5–93; 2:31 pm]

BILLING CODE 7555–01–M

federal register

Thursday
October 7, 1993

Part II

Department of Health and Human Services

Social Security Administration

20 CFR Parts 404 and 416
Federal Old-Age, Survivors and Disability Insurance and Supplemental Security Income; Listing of Impairments—Respiratory System; Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

20 CFR Parts 404 and 416

[Regulations No. 4 and 16]

RIN 0960–AB00

Federal Old-Age, Survivors and Disability Insurance and Supplemental Security Income; Listing of Impairments—Respiratory System

AGENCY: Social Security Administration, HHS.

ACTION: Final rules.

SUMMARY: These amendments revise the criteria in the Listing of Impairments (the listings) that we use to evaluate respiratory impairments for adults and children who claim Social Security benefits or supplemental security income (SSI) payments based on disability under title II and title XVI of the Social Security Act (the Act). The revisions reflect advances in medical knowledge, treatment, and methods of evaluating respiratory impairments.

EFFECTIVE DATE: These rules are effective October 7, 1993.

FOR FURTHER INFORMATION CONTACT: Cassandra Bond or Alicia Matthews, Legal Assistants, 3–B–1 Operations Building, 6401 Security Boulevard, Baltimore, MD 21235, (410) 965–1794 or 965–1713.

SUPPLEMENTARY INFORMATION: The Act provides, in title II, for the payment of disability benefits to workers insured under the Act. Title II also provides for the payment of child's insurance benefits for persons who became disabled before age 22 and widow's and widower's insurance benefits based on disability for widows, widowers and surviving divorced spouses of insured individuals. In addition, the Act provides, in title XVI, for SSI payments to persons who are disabled and have limited income and resources. For workers insured under title II, for children of workers insured under title II who become disabled before age 22, for widows, widowers and surviving divorced spouses claiming widow's or widower's insurance benefits based on disability under title II, and for adults claiming SSI benefits based on disability, "disability" means inability to engage in any substantial gainful activity. For children under the age of 18 who apply for SSI payments based on disability, "disability" means that the child's physical or mental impairment(s) is of comparable severity to an impairment that would make an adult (a person age 18 or older) disabled. Under both title II and title XVI, "disability" must be by reason of a medically determinable physical or mental impairment or combination of impairments which can be expected to result in death or which has lasted or can be expected to last for a continuous period of at least 12 months.

Under the sequential evaluation process, if the evidence shows that an individual is not engaging in substantial gainful activity and has an impairment(s) that meets the statutory duration requirement, is severe, and meets or equals in severity a listing criteria, the individual is disabled. (In the case of a child applying for SSI, this includes consideration of whether the child's impairment(s) is functionally equivalent to a listed impairment, as defined in § 416.926a.) If the impairment(s) does not meet or equal in severity any listing criteria, no conclusion regarding disability is made. Rather, we evaluate all signs, symptoms, laboratory findings, and other evidence to determine whether the person is disabled. For an adult, we assess residual functional capacity and, based on that assessment, determine whether the claimant retains the capacity to perform past relevant work, or, if not, whether he or she retains the capacity to perform any other work considering his or her residual functional capacity, age, education, and work experience. If not, the adult is disabled. For a child under the age of 18 applying for SSI, we individually assess the child's ability to function to determine whether there is a substantial reduction in the child's ability to function independently, appropriately, and effectively in an age-appropriate manner. If there is such a substantial reduction, the child is disabled.

Medical criteria for evaluating disability and blindness at the third step of the sequential evaluation processes for adults and children are found in the listings which are set out as appendix 1 to subpart P of part 404 of our regulations. The listings include examples of the most commonly occurring medical conditions for persons who file applications for disability benefits. It describes, for each of 13 major body systems, impairments that are considered severe enough to prevent an individual from engaging in any gainful activity, or in the case of a child under the age of 18 applying for SSI, examples of impairments that are severe enough to prevent a child from functioning independently, appropriately, and effectively in an age-appropriate manner. Most of the listed impairments are permanent or are expected to result in death; in some instances, a specific durational requirement is a part of the medical criteria for the impairment (in addition to the 12-month duration requirement that applies to all impairments that are not expected to result in death).

Appendix 1 consists of two parts, part A and part B. The criteria in part A apply to the evaluation of impairments of adults but may, in some cases, be appropriate for evaluating impairments in children under age 18. Part B contains medical criteria for the evaluation of impairments in children under age 18 when the criteria in part A do not give appropriate consideration to the particular effects of the disease processes in childhood. In evaluating disability for a child under age 18, we use part B first. If the criteria in part B do not apply, then we use the medical criteria in part A, when the criteria are appropriate. To the extent possible, we maintain a structural and content relationship between parts A and B (see §§ 404.1525 and 416.925). When part A criteria are repeated in part B, our intent is to eliminate any question about their application to children.

When we revised the listings on December 6, 1985 (50 FR 50068), we indicated that medical advancements in disability evaluation and treatment and program experience would require that the listings periodically be reviewed and updated. Accordingly, we specified termination dates ranging from 4 to 8 years for each of the specific body system listings. These dates currently appear in the introductory paragraphs of the listings. One extension for the termination date for part A of the respiratory system appeared in the **Federal Register** of November 27, 1991 (56 FR 60059), and extended the original date on which the part A listings would no longer be effective from December 6, 1991, to December 7, 1992. A second extension for the termination date for part A of the respiratory system appeared in the **Federal Register** of December 7, 1992 (57 FR 57665), and extended the termination date to June 7, 1993. A third extension for part A of the respiratory system appeared in the **Federal Register** of June 7, 1993 (58 FR 31906), and extended the date on which the listings would no longer be effective to December 6, 1993. We are now updating the respiratory system listings in both 3.00 (part A) and 103.00 (part B), and extending the effective date of these revised listings for 7 years from the date of their publication. Therefore, 7 years after publication of these final rules, these regulations will cease to be effective, unless they are extended by

the Secretary or revised and promulgated again.

We published these regulations in the **Federal Register** (56 FR 52231) as a Notice of Proposed Rulemaking (NPRM) on October 18, 1991. Interested persons, organizations, Government agencies, and other groups were given 60 days to comment. The comment period ended December 17, 1991. We received letters from 11 commenters. These comments are addressed below.

Explanation of the Final Rules

We have updated these final rules to provide criteria for evaluating respiratory impairments at the listing level of severity reflecting state-of-the-art medical science and technology. The basic approach underlying the final respiratory system listings is to place less emphasis on the diagnosis of disease, and to emphasize the impact of the impairment(s) on a person's ability to perform work-related activities or, in the case of a child applying for SSI payments based on disability, on the child's ability to function independently, appropriately, and effectively in an age-appropriate manner.

We revised the respiratory system listings with information we received from individuals recommended by various medical professional groups, including the American Medical Association, the American Thoracic Society, the American Lung Association, the American College of Chest Physicians, the American Society of Internal Medicine, the American College of Physicians, the Cystic Fibrosis Foundation, and the American Nurses Association. We also received information from individual Federal and State representatives who have expertise in evaluating disability claims involving respiratory impairments. We also obtained information from individual pediatric experts to revise the part B listings.

The final listings revise the criteria to encompass disorders for which specific criteria have not been previously published (e.g., sleep-related breathing disorders) and to include state-of-the-art evaluative techniques. All of the techniques (tests, procedures, etc.) cited in the regulations are generally available and are included in the cumulative list of New or Improved Diagnostic Techniques, as published in the **Federal Register** on May 9, 1990, at 55 FR 19357.

The following is a summary of the provisions of the final rules and the changes we have made to the text of the NPRM. Finally, we have made a number of minor editorial changes throughout the rules to correct errors in the NPRM, to make the rules internally consistent, and to conform the style of these listings to our other listings.

Revisions to Part A of Appendix 1

3.00 Preface

In a technical correction, we are deleting the opening statement after the heading because it was redundant. The sentence repeated, almost verbatim, the statement in the third paragraph of the introductory text to appendix 1 that the respiratory system listings will no longer be effective 7 years after publication of the final rules unless extended by the Secretary or revised and promulgated again. In addition, our inclusion of the statement in 3.00 was inconsistent with all of the other listings sections except 12.00, the only other section in part A and part B that repeated the expiration date in its opening text.

3.00A Introduction. We have modified the first paragraph of final 3.00A and made conforming changes to the first paragraph of 103.00A so that both paragraphs explain that the listings for respiratory impairments describe impairments based on symptoms, physical signs, laboratory test abnormalities, and response to a regimen of treatment which may have been prescribed by a treating source. The proposed rules referenced a regimen of therapy; however, for clarity the word "therapy" has been changed to the broader term "treatment" in this paragraph and throughout these regulations. No substantive change is intended by this technical correction.

In addition, as a result of public comments, we deleted the last sentence of the first paragraph of proposed 3.00A which indicated that the functional evaluation of the severity and duration of a respiratory disorder should be performed only after prescribed therapy has been instituted and sufficient time has elapsed for the results to be evaluated. We have, however, added a new second paragraph to 3.00A and 103.00A to indicate that, when there is evidence of medically prescribed treatment, the clinical record must include a description of the treatment prescribed by the treating source and response, in addition to information about the nature and severity of the impairment. This paragraph notes that it is important to document the prescribed treatment and response because this medical management may have improved the individual's functional status.

We added the third paragraph in response to comments which pointed out that some people do not receive treatment, and that some do not have an ongoing relationship with the medical community. The new paragraph explains that an individual who does not receive treatment may or may not be able to show the existence of an impairment that meets the listings. Even if an individual does not show that he or she has an impairment that "meets" the criteria of the listings, the individual may still have impairments that are "equal" in severity to a listed impairment or he or she may be found disabled at the last step of the sequential evaluation process. To be consistent with the adult rules, we also added a third paragraph to final 103.00A of the preface to the childhood listings; the paragraph contains provisions similar to the adult rules.

In the third sentence of the fourth paragraph when we discuss the evidence needed to establish the presence of chronic pulmonary disease, we have added other appropriate imaging techniques after x-ray to recognize there are now other technologies used for imaging. We have made a similar change in the first paragraph of 3.00F1, and in 3.00F3.

We also have included in the sixth paragraph a discussion of the documentation which may be needed with a diagnosis of diffuse interstitial fibrosis or clinical findings suggesting cor pulmonale, such as cyanosis or secondary polycythemia. This documentation may require measurement of carbon monoxide diffusing capacity or arterial blood gases at rest and infrequently during exercise in addition to evidence of the clinical evaluation and chest x-ray or other appropriate imaging techniques and spirometry. We also clarified the discussion of pulmonary vascular disease with its specific documentation requirements to state that right heart catheterization with angiography and/or direct measurement of pulmonary artery pressure may have been done. We further state that when performed, the results should be obtained because the results may be useful in evaluating impairment severity.

The final paragraph of 3.00A is a new paragraph that we added to clarify that the listings can never be used to deny claims. It is a reminder that claimants whose impairments do not "meet" any listing may still be found to have impairments that are "equal" in severity to a listing, and that the listings can only be used to find a person disabled, but not to find a person "not disabled." The new paragraph stresses the importance of an individualized residual functional capacity assessment,

which may or may not result in a finding of disability, whenever a person's severe impairment(s) does not meet or equal the requirements of a listing. To be consistent with the adult rules, we also added a final paragraph to 103.00A of the preface to the childhood listings emphasizing the importance of equivalence determinations and individualized functional assessments when childhood impairments do not meet a listing.

3.00B Mycobacterial, Mycotic, and Other Chronic Persistent Infections of the Lung. The final rules in 3.00B include other chronic persistent infections of the lung, in addition to mycobacterial and mycotic infections. We removed, without replacement, the proposed last sentence of this section, which indicated that chronic pulmonary infection occurring in the setting of immunodeficiency should be evaluated under the criteria for the appropriate underlying disorder because we believe it to be unnecessary. Our adjudicators know that we have separate criteria for the evaluation of impairments of the immune system, including human immunodeficiency virus.

3.00C Episodic Respiratory Disease. In 3.00C, we specify the documentation requirements for episodic respiratory disease. Documentation must include information relating to the adherence to a prescribed therapeutic regimen, thus, again, serving to emphasize the importance of treatment that the claimant is expected to have received. The documentation requirements define the severity of an attack fulfilling the intensity component of the listing criteria, and define hospital admissions as inpatient hospitalizations for longer than 24 hours. Based upon a public comment which questioned the need for spirometric results between attacks of episodic respiratory diseases (asthma, cystic fibrosis, and bronchiectasis), we clarified that this rule pertains only to cases of asthma, as explained in more detail in the public comments section.

3.00D Cystic Fibrosis. Paragraph D is being added to the introductory material in 3.00 to recognize the increasing number of children with cystic fibrosis surviving to adulthood. The adult listings, therefore, explicitly recognize this condition, and in the first sentence, we indicate that this disorder may affect either the respiratory or digestive body systems or both. We provide a description of cystic fibrosis, including information concerning the proper diagnostic approach. In response to public comments, we added a reference to the medical literature which describes the diagnostic test (i.e., the quantitative pilocarpine iontophoresis sweat test). We also add that there are two methods of sweat collection, the Gibson-Cooke and Wescor Macroduct systems; however, to establish the diagnosis of cystic fibrosis, the sweat sodium or chloride content must be analyzed quantitatively using an acceptable laboratory technique. The pilocarpine method, the specifications for which are published by the Cystic Fibrosis Foundation, is an acceptable testing procedure. The pilocarpine method has the lowest false positive and false negative results of any sweat collection technique that is currently available to confirm the diagnosis of cystic fibrosis. The test is available in all Cystic Fibrosis Centers affiliated with the Cystic Fibrosis Foundation, as well as in major university medical centers. In addition, we have identified and included another test for diagnosing cystic fibrosis. It is the genetic test for homozygosity of the cystic fibrosis gene and is known as "CF gene mutation analysis."

In the penultimate sentence, in response to a public comment, we reference the digestive body system as the other nonpulmonary body system which could be affected by cystic fibrosis. We clarified the last sentence to indicate that the combined effects of the involvement of the respiratory and digestive body systems must be considered in case adjudication.

3.00E Documentation of Pulmonary Function Testing. For consistency with the terminology used throughout these regulations, in the title and in the second sentence, we have changed "ventilatory" function testing to "pulmonary" function testing. We have made a similar change in 103.00B. We expanded 3.00E, designated as 3.00D in our prior rules, to include more specific requirements for documentation of pulmonary function tests. The revision is consistent with published standards for test performance approved by the American Thoracic Society in the "American Review of Respiratory Disease," Vol. 136, No. 5: pp. 1285–1298, 1987, and the National Institutes of Health Epidemiology Standardization Project. Criteria are outlined specifying what constitutes an acceptable study. These criteria include the use of the back-extrapolation technique for zero time, the requirement for early onset of peak flow rates, and specific criteria for reproducibility. Performance standards require that at least three acceptable spirograms be obtained, two of which are reproducible. Comprehensive standards are provided for calibration of instruments other than those that generate the spirogram by direct pen linkage to a mechanical displacement-type spirometer. Three levels of calibrations are required for primary flow sensing devices because some of these devices are not linear over the wide range of flow rates which occur in the spirogram. These requirements for accuracy and calibration are consistent with the standards for spirometers endorsed by the American Thoracic Society.

The maximum voluntary ventilation requirement in our prior rules was deleted as a criterion because it was considered to be effort-dependent, infrequently used in clinical practice, and poorly standardized among laboratories. In the prior rules, the major usefulness of the maximum voluntary ventilation requirement was that it provided confirmation of the degree of impairment indicated by the one second forced expiratory volume (FEV_1) when the test was of less than optimal quality. These final listings incorporate specific requirements to ensure the quality of forced expiratory spirometry studies.

We added two new sentences to the second paragraph of 3.00E and 103.00B to indicate first that pulmonary function studies should not be performed unless the claimant's clinical status is stable. The second sentence indicates that wheezing *per se* does not necessarily preclude performance of a pulmonary function test because wheezing is common in asthma, chronic bronchitis, or chronic obstructive pulmonary disease. Also, in the last sentence of this paragraph, we defined "most stable state of health" as "any period in time except during or shortly after an exacerbation."

In response to a public comment, we added language to the last sentence in the fifth paragraph of 3.00E and 103.00B to explain that the calibration tracings, as well as the spirograms, must be presented in a volume-time format at a speed of at least 20 mm/sec and a volume excursion of at least 10 mm/liter to permit independent evaluation.

3.00F Documentation of Chronic Impairment of Gas Exchange. In 3.00F1, we include a detailed description of the specifications for performance of the diffusing capacity of the lungs for carbon monoxide study to evaluate impairment of gas exchange. These listings place greater emphasis on the use of diffusing capacity of the lungs for carbon monoxide study as a measure of gas exchange prior to consideration of purchasing arterial gas analysis and exercise testing. The use of a diffusing capacity of the lungs for carbon monoxide study to estimate gas exchange impairment is based on state-of-the-art information that diffusing capacity is an important indicator of gas exchange and work capacity, and is an

important predictor of mortality in lung disorders. The performance criteria for the test have been standardized by the American Thoracic Society in the "American Review of Respiratory Disease," Vol. 136, No. 5: pp. 1299–1307, 1987, and the standardization of criteria has been incorporated into the listings.

In the last sentence of the first paragraph of 3.00F1, we clarified the language on purchase of a diffusing capacity of the lungs for carbon monoxide study to indicate that purchase of a diffusing capacity of the lungs for carbon monoxide study may be appropriate when there is a question of whether an impairment meets or is equivalent in severity to the listing, and the claim cannot otherwise be favorably decided.

We provide criteria in 3.00F2 for resting arterial blood gas studies. In 3.00F2 and 3.00F3, we also specify that before purchase of arterial blood gas studies at rest or during exercise, a program physician, preferably one with experience in the care of patients with pulmonary disease, must review all clinical and laboratory data in the record to determine whether obtaining the test would present a significant risk to the individual. In 3.00F2, we also state that arterial blood gas studies at rest or on exercise should be purchased only from a laboratory certified by a State or Federal agency.

In the second paragraph of 3.00F2 and 103.00C1, we clarified our language on purchase to indicate that purchase of resting arterial blood gas studies may be appropriate when there is a question whether an impairment meets or is equivalent in severity to a listing and the claim cannot otherwise be favorably decided. To further clarify our intent on the purchase of resting arterial blood gas studies, we added a sentence to the second paragraph of 3.00F2 that indicates if the results of a diffusing capacity of the lungs for carbon monoxide study are greater than 40 percent of predicted normal but less than 60 percent of predicted normal, purchase of resting arterial blood gas studies should be considered.

In 3.00F3, we reorganized the first paragraph as it appeared in the NPRM to indicate that arterial blood gas studies with exercise may be appropriate in cases in which there is documentation of chronic pulmonary disease, but full development, short of exercise testing, is not adequate to establish if the impairment meets or is equivalent in severity to a listing, and the claim cannot otherwise be favorably decided. As a result of this reorganization, we deleted the fourth sentence of the proposed rule because it was redundant in light of the revision to the first sentence. Exercise testing with blood gas analysis should only be done after the diffusing capacity of the lungs for carbon monoxide study has been estimated and the documentation has been found to be inadequate for the evaluation of the severity of functional impairment. In 3.00F3, we deleted the language regarding a FEV_1 greater than 2.5 liters from the second paragraph of the proposed rule because it was medically inaccurate in that this finding is not a sensitive marker for absence of a gas exchange impairment. We have, however, retained language that when an individual has a diffusing capacity of the lungs for carbon monoxide greater than 60 percent of predicted normal, an exercise blood gas study generally would not be needed.

In 3.00F4, we revised the methodology for performance of an exercise test to include use of measurements at two exercise levels if the individual can satisfactorily complete the lower level of exercise at approximately 5 METs. In the third sentence, we reflect the weight in both pounds and kilograms for clarity. We expanded the last sentence of the fifth paragraph to indicate that the statement the laboratory provides concerning why the claimant failed to complete 4 to 6 minutes of steady state exercise, provides information which may be useful for determining whether effort was limited by lack of effort or another impairment which affected the claimant's ability to exercise.

3.00G Chronic Cor Pulmonale and Pulmonary Vascular Disease. In 3.00G, we provide a more detailed description of chronic cor pulmonale and pulmonary vascular disease for which specific new criteria are provided in 3.09. We clarified that the establishment of an impairment attributable to irreversible cor pulmonale secondary to chronic pulmonary hypertension requires documentation by signs and laboratory findings of right ventricular overload or failure. This was the intent of the language which appeared in the NPRM. We also clarified that hypoxemia may accompany heart failure and is also a cause of pulmonary hypertension and also that polycythemia with an elevated red blood cell count and hematocrit may be found in the presence of chronic hypoxemia.

3.00H Sleep-Related Breathing Disorders. We are also adding 3.00H to provide a description of sleep-related breathing disorders, which are not addressed in the prior listings. Reference criteria are provided for the evaluation of these disorders in 3.10. In response to a public comment to provide more detailed information on the effect of sleep apnea on an individual, we have added a sentence recognizing that because daytime sleepiness can affect memory, orientation, and personality, a longitudinal treatment record may be needed to evaluate mental functioning. We also added a sentence to clarify that chronic hypoxemia due to episodic apnea may cause pulmonary hypertension. Daytime somnolence may be associated with disturbance in cognitive vigilance. Impairment of cognitive function may be evaluated under organic mental disorders (12.02). If the sleep disorder is associated with gross obesity, evaluation will be under the applicable obesity listing.

Listings

3.01 Category of Impairments, Respiratory System

3.02 Chronic Pulmonary Insufficiency. Paragraph A of 3.02 and table I now only require one-second forced expiratory volume values rather than both FEV_1 and maximum voluntary ventilation results. The FEV_1 values are substantively unchanged from our prior rules. Table I, however, is constructed so that rounding of reported volume values will not be necessary. For clarity, the heights are shown in centimeters and inches rather than just inches. In addition, in paragraph A, for clarity, we have made a nonsubstantive change from the NPRM and added "due to any cause" after the opening phrase, "Chronic obstructive pulmonary disease." This phrase is also in our prior rules. For consistency, we included it in 103.02A. For clarity, we also added, in parentheses, the cross reference to 3.00E for guidance on determining the height of an individual with marked spinal deformity.

In the first sentence of 3.02B, we added "due to any cause" after "chronic restrictive ventilatory disease" and in 103.03B. In final 3.02, paragraph B has been clarified by adding a cross reference to 3.00E for cases of marked spinal deformity rather than repeating, as we did in the NPRM, the same information that is already contained in the introductory material in 3.00E. Table II is modified so that rounding of reported forced vital capacity values will not be necessary and the heights are shown in both inches and centimeters.

Final 3.02C, provides criteria for evaluating a gas exchange abnormality based on a diffusing capacity of the lungs for carbon monoxide study, arterial blood gas studies at rest or

exercise testing with measurement of arterial blood gas studies. The diffusing capacity of the lungs for carbon monoxide criteria have been modified from the values in our prior rules (less than 9 ml/min/mm Hg, or less than 30 percent of the predicted normal value) to less than 10.5 ml/min/mm Hg, or less than 40 percent of the predicted normal value. This revision represents updated information from the American Thoracic Society correlating these values for diffusing capacity of the lungs for carbon monoxide with work capacity and mortality. ("American Thoracic Society Statement on Evaluation of Impairment/Disability Secondary to Respiratory Disease", "American Review of Respiratory Disease," Vol. 133, No. 6, pp. 1205–09, 1986.) Because of the variation in published predicted values, the listing criteria specify that the source of the predicted values should be reported or, if not published, should be submitted in the form of a table or nomogram.

Paragraph C2 of 3.02 provides criteria for resting arterial blood gas studies. Resting arterial hypoxemia is associated with increased mortality and development of pulmonary hypertension and cor pulmonale. Based upon a public comment that there could be misapplication of this listing, we have included again tables III-A, III-B, and III-C from the prior listing 3.02 to provide for the evaluation of hypoxemia at three altitudes. We have deleted the proposed criteria for evaluating hypoxemia at two altitudes (i.e., less than 4000 feet and 4000 feet and greater). The correction for hypoxemia for carbon dioxide tension is contained in tables III-A, III-B, and III-C. The requirement in paragraph C2 that the two measurements of resting arterial oxygen tension (PO_2) be separated by an interval of three or more weeks within a six-month period in order to meet the requisite level of hypoxemia is based upon the degree of technical and biologic variability of arterial oxygen levels and is consistent with standards used in studies on mortality and performance in persons with chronic lung disease.

Paragraph C3 has been revised based upon public comments to reflect arterial blood gas values of PO_2 and simultaneously determined PCO_2 during steady state exercise with a parenthetical statement defining the exercise level and referencing to tables III-A, III-B, and III-C.

3.03 Asthma. In 3.03, paragraph B provides that hospitalization for longer than 24 hours for control of asthma counts as two asthma attacks for purposes of meeting the frequency requirement of at least one attack every 2 months, or at least six times a year. Paragraph B also states that medical evidence of record over a period of at least 12 consecutive months must be used to determine the frequency of attacks.

3.04 Cystic Fibrosis. Listing 3.04 has been added to establish criteria for evaluating cystic fibrosis in adults because an increasing number of individuals with this disease are now living into adulthood. The listing provides new criteria for the evaluation of the pulmonary manifestations of this disorder. Based upon public comments, we revised 3.04A to include a separate table (table IV) to be used only for the evaluation of cystic fibrosis in adults, as is done in the childhood rules in 103.04A. We also added 3.04C to include those criteria shown in 103.04C because some adults could manifest the findings shown.

3.06 Pneumoconiosis. Listing 3.06 is a cross-reference listing by which pneumoconiosis demonstrated by appropriate imaging techniques can be evaluated under the appropriate criteria in listing 3.02.

3.07 Bronchiectasis. Bronchiectasis, 3.07, is somewhat similar to the clinical aspects of asthma and cystic fibrosis in that the course may be characterized by exacerbations and remissions. Therefore, a new paragraph B is provided to make the criteria for episodes of bronchitis or pneumonia or hemoptysis or respiratory failure consistent with 3.03 (asthma) and 3.04 (cystic fibrosis). Paragraph B indicates that episodes of bronchitis or pneumonia or hemoptysis or respiratory failure requiring physician intervention at least six times a year will meet the requirements of the listing.

3.08 Mycobacterial, Mycotic, and Other Chronic Persistent Infections of the Lung. In response to a public comment, we have combined proposed 3.08 and 3.09 into one reference listing and retitled it as shown above.

3.09 Cor Pulmonale Secondary to Chronic Pulmonary Vascular Hypertension. Because we combined proposed 3.08 and 3.09 into final 3.08, we have renumbered this listing as 3.09. More specific criteria are provided requiring the establishment of an impairment due to chronic cor pulmonale. Additional criteria to those in 4.02 are provided to facilitate adjudication when resting arterial blood gases have been measured and hypoxemia fulfills 3.02C2. Also, we have clarified paragraph B for arterial hypoxemia to cross-refer to 3.02C2 for the evaluation of arterial hypoxemia. We have revised 3.09C to merely reference 4.02 so that this listing will remain current even if future revisions are made to the 4.02 criteria.

3.10 Sleep-related Breathing Disorders. Based upon the reorganization discussed previously, this listing is now designated 3.10 (3.11 in the NPRM). This is a new listing for sleep-related breathing disorders and refers to the persistent functional consequences of this condition. When a sleep-related breathing disorder limits or precludes work activity, the physiologic basis for the impairment may be chronic cor pulmonale, or a disturbance in cognitive performance. Some individuals with this disorder are morbidly obese. Reference listings are provided for the evaluation of these manifestations.

Revisions to Part B of Appendix 1

103.00 Preface

Consistent with our discussion of revisions to part A of appendix 1, we have deleted the language we proposed in the NPRM which repeated in 103.00 the sunset provision for the respiratory listings in part B. This statement in the childhood rules would not only have been redundant of the opening text, but would also have made 103.00 inconsistent with all other listings sections except 12.00, the only other section that repeats the sunset provision in its opening text.

103.00A Introduction. In addition to the changes explained in 3.00A, we added a final sentence to the first paragraph to indicate that reasonable efforts should be made to ensure evaluation of the child's claim by a program physician specializing in childhood respiratory impairments or a qualified pediatrician. We also added introductory material in the third paragraph of 103.00A to provide a discussion that evaluation should include consideration of the adverse effects of respiratory disease in all relevant body systems, and especially on the child's growth and development or mental functioning.

103.00B Documentation of Pulmonary Function Testing. We have retitled 103.00B to be consistent with 3.00E. We removed the reference to 103.10 contained in the NPRM because there was no such listing in the NPRM or in these final regulations. The updated standards for pulmonary function testing and the rationale for including them are essentially the same as those under 3.00E. A statement describing the child's ability to understand directions and the child's effort and cooperation in the testing should still be included as part of the

report. Criteria are outlined specifying what constitutes an acceptable study. These criteria include the use of the back-extrapolation technique for zero time, the requirement for early onset of peak flow rates, and specific criteria for reproducibility. Performance standards require that at least three acceptable spirograms be obtained, two of which are reproducible. Criteria are included for when spirometry should be repeated after administration of an aerosolized bronchodilator. Comprehensive standards are provided for calibration of instruments other than those that generate the spirogram by direct pen linkage to a mechanical displacement-type device. Three levels of calibrations are required for primary flow sensing devices because some of these devices are not linear over the wide range of flow rates which occur in the spirogram.

As a result of a public comment, we eliminated the discussion on rounding and constructed the tables similar to the adult tables.

In response to a public comment, we have added a new seventh paragraph to explain that performance of a pulmonary function test is appropriate only when the child is capable of performing reproducible forced expiratory maneuvers. This capability usually occurs around age 6.

103.00C Documentation of Chronic Impairment of Gas Exchange. This section has been redesignated 103.00C (it was proposed 103.00B2) because we decided to reorganize these rules to be consistent with the rules in part A. In 103.00C1, "Arterial blood gas studies (ABGS)," we provide the documentation requirements for chronic impairment of gas exchange and guidance regarding the performance of blood gas studies. In 103.00C2, we provide guidance on the use of pulse oximetry as a substitute for arterial blood gas testing in children under age 12. The proposed rules had age 3 as the cut-off point, but based upon a public comment and advances in medical science, we increased the age to 12. Based on a public comment, we also added a statement at the end of the first paragraph to indicate that the report of the pulse oximetry test should include a statement on the child's cooperation during the test. The pulse oximetry provision for documenting gas exchange abnormalities is necessary because arterial blood samples are difficult to obtain in children under 12 years of age, and many children being evaluated will require oxygen periodically, during which times blood gas determinations cannot be made. Further, invalid values can result because the procedure is painful and frequently causes crying. Pulse oximetry has been established as a safe and relatively painless procedure. It is more repeatable than ABGS and more accurate than transcutaneous techniques. It is becoming the state-of-the-art procedure for determining gas exchange abnormalities in young children and is as available in hospitals and clinics as are blood gas determinations.

For clarity, in the last sentence of 103.00C1, we indicated that the program physician who determines whether to purchase a resting arterial blood gas study should preferably be one experienced in the care of children (the NPRM indicated patients) with pulmonary disease.

For consistency with the adult rules and based upon a public comment, we added a new paragraph to 103.00C1 and C2 which discusses when purchase of a resting ABGS or oximetry may be appropriate (i.e., when there is a question of whether an impairment meets or is equivalent in severity to a listing, and the claim cannot otherwise be favorably decided).

103.00D Cystic Fibrosis. This section has been redesignated 103.00D (it was 103.00C in the NPRM) because of the reorganization discussed above. Based upon a public comment, we revised the first sentence to indicate that this disorder can affect either the respiratory or digestive body systems or both, as well as impact the child's growth and development. In response to public comments, we have provided additional guidance on tests which can be used for the diagnosis of cystic fibrosis. The quantitative pilocarpine iontophoresis procedure for collection of sweat content must be utilized. We note that the Gibson-Cooke and Wescor Macroduct methods are acceptable. The sweat sodium or chloride content must be analyzed quantitatively using an acceptable laboratory technique. This pilocarpine method, published by the Cystic Fibrosis Foundation, is an acceptable testing procedure as it has the lowest false positive and false negative results of any sweat collection technique that is currently available to confirm the diagnosis of cystic fibrosis. The test is available in all Cystic Fibrosis Centers affiliated with the Cystic Fibrosis Foundation, as well as in major university medical centers. In addition, we are including another diagnostic technique which is a genetic test for homozygosity of the cystic fibrosis gene and is called "CF gene mutation analysis." Most children with suspected cystic fibrosis are referred to these centers for the diagnosis, evaluation, and ongoing management of this disorder. We clarified the last sentence contained in 103.00C of the NPRM to indicate that the combined effects of the involvement of the respiratory and digestive body systems, as well as the impact of the disorder on a child's growth and development should be considered in case adjudication.

103.00E Bronchopulmonary Dysplasia (BPD). This section has been redesignated 103.00E (it was 103.00D in the NPRM) because of the reorganization above. We added new material to the introduction in 103.00E to provide an explanation of bronchopulmonary dysplasia (BPD) and the requirements for establishing the diagnosis. BPD was first reported in 1967 and had a very high mortality rate. Improvements in technology and patient management have resulted in increased survival and recovery of premature infants. Although the majority of infants with BPD do recover, some progress to chronic pulmonary disease, resulting in severe respiratory and related functional impairments.

103.01 Category of Impairments, Respiratory System. The revisions to the part B respiratory listings maintain structural and content comparability with part A to the extent applicable. As in the sections of 103.00, there were a few instances in which we were able to incorporate language from the adult rules into the childhood listings language we proposed in the NPRM, or to make the same or similar revisions in both parts for even greater consistency between parts A and B.

103.02 Chronic Pulmonary Insufficiency. In a technical, nonsubstantive change, we have redesignated the listing we proposed as 103.14 in the NPRM as final 103.02 and revised the final listing in order to preserve structural and content comparability with part A. Thus, final 3.02 and 103.02 now both list impairments that fall under the heading of chronic pulmonary insufficiency, including chronic obstructive and chronic restrictive pulmonary impairments.

We revised final 103.02A from the language in proposed 103.14A to confine its criteria to chronic obstructive pulmonary disease due to any cause, in order to maintain structural and content comparability with 3.02A. For the same reason, we moved table I from 103.03 of the NPRM to final 103.02A. Table I is constructed so that rounding of reported volume values will not be necessary. For clarity, the heights are shown in centimeters and inches. We also added a statement, like the statement in the corresponding adult rule, that the height in the table refers to height without shoes and

added a cross reference to 103.00B for the discussion of measurement of children who have marked spinal deformity. Similarly, we revised the first column heading in table I to indicate that the height is without shoes. None of these revisions is substantive. We have merely incorporated the guidance that was already in proposed 103.00B directly into the listing and the table in order to make them clearer and consistent with the analogous adult rule. Finally, we made minor editorial changes to the language of the provision for clarity and consistency with other provisions.

Final listing 103.02B is now applicable to chronic restrictive ventilatory disease due to any cause, and corresponds to adult 3.02B. As in final 103.02A, we incorporated the guidance on height and a cross reference to 103.00B. Because of the restructuring of the rules, we redesignated table III of proposed 103.14 as table II in final 103.02B and modified it so that rounding of reported forced vital capacity values will not be necessary. The heights are shown in centimeters and inches.

Final 103.02 A and B, as in the NPRM, still provide a means for evaluating chronic pulmonary impairments not covered under 103.03 and 103.04.

Because we divided proposed 103.14 A into two listings (final 103.02 A and B), we redesignated the subsequent paragraphs of the rule. Paragraphs B through G of the proposed rules are, therefore, paragraphs C through H in the final listing. Paragraphs C, D, and E of final 103.02 (paragraphs B, C, and D of proposed 103.14) were developed specifically for the evaluation of children who have experienced respiratory distress in the neonatal period and subsequently develop chronic lung disorders such as BPD. However, other conditions such as congenital or acquired defects of the larynx and trachea, neuromuscular disorders and spinal cord injuries affecting respiration, and central nervous system mediated hypoventilation can also be evaluated under these listings.

We made a technical correction to listings 103.02C and 103.02E5 to make these regulations internally consistent. In these regulations, we changed the word "continuous" to "frequent."

In paragraphs 103.02 E6 and F2, we clarified the language as a result of a public comment that we should define "poor weight gain." We revised final listings 103.02 E6 and F2 to provide criteria for the evaluation of involuntary weight loss or failure to gain weight at an appropriate rate for age. In this way, we not only include children who have stopped gaining weight but also children who do not gain enough weight. We also explicitly provide for the possibility that a child will actually lose weight. Paragraphs F and G of final 103.02 (paragraphs E and F of proposed 103.14) specify other criteria for assessing manifestations of a pulmonary impairment in children, such as recurrent lower respiratory infection, acute respiratory distress, chronic hypoventilation or chronic cor pulmonale. In paragraph F, we clarified that the two hospital admissions within a 6-month period must be required and each must be for more than 24 hours.

Paragraph H of final 103.02 (paragraph G of proposed 103.14) provides criteria for evaluating interference with linear growth as a manifestation of lung disease. In a minor change from the NPRM, we revised the reference from a reference to 100.02 to a more general reference to the growth impairment listings in 100.00. In this way, 103.02H will remain current regardless of any revisions we may make to the listings in 100.00.

103.03 Asthma. Paragraphs A and B of 103.03 ensure greater structural and content relationship with paragraphs A and B of 3.03 in part A. Paragraph A of 103.03 and the values specified in table I (following final 103.02A) provide for the use of pulmonary function testing, and paragraph B of 103.03 provides the clinical criteria for assessing pulmonary insufficiency. These listings are intended to represent the childhood counterparts of the proposed paragraphs A and B of 3.03 in part A. Because we moved table I from proposed 103.03 into final 103.02A, we have revised the text of final 103.03A to indicate the location of table I.

Paragraph C of 103.03 recognizes that some children have persistent symptomatology related to bronchial asthma that may not meet or equal in severity the listing criteria in 103.03 A and B, in part because of their drug regimen. In response to a public comment, we revised 103.03C. We deleted proposed 103.03C2 (barrel or pigeon chest deformity related to underlying pulmonary dysfunction) because these were merely descriptive anatomical deformities subject to various interpretations, and we renumbered proposed 103.03C3 to 103.03C2. We also revised 103.03C to now require one of the two criteria.

Paragraph D to 103.03 provides that a growth impairment related to asthma should be evaluated under the criteria in 100.00.

103.04 Cystic Fibrosis. Paragraph A of 103.04 incorporates and revises the criteria in paragraphs A and B of 103.13 of our prior rules, and revises the FEV_1 values. The values in our rules now being updated were set at 50 percent of predicted normal, and the final values have been set at 60 percent of predicted normal. The higher values in the final rules are more consistent with studies that show good correspondence between clinical scoring systems based on the manifestations of lung disease and FEV_1 values set at the higher standard. Such scoring systems primarily reflect pulmonary status as measured by physical pulmonary findings, including radiographic evidence, nutritional status and level of activity. As a result of this change, forced expiratory pulmonary testing will permit more reliable evaluation of a functional impairment. Consistent with the revision of the FEV_1 threshold necessary to establish a disabling impairment, the extent of clinical evidence needed under paragraph B of 103.04 for children in whom pulmonary function testing cannot be performed will now require that two of three listed manifestations be present, rather than all three as the rules being updated required. Table III is constructed so that rounding of reported volume values will not be necessary and the height is shown in centimeters and inches.

Paragraph C of 103.04 provides for the evaluation of persistent pulmonary infections accompanied by superimposed, recurrent, symptomatic episodes of increased bacterial infection requiring intravenous or nebulization antimicrobial treatment. We added nebulization treatment because that is becoming more widely used.

Paragraph D was added and provides for the evaluation of episodes of bronchitis, pneumonia, hemoptysis, or respiratory failure. This is a technical change which adds to the childhood listings of these manifestations of cystic fibrosis which had been included only in the proposed adult listings.

Paragraph E of 103.04 provides that a growth impairment related to cystic fibrosis should be evaluated under the criteria in 100.00.

Public Comments

Following the publication of the NPRM in the **Federal Register**, we received 11 letters containing comments pertaining to the changes we proposed. The letters came primarily from advocates of the rights of individuals with respiratory disease (including both legal advocates and medical associations).

We have carefully considered all of the comments and have adopted many of the recommendations. These changes are identified in the following discussion of issues that were raised in the comments.

A number of the comments were quite long and detailed. Of necessity, therefore, we have condensed, summarized, or paraphrased them. However, we have tried to express everyone's views adequately and to respond to all of the relevant issues raised. There were also a few comments that we do not address below; this is because they were minor editorial comments pointing out typographical errors, or administrative matters that are not appropriate to the final rules.

For ease of reference, we have organized the comments and responses as follows: We first address general comments, i.e., comments that are either about the rules as a whole or that apply to more than one section of the rules. We then address the remaining comments, which pertain to specific sections of the rules. The section references in the headings below refer to the final rules. In those instances in which we changed the section numbers or headings in the final rules, we provide both the NPRM and final references in the text of the comment and response.

General Issues

Comment: A commenter thought that the proposed 7-year expiration date for these rules was too long and recommended a 5-year period because rapidly developing medical technologies could make these listings obsolete.

Response: We did not adopt the comment because we are not bound to wait 7 years before promulgating new rules. If there are medical advances that should be reflected in our regulations, we can at any time before the expiration of the 7-year period revise all or part of the rules.

Comment: A commenter indicated that the requirement for an evaluation period of at least 12 consecutive months in order to determine the frequency of episodes for asthma, cystic fibrosis, and bronchiectasis was much too stringent.

Response: We did not modify our requirement in listings 3.03 and 103.03 (asthma), 3.04 and 103.04 (cystic fibrosis) and 3.07 (bronchiectasis) for an evaluation period of at least 12 consecutive months. These listings are intended to be used in the most medically severe cases of asthma, cystic fibrosis, and bronchiectasis. Severity for these listings is predicated on the frequency and intensity of episodes. We need an evaluation period of at least 12 months to establish a longitudinal clinical picture because there are a number of factors which may require this much time in order to evaluate the functional impact of the impairment on the individual. For example, the therapeutic adjustments or modifications made in the prescribed treatment and the response are variable because some individuals may not respond initially to a particular regimen and will later need frequent adjustments to their treatment regimen. We also need information on the optimal benefit which has been achieved from the treatment modalities. This cannot be assessed until an effective regimen has been achieved and enough time has elapsed for the regimen to be effective. In addition, there may be a seasonal component contributing to the frequency of attacks, and we want to determine from the longitudinal record whether this is a temporary factor contributing to the exacerbation of an episodic respiratory disease. Nonetheless, if disability can be established at any point in the claims development process, we will do so.

3.00 Preface to Part A

3.00A Introduction. Comment: A few commenters were concerned about the requirement that the functional evaluation of the severity and duration of a respiratory disorder should be performed only after prescribed treatment has been instituted and sufficient time has elapsed for the results to be evaluated. They said that many claimants do not have access to this type of treatment or cannot afford medications. These commenters wanted a definition of "sufficient time" because some respiratory impairments respond more quickly to treatment than others and without such a definition, various interpretations could result. Another commenter noted an inconsistency in the preamble language which explained this change and the actual language in 3.00A. The explanation in the preamble indicated that the evaluation of the severity and duration of a respiratory disorder should be performed only after prescribed treatment has been instituted and expected therapeutic benefits have been achieved. The commenter noted that this language difference would require different documentation and evaluation judgments. One commenter wanted to know how to handle situations in which the treating physician advises the patient to stop smoking, yet the claimant continues to smoke.

Response: We deleted the last sentence of the first paragraph of proposed 3.00A and revised the final rules by adding a new second paragraph in final 3.00A, and for consistency, we made the same addition in 103.00A of part B. In the new second paragraph of final 3.00A and 103.00A, we now indicate that many individuals who have "listing-level" impairments will have received the benefit of medically prescribed treatment and that, whenever there is such evidence, the longitudinal clinical record must include a description of the treatment prescribed by the treating source and the response (which would include evidence of the effects of not smoking), in addition to information about the nature and severity of the impairment. Although we agree that people with impairments of lesser severity than those in the listings may not necessarily receive this kind of treatment, we believe that the listing-level impairments are so severe that many, if not most, individuals with such serious impairments will be placed on some sort of medical treatment. We have added a new third paragraph to recognize that there will be some individuals who, despite the existence of a severe impairment, will not have received ongoing treatment. Such an individual may or may not be able to show the existence of an impairment that meets the criteria of a listing. Even if an individual does not show that his or her impairment meets the criteria of a listing, he or she may have an impairment(s) equivalent in severity to one of the listed impairments or be disabled because of a limited residual functional capacity.

We need a longitudinal record to establish the severity and duration of the impairment, especially for those impairments that may be amenable to treatment. Because, as the commenter noted, some respiratory impairments respond more quickly to treatment than others, it is not possible to provide specific criteria as to what is a sufficient period of time. Our rules allow the adjudicator to decide, on a case-by-case basis, if sufficient evidence is available for a determination or decision.

To underscore our policy that we never deny claims because of failure to meet or equal the listings, we added new paragraphs in final 3.00A and 103.00A which stress the necessity for making an equivalence determination when a claimant's impairment(s) does not meet a listing, and for assessing residual functional capacity (or performing an individualized functional assessment) when a claimant's severe impairment(s) neither meets nor equals in severity any listing.

Finally, the rules on failure to follow prescribed treatment are quite complex,

but have one simple underpinning: They do not come into play unless an individual's treating source has prescribed treatment for the individual which the individual is not following. If the individual's treating source has not prescribed treatment, or the individual does not have a treating source, the principle does not apply.

If the issue arises in which a physician advises a claimant to stop smoking, and he or she does not, a judgment will need to be made on a case-by-case basis to determine if the physician's advice was directly related to or part of the treatment regimen for the respiratory impairment.

Comment: A commenter suggested that pulse oximetry or ear oximetry be included in proposed listings 3.02C2 and 3.10B (now renumbered 3.09) for adults and children over the age of 3 as alternative documentation to arterial blood gas studies.

Response: We did not accept the comment to include oximetry results for adults, but we revised the age limit for children to age 12 because, as stated previously, pulse oximetry in children is becoming the state-of-the-art procedure for determining gas exchange abnormalities in young children. We accept pulse oximetry in a child under age 12 because of technical problems with arterial puncture. However, oximetry provides only a single value for measuring the degree to which oxygen is bound to hemoglobin (oxygen saturation). It is not as complete a measure of gas exchange as arterial blood gas studies. Arterial blood gas studies provide information about other factors such as the amount of carbon dioxide in the blood and metabolic status. The evaluation of all these factors provides a more sensitive and specific indicator of a disabling gas exchange impairment.

3.00B Mycobacterial, Mycotic, and Other Chronic Persistent Infections of the Lung. Comment: A commenter welcomed the broadening of the applicability of the listings to consider chronic persistent lung infections other than mycotic or mycobacterial infections, and recommended that the title of listings 3.08 and 3.09 also include this information.

Response: We agree with the commenter that the title of listings 3.08 and 3.09 should be broadened to include chronic persistent lung infections. In addition, because both these listings contain cross references to listing 3.02 and section 3.00B, we combined them into one listing now numbered 3.08 and retitled it, "Mycobacterial, mycotic, and other chronic persistent infections of the lung."

3.00C Episodic Respiratory Disease. Comment: Two commenters suggested that we clarify the requirement for information documenting adherence to a prescribed therapeutic regimen. They questioned whether therapeutic blood levels of theophylline or other drugs will be required as documentation of adherence to prescribed treatment. They also felt that the requirement for spirometric results obtained between attacks appears to be unnecessary if the listing is satisfied by attacks meeting the severity and frequency criteria described in proposed listing 3.03B.

Response: Therapeutic blood levels of theophylline or other drugs are not required because theophylline is not prescribed in all cases. Many factors other than compliance with medication affect blood levels through alterations in absorption and metabolism. We believe that the treating source should be able to supply this information because if an individual truly has a listing-level impairment, it would be unusual for him or her not to be receiving ongoing treatment from a treating source who has longitudinal evidence on the prescribed treatment and response.

We revised the last sentence of 3.00C because the requirement for spirometric results between attacks pertains only to asthma. We now require spirometry between asthma attacks because spirometry showing reversible bronchospasm between attacks with improvement in the one-second forced expiratory volume post bronchodilator is needed to document the severity of asthma.

3.00D *Cystic Fibrosis. Comment:* One commenter suggested that the pilocarpine techniques should be specified in this section as they are in 103.00C.

Response: We agree and have added appropriate language to 3.00D.

Comment: A commenter requested that we specify that the other body systems which can be affected by cystic fibrosis are the gastrointestinal and cardiovascular systems. This commenter also noted that the references to sweat tests in proposed sections 3.00D and 103.00C were insufficient and suggested we include the Gibson-Cooke method and the Wescor Macroduct system.

Response: We partially agree with the first comment and have modified 3.00D and 103.00D to specifically reference the digestive system. In the childhood rules (103.00D), we also indicate that cystic fibrosis can adversely impact a child's growth and development. We did not reference the cardiovascular body system because the manifestation involved would be cor pulmonale, and that is covered by these listings. We included references to the Gibson-Cooke procedure and the Wescor Macroduct system in 3.00D and 103.00D. We indicate that both methods can be used for sweat collection, but the sweat or chloride content must be analyzed quantitatively using an acceptable laboratory technique.

3.00E Documentation of Pulmonary Function Testing. Comment: One commenter suggested that we address the acceptability of pulmonary function tests in the presence of bronchospasm.

Response: We agree with the commenter and have added language to the second paragraph of 3.00E to indicate that pulmonary function studies should not be performed unless the individual's clinical status is stable, and the individual is not, for example, suffering an episodic respiratory attack, acute respiratory infection or other chronic illnesses. We also provide that wheezing, *per se*, does not preclude testing and is commonly found in asthma between attacks, in chronic bronchitis, and in chronic obstructive pulmonary disease.

Comment: One commenter felt that requiring documentation on the manufacturer and model number of the device used to measure and record the spirogram was excessive. The commenter indicated that if the Agency knows about the acceptability of various devices, it should publish such a notice in the **Federal Register** for notice and comment.

Response: We did not accept the comment because the manufacturer and model number of spirometric devices may be helpful particularly when the adjudicator must review an incompletely labeled or calibrated spirogram, and either through program experience or reference materials available to the adjudicator, he or she can determine if the test results are acceptable. It may then be unnecessary to contact the source which performed the test for additional information if the specific information regarding the spirometer is available. We feel the time required to report the manufacturer and model number is less costly and time consuming than the possible recontact. In addition, as clearly indicated in 3.00E, this evidence "should" be stated. There is not an absolute requirement that the manufacturer and model number be a part of the record in order for the claim to be decided. If all the evidence supports a favorable decision, the claim would not be delayed merely to document this piece of evidence. In addition, this is not a new requirement. It is in section 3.00D of the prior rules,

and there have been no problems with this aspect of documentation. We did not accept the comment that if the Agency knows about the acceptability of various devices, we should publish such a list in the **Federal Register** for notice and comment. We do not certify acceptability of spirometers nor do we maintain a list of acceptable devices. Rather, we provide rules defining what data are acceptable for program purposes, and, in turn, we accept the results of spirometry from any equipment that can provide these data.

Comment: The same commenter felt that the calibration tracings, as well as the spirograms, must have a time scale of at least 20 mm/sec and a volume scale of at least 10 mm/liter to permit independent measurement of the spirogram.

Response: We agree with the comment and have added the language to the last sentence of the fifth paragraphs of 3.00E and 103.00E that the spirogram and the calibrations must be presented in a volume-time format at a speed of at least 20 mm/sec and a volume excursion of at least 10 mm/L to permit independent evaluation.

3.00F Documentation of Chronic Impairment of Gas Exchange. Comment: One commenter requested clarification as to when to consider purchase of a diffusing capacity of the lungs for carbon monoxide or resting arterial blood gas studies. The commenter noted that this section says these tests should be purchased in cases in which "there is documentation of chronic pulmonary disease, but the existing evidence, including properly performed spirometry, is not adequate to establish the level of functional impairment." The commenter questioned whether chronic pulmonary disease specifically refers to those diseases that may result in significant impairment of gas exchange and whether this will result in an increase in the need to purchase diffusing capacity of the lungs for carbon monoxide and arterial blood gas studies. The commenter questioned whether there is a specific sequence of development that is required. He said proposed section 3.00F3 indicates that an exercise arterial blood gas study should be purchased only if full development is not adequate to establish the level of functional impairment and goes on to note that full development means the results of spirometry and measurement of diffusing capacity of the lungs for carbon monoxide and resting arterial blood gas studies have been obtained. This implies that both these studies may be purchased before exercise arterial blood gas studies.

Response: It is not possible to provide an exact sequence which should always be followed in purchasing tests. Chronic pulmonary insufficiency, as designated in listing 3.02, may be the result of many disorders which may alter pulmonary function, including, but not limited to, chronic obstructive pulmonary disease, emphysema, chronic bronchitis, bronchiectasis, pneumoconiosis, infection, cystic fibrosis, asthma, pulmonary infiltrative disorders, and pulmonary resection. The important issue in documentation of severity in these disorders is to have sufficient information to identify those individuals with disabling functional loss. Because each disease process may manifest itself differently, each case needs to be independently evaluated in light of the pertinent evidence already in file and the likelihood that a particular study will provide additional information for accurate adjudication. We have, however, modified the language in 3.00F1 and 3.00F2 to clarify that purchase of a diffusing capacity of the lungs for carbon monoxide and arterial blood gas studies may be appropriate when there is a question of whether an impairment meets or is equivalent in severity to a listing and the claim cannot otherwise be favorably decided. We may purchase exercise arterial blood gas studies if full development is not sufficient to establish if the claim meets or is equivalent in severity to a listing and the claim cannot otherwise be favorably decided. "Full development" can include spirometry, diffusing capacity of the lungs for carbon monoxide or resting arterial blood gas studies, available either through evidence of record or purchase, and all other available evidence, including but not limited to medical history, physical examination, chest x-ray or other appropriate imaging techniques, electrocardiogram, hematocrit or hemoglobin.

Listings

3.02 Chronic Pulmonary Insufficiency. Comment: One commenter indicated that arterial blood gases are simplified in the proposed rules and was concerned about eliminating carbon dioxide (CO_2) tension. The commenter believed that even if two tests are done three weeks apart, the test results can be influenced significantly and easily by such things as a little anxiety, or breath holding. In addition, the commenter explained that a person with a resting PaO_2 of 60–65 could be really hypoxic if the individual were hyperventilating. Although the commenter believed that the use of the diffusing capacity of the lungs for carbon monoxide or arterial blood gas studies are appropriate, the commenter suggested that revisions should be made in 3.02 to include CO_2–O_2 correlations.

Response: We agree with the commenter that the results of an arterial blood gas study could be influenced by such things as a little anxiety or breath holding. To avoid any misapplication, we amended listing 3.02 C2 and C3 to delete the values at two altitudes (designated 3.02C2 a and b in the NPRM). We revised these listings to include again tables III–A, III–B and III–C from our prior 3.02 listings because these criteria are more sensitive indicators of disabling impairment of gas exchange and include correction for hypoxemia for carbon dioxide tension.

Comment: A commenter recommended that listings 3.02 C2 and C3 specify that the values are based on breathing room air.

Response: We agree and have added "breathing room air" to 3.00F2, 3.00F4, 103.00C1 and listings 3.02 C2 and C3.

Comment: One commenter was concerned with the requirement in listing 3.02C2 for resting arterial blood gases in a stable state 3 or more weeks apart. The commenter indicated that getting resting arterial blood gas studies performed in stable state on one occasion is difficult, but it will be even harder to get these results on two occasions. The commenter felt that this requirement precludes the use of medical evidence of record.

Response: We did not adopt the comment. This requirement for results on two different occasions is included in these final rules because repeat testing increases the probability that hypoxemia is chronic. This requirement also ensures that inappropriate decisions will not be made utilizing blood gas values during an acute illness which is not expected to result in a chronic gas exchange impairment. We believe that in some cases evidence of record may contain applicable pre-discharge reports from a hospitalization for an intercurrent acute illness, or out-patient records may have the test results that are applicable, particularly when chronic home oxygen therapy is contemplated.

Comment: Two commenters indicated that the heights listed in tables I and II should be listed in either inches or centimeters, and the English and metric system should not be mixed by using tenths of an inch. They also indicated that because the one-second forced expiratory volume cannot be estimated more closely than to tenths of a liter, the listing requirements should not be shown in hundredths of a liter.

Response: We decided that rather than showing the heights in tables I and II in either inches or centimeters, it would be clearer if we indicated both. We have revised the tables accordingly. We do not agree with the commenter that one-second forced expiratory volume results cannot be estimated more closely than to tenths of a liter because it has been our program experience that many times results are reported beyond a tenth of a liter, and that impairment severity assessment can be made more accurately with these results.

Comment: One commenter suggested that we not permit the purchase of arterial blood gases with exercise and clarify that such tests be evaluated only when obtained as medical evidence of record. The commenter did not feel that this test provided information of greater adjudicative value than other testing methods that are more readily available and less risky to the claimant.

Response: We did not accept the comment because these rules provide that exercise testing should only be purchased in infrequent instances in which the other studies may underestimate the degree of functional loss. Further, our rules in 3.00F3 specify that exercise arterial blood gas measurements should only be purchased after careful review of the medical history, physical examination, chest x-ray or other appropriate imaging techniques, spirometry, diffusing capacity of the lungs for carbon monoxide study, electrocardiogram, hematocrit or hemoglobin, and resting blood gas results by a program physician, preferably one with experience in the care of patients with pulmonary disease, to determine whether obtaining the test would present a significant risk to the individual. The purchase of such tests on infrequent occasions is designed to benefit claimants by providing another means by which a disabling impairment can be established.

Comment: Three individuals noted that proposed listing 3.02C2b should read, "At an altitude of 4000 feet or greater. * * *"

Response: We did not accept the comment because we have removed the altitude criteria of proposed listing 3.02 C2a and C2b and revised the listing to include tables III–A, III–B, and III–C from 3.02 of the prior rules.

Comment: A physician commented that the separation of ventilatory impairments (chronic obstructive and chronic restrictive diseases) into two separate listings tends to be confusing and implies an importance in establishing a diagnosis. To simplify the process, the commenter suggested we have one listing that provides for either a one-second forced expiratory volume equal to table I or a forced vital capacity equal to table II. This person believed that one listing would suffice because someone with chronic obstructive pulmonary disease could be considered as meeting the listings in either table I or table II. The same would be true if the person has a predominantly restrictive disease.

Response: We did not accept this comment because an individual with a predominantly air obstructive impairment that meets table II would nearly always meet table I. (These tables are contained in listing 3.02.) However, an individual with a restrictive impairment that meets table II may not meet table I. We do not want to construct a listing that will disadvantage anyone. In addition, the designations, "one-second forced expiratory volume" and "forced vital capacity," are used in clinical practice and connote different physiologic deficits. For these reasons, we prefer to incorporate the one-second forced expiratory volume and the forced vital capacity in listing 3.02 as we have constructed it.

3.04 Cystic Fibrosis. Comment: Several commenters were concerned that the criteria for adults to qualify for benefits with cystic fibrosis are more stringent than the criteria for children with cystic fibrosis. Under the proposed criteria, a child who is 67 inches tall has to have a one-second forced expiratory volume of 1.6 to meet the childhood listings. An adult 67 inches in height would require a one-second forced expiratory volume of 1.45 to meet the adult listing. The commenters noted that the one-second forced expiratory volume values for adults are those established for the evaluation of adults with chronic pulmonary insufficiency while a separate table just for cystic fibrosis has been established for children. A commenter noted that we did not list any manifestation of cystic fibrosis to aid in the evaluation of adults similar to the childhood manifestations. The commenters urged that more realistic criteria, similar to the criteria proposed for children, be provided for adults.

Response: We agree with the commenters that the criteria for adults with cystic fibrosis could be revised. We revised 3.04A to now include a table (table IV) which will be used solely for the evaluation of adults with cystic fibrosis, similar to the approach used in 103.04A of the childhood listings. We have included the criteria from 103.04C of the childhood listing in the adult listings at 3.04C. In turn, we revised the childhood criteria to include the criteria in 3.04B in the childhood listing (now in 103.04D). We believe that these changes will provide a fair and equitable means for evaluating both adults and children.

3.09 Pulmonale Secondary to Chronic Pulmonary Vascular Hypertension. Comment: A commenter noted that this listing (proposed listing 3.10) requires arterial blood gas studies on at least two occasions, 3 or more weeks apart, but the listing did not set an outside limit for this requirement. The commenter felt a limit should be set or situations may arise when, for example, one study was performed in 1989 and another in 1991, and the listing requirement would be satisfied.

Response: We agree with the comment and have revised the final listing by including a cross reference to listing 3.02C2 which indicates that these studies be within a 6-month period.

3.10 Sleep-Related Breathing Disorders. Comment: A commenter objected to this listing because it merely provides cross references to other listings for cor pulmonale, obesity, and organic brain syndrome to evaluate the manifestations of sleep apnea. The commenter felt that specific criteria should be developed for the evaluation of this disorder that weigh more heavily on the disabling effects of daytime drowsiness. The commenter suggested that it ought to be possible to develop a listing for sleep apnea that relies upon sleep laboratory studies and suggested the listing could perhaps be based upon either the number of instances of arousal due to sleep apnea or the degree of hypoxemia demonstrated during sleep testing.

Response: We did not accept this comment because we are not aware of any data to support a relationship between the findings of sleep studies (number of apneas, arousals, severity of desaturation during sleep) and the individual's remaining daytime functional capacity. There are considerable data available relating functional limitations due to extreme obesity, impaired cardiopulmonary function and hypoxemia while awake. We acknowledge that excessive daytime drowsiness can lead to cognitive and personality changes, as well as affective disturbances which result in impaired daytime functioning. Individuals with excessive daytime drowsiness may have disturbances in orientation, memory and personality and these manifestations can be considered under listing 12.02. However, to make our intent clearer, we modified 3.00H to elaborate that daytime drowsiness may affect memory, orientation, and

personality and that longitudinal treatment records may be needed to evaluate mental functioning.

103.00 Preface to Part B

103.00A Introduction

Comment: One commenter noted that this section emphasizes medical evaluation and does not mention the importance of nonmedical evidence in evaluating impairment severity. The commenter indicated that valuable information about a child's condition can often be given by a parent or other caregiver. This individual also indicated that the requirement that respiratory disorders be evaluated by a specialist at the State agency may send a message that medical evidence provided by nonspecialist treating sources will not be considered important.

Response: The listings contain examples of some of the most common impairments in the disability program. The criteria include specific symptoms, signs, and laboratory findings that are considered to characterize impairments severe enough to prevent a child applying for benefits under the SSI program from functioning independently, appropriately, and effectively in an age-appropriate manner. Claimants may be found disabled based on medical factors alone if their impairment(s) meets or equals the medical criteria in a listing. If the severity of a claimant's impairment(s) does not meet or equal medically the severity of an impairment in the listings, we then, in the case of a child under the SSI program, determine whether the impairment(s) functionally equals the listings and, if not, then perform an individualized functional assessment to determine whether the child has an impairment(s) of comparable severity to one that would disable an adult. Thus, following this sequential evaluation process, nonmedical evidence is considered at all appropriate steps in the process—and especially for children at the equals step and in performing an individualized functional assessment. Nonetheless, to clarify this point, we have expanded the fourth paragraph to emphasize the importance of equivalence determinations and individualized functional assessments. In addition, we clarified the language that concerned the commenter, which was that a child's respiratory disorder will be evaluated, if possible, by a pediatrician or by a specialist in respiratory diseases of children. Our intent for this requirement was to recognize the importance of specialization in childhood respiratory disease, not to send a message that evidence provided by a nonspecialist treating source will not be considered important. To clarify our intent, we have added a statement at the end of the first paragraph in 103.00A to indicate that reasonable efforts should be made to ensure review by a program physician specializing in the evaluation of childhood respiratory disease or by a qualified pediatrician. This language is adapted from section 1614(a)(3)(H) of the Act and merely reflects our current policy.

103.00B and 103.00C Documentation of Pulmonary Function Testing and Documentation of Chronic Impairment of Gas Exchange

Comment: A commenter indicated that the proposed rules did not provide enough detailed information on when to purchase the various pulmonary tests. The commenter indicated that the rules should discuss the value of studies performed during or soon after an acute respiratory illness. Two commenters suggested that providing a minimum age for spirometry would be helpful.

Response: We agree with the commenter that our rules should provide more detailed information on when to purchase the various pulmonary tests. Accordingly, we added a new seventh paragraph to 103.00B and a new second paragraph to 103.00 C1 and C2 which indicates that purchase may be appropriate when there is a question of whether an impairment meets or is equivalent in severity to a listing and the claim cannot otherwise be favorably decided. In addition, in the seventh paragraph of 103.00B, we indicate that purchase of a pulmonary function test is appropriate only when the child is capable of performing reproducible forced expiratory maneuvers, and that this capability usually occurs around age 6.

Comment: A commenter indicated that in cases of cystic fibrosis, pulmonary functioning may be extremely and progressively impaired most of the time. Therefore, children with cystic fibrosis should be excluded from the requirement stated in 103.00B that the criteria in 103.04 (incorrectly referred to as 103.10 in the NPRM) can only be applied during the child's most stable state of health because these children's most stable state of health may occur only upon discharge from a hospital and thereafter begin to deteriorate.

Response: We have modified the language in this section and 3.00E to define "most stable state of health" to mean any period in time except during or shortly after an exacerbation. In addition, in evaluating a child's claim for disability, we consider all available evidence related to the child's impairment so that we have a longitudinal view of the impact of the impairment on the child.

Comment: A commenter suggested that we consider the use of pulse oximetry for older children, and stated that the protocol for the test should require a statement regarding the child's cooperation or behavior.

Response: We agree with the commenter that the use of pulse oximetry should be extended to older children, and we have amended 103.00C2 to indicate that pulse oximetry may be substituted for arterial blood gases in children under 12 years of age. The use of pulse oximetry to assess oxygenation status (rather than obtaining arterial blood gas samples through arterial puncture) has become the standard of care in the pediatric community. Experience has shown that pediatric patients infrequently have arterial gases drawn unless they already have an indwelling arterial line or are in an emergency intensive care setting. We have also added a statement to 103.00C2 that the report of the test should include information on the child's cooperation in performing the test.

Comment: A few commenters suggested that, rather than having an explanation of rounding in 103.00B, we use the same format for recording height, one-second forced expiratory volume and vital capacity as is used in the adult listings in 3.02A and 3.02B. These same commenters suggested that in proposed 103.02 table I, 103.02 table II, and 103.14 table III we show the heights in inches and centimeters because some facilities report both ways.

Response: We agree and have modified the tables accordingly.

103.00D Cystic Fibrosis

Comment: A commenter recommended that we consider adding the stool trypsin test for use in the evaluation of cystic fibrosis in young babies and to confirm gastrointestinal involvement. The commenter indicated that the diagnosis of cystic fibrosis may be based on this test in the "neonate period."

Response: We did not accept the comment because the stool trypsin test is not considered an acceptable diagnostic test for cystic fibrosis. The test can be considered only as a gross screening test for pancreatic insufficiency due to any cause and is, therefore, nonspecific for cystic fibrosis. We have, however, added to 103.00D another diagnostic test, the "CF gene mutation analysis."

Listings

103.02 Chronic Pulmonary Insufficiency (Numbered 103.14 in the NPRM and Titled Chronic Obstructive or Restrictive Pulmonary Disease Due to Any Cause)

Comment: One commenter suggested that we should explain what we mean by "poor weight gain" in 103.02E6 and F2 (designated 103.14D6 and E2 in the NPRM) and also specify if loss of weight could meet these listings requirements.

Response: We agree with the commenter and have clarified 103.02E6 and F2. We deleted "poor weight gain," and, to avoid any ambiguity, we now provide criteria for the evaluation of involuntary weight loss or failure to gain weight at an appropriate rate. In this way, we not only include children who have stopped gaining weight but also children who do not gain enough weight. We also provide for the possibility that a child will actually lose weight.

Comment: A commenter indicated that the requirement in 103.02F (designated 103.14E in the NPRM) for two hospital admissions within a 6-month period seemed to be set at a higher level of severity than the requirement in 103.04C of one episode of infection every 6 months. This commenter believed that requiring hospitalization as a criterion of severity discriminates against children who are uninsured or underinsured.

Response: We do not agree with the comment. The requirement of only one increased bacterial infection under 103.04C (103.04B in the NPRM) within a 6-month period is in relation to cystic fibrosis, which is a condition affecting multiple systems associated with progressive irreversible pulmonary morbidity and death during early to mid-adult life. The occurrence of more than one exacerbation for a child with cystic fibrosis during a 6-month period for recurrent respiratory infection is normally associated with progression and a superimposed underlying persistent pulmonary infection and functional impairment. On the other hand, repeated hospital admissions for lower tract respiratory infection in children with other types of chronic pulmonary disease more commonly reflect acute intermittent episodes that are not related to chronic persistent underlying pulmonary infection. These criteria do not discriminate against any class of children, but only provide criteria to quickly allow the most seriously impaired individuals. This is not to imply that children who do not meet or equal in severity a listing cannot be found disabled at the final step of the sequential evaluation process.

103.03 Asthma

Comment: A legal group commented that the requirement in 103.03C that a child must meet two of the three listed criteria seemed excessive because if a child has asthma as severe as described, it should be enough to meet one of the three listed criteria. Another commenter noted that proposed 103.03C and 103.03C3 should include the use of inhaled steroid as well as oral steroid. The commenter also suggested that administration of intravenous fluids should be equated with intravenous administration of a bronchodilator and antibiotics.

Response: We agree with the commenter that the requirement in proposed 103.03C for two of the three listed criteria could be problematic. We, therefore, have deleted the criterion in proposed 103.03C2 because "barrel or pigeon chest" deformity was merely a description of anatomical deformities which may have led to various interpretations. We also revised the listing to require only one of the two remaining criteria. We did not include the use of inhalant steroids in 103.03C1 or 103.03C2 (103.03C3 in NPRM), because this form of treatment does not in itself imply the required level of severity that is intended by this listing. We did not accept the comment to equate administration of intravenous fluids with intravenous administration of a bronchodilator and antibiotics because the need for intravenous fluids generally is not a serious manifestation of chronic disease. The administration of intravenous fluids is merely a treatment modality for an acute episode of asthma.

103.04 Cystic Fibrosis

Comment: A commenter indicated that the listing for cystic fibrosis is problematic. The commenter indicated that this listing requires very low one-second forced expiratory volume values and totally disregards functioning except in children who cannot have spirometry performed. According to the commenter, the reliance on spirometry results is particularly unwise because of the episodic nature of the progression of the disease over time. The commenter believed that we should evaluate the underlying data rather than relying on proxies which are statistically associated with them. This individual recommended that proposed 103.04A1 should be separated into two different parts and proposed 103.04A2 and A3 be renumbered 3 and 4 (i.e., 1. History of dyspnea on exertion and 2. Accumulation secretions as manifested by repetitive coughing or cyanosis; or * * *). In addition, this person believed that the specification of intravenous treatment in proposed 103.04B (final 103.04C) is unwise given the constantly changing nature of treatment. The commenter said that the same criticism could be made of the decision to rely on the quantitative iontophoretic test for the diagnosis of cystic fibrosis. This individual believed that, not only may there be advances in diagnostic techniques within the next 7 years, but also many SSI eligible children would not have access to the designated test, and no child with an impairment as severe as that required by the criteria in 103.04 should be determined not to meet the listings simply because cystic fibrosis has not been diagnosed by the most accurate technique in existence.

Response: We did not accept the comment about low one-second forced expiratory volume values or proxy values. We use one-second forced expiratory volume results in children with cystic fibrosis because it is the testing procedure that is most widely accepted by pediatric specialists to evaluate pulmonary functional status. The one-second forced expiratory volume value set at 60 percent of predicted normal is not low, but higher than the former value, which was set at 50 percent. The one-second forced expiratory volume value is not a proxy measurement for other underlying impairments but a direct measurement of the respiratory system's ability to perform a vital life function. The 60 percent value selected correlates reasonably well with clinical scoring systems that reflect other manifestations of pulmonary impairment, including activity levels, radiographic findings, and nutritional state. Studies also indicate that very few children with cystic fibrosis and one-second forced expiratory volume values that exceed 60 percent of predicted normal are found to experience significant limitation of activity, malnutrition or other evidence of severe disease. Although medical progress in the management of cystic fibrosis continues, intravenous or inhalant antimicrobial therapy is expected to be a necessary modality for the large majority of children with cystic fibrosis for at least the next 5 years.

As mentioned in our discussion in the comment and response on 3.00D, we have revised the methods for diagnosing cystic fibrosis in 3.00D and 103.00D. We did not accept the comment that 103.04B1 (referred to by the commenter as 103.04A1) be separated into two criteria. The criteria in 103.04B1 refer to

a history of signs and symptoms and 103.04B2 and B3 are criteria for clinical and laboratory findings, respectively. If we separated 103.04B into two criteria, a child could then meet the listing based on a history of signs and symptoms with no definitive clinical and laboratory findings. This would be contrary to statutory and regulatory requirements that disability be established based on signs, symptoms, and laboratory findings. We also do not believe that an earlier expiration date for these listings should be set. As previously stated, if there are medical advances which should be reflected in our listing criteria, we can revise all or portions of our listings at any time before the end of the 7-year expiration date. Finally, as we make clear in these listings, because an individual fails to meet the requirements of a listing does not mean the claim is denied. We have explained this longstanding policy in our final rules (3.00A and 103.00A) and discussed it under our explanation of the final rules.

Additional Change

In a technical change required by these final rules, we revised § 416.926a(d)(3) and (d)(12) to be consistent with the new listings. Paragraph (3) formerly included mechanical ventilation as an example of a life-sustaining device. Inasmuch as final listing 103.02C1, provides for the frequent need for mechanical ventilation, we are removing mechanical ventilation from this functional equivalence example. In its place, we include central venous alimentation catheter as an example of a life-sustaining device. Paragraph 12 formerly included tracheostomy in a child who had not attained age 3 as an example of a consequence of an impairment that would establish functional equivalence to the listings. Inasmuch as final listing 103.02D (proposed listing 103.14C) incorporates tracheostomy in a child who has not attained age 3 into the listings, equivalence in this situation is no longer an issue.

Regulatory Procedures

Executive Order 12291

The Secretary has determined that these are not major rules under Executive Order 12291 because these regulations do not meet any of the threshold criteria for a major rule. Therefore, a regulatory impact analysis is not required.

Paperwork Reduction Act

These regulations impose no new reporting/recordkeeping requirements necessitating clearance by the Office of Management and Budget.

Regulatory Flexibility Act

We certify that these regulations will not have a significant economic impact on a substantial number of small entities because they affect only disability claimants and beneficiaries under title II and title XVI of the Social Security Act.

(Catalog of Federal Domestic Assistance Program Nos. 93.802, Social Security-Disability Insurance; 93.803, Social Security-Retirement Insurance; 93.807, Supplemental Security Income)

List of Subjects

20 CFR Part 404

Administrative practice and procedure, Death benefits, Disability benefits, Old-age, survivors, and disability insurance, Reporting and recordkeeping requirements.

20 CFR Part 416

Administrative practice and procedure, Aged, blind, disability benefits, Public assistance programs, Supplemental security income, Reporting and recordkeeping requirements.

Dated: April 8, 1993.

Louis D. Enoff,

Deputy Commissioner of Social Security.

Approved: May 12 1993.

Donna E. Shalala,

Secretary of Health and Human Services.

For the reasons set out in the preamble, parts 404 and 416 of chapter III of title 20 of the Code of Federal Regulations is amended as follows:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950-)

Subpart P—[Amended]

1. The authority citation for Subpart P continues to read as follows:

Authority: Secs. 202, 205(a), (b), and (d) through (h), 216(i), 221(a) and (i), 222(c), 223, 225, and 1102 of the Social Security Act; 42 U.S.C. 402, 405(a), (b), and (d) through (h), 416(i), 421(a) and (i), 422(c), 423, 425, and 1302; sec. 505(a) of Pub. L. 96–265, 94 Stat. 473, secs. 2(d)(2), (5), (6) and (15) of Pub. L. 98–460, 98 Stat. 1797, 1801, 1802, and 1808.

2. Appendix 1 to subpart P (Listing of Impairments) is amended by revising the third paragraph of the introductory text to read as follows:

Appendix 1—[Amended]

* * * * *

The respiratory system listings of part A (3.00) and part B (103.00) will no longer be effective on October 9, 2000, unless extended by the Secretary or revised and promulgated again.

* * * * *

3. Part A of appendix 1 (Listing of Impairments) of subpart P is amended by revising 3.00, Respiratory System, to read as follows

PART A

* * * * *

3.00 Respiratory System

A. *Introduction.* The listings in this section describe impairments resulting from respiratory disorders based on symptoms, physical signs, laboratory test abnormalities, and response to a regimen of treatment prescribed by a treating source. Respiratory disorders along with any associated impairment(s) must be established by medical evidence. Evidence must be provided in sufficient detail to permit an independent reviewer to evaluate the severity of the impairment.

Many individuals, especially those who have listing-level impairments, will have received the benefit of medically prescribed treatment. Whenever there is evidence of such treatment, the longitudinal clinical record must include a description of the treatment prescribed by the treating source and response in addition to information about the nature and severity of the impairment. It is important to document any prescribed treatment and response, because this medical management may have improved the individual's functional status. The longitudinal record should provide information regarding functional recovery, if any.

Some individuals will not have received ongoing treatment or have an ongoing relationship with the medical community, despite the existence of a severe impairment(s). An individual who does not receive treatment may or may not be able to show the existence of an impairment that meets the criteria of these listings. Even if an individual does not show that his or her impairment meets the criteria of these listings, the individual may have an impairment(s) equivalent in severity to one of the listed impairments or be disabled because of a limited residual functional capacity. Unless the claim can be decided favorably on the basis of the current evidence, a longitudinal record is still important because it will provide information about such things as the ongoing medical severity of the impairment, the level of the individual's functioning, and the frequency, severity, and duration of symptoms. Also, the

asthma listing specifically includes a requirement for continuing signs and symptoms despite a regimen of prescribed treatment.

Impairments caused by chronic disorders of the respiratory system generally produce irreversible loss of pulmonary function due to ventilatory impairments, gas exchange abnormalities, or a combination of both. The most common symptoms attributable to these disorders are dyspnea on exertion, cough, wheezing, sputum production, hemoptysis, and chest pain. Because these symptoms are common to many other diseases, a thorough medical history, physical examination, and chest x-ray or other appropriate imaging technique are required to establish chronic pulmonary disease. Pulmonary function testing is required to assess the severity of the respiratory impairment once a disease process is established by appropriate clinical and laboratory findings.

Alterations of pulmonary function can be due to obstructive airway disease (e.g., emphysema, chronic bronchitis, asthma), restrictive pulmonary disorders with primary loss of lung volume (e.g., pulmonary resection, thoracoplasty, chest cage deformity as in kyphoscoliosis or obesity), or infiltrative interstitial disorders (e.g., diffuse pulmonary fibrosis). Gas exchange abnormalities without significant airway obstruction can be produced by interstitial disorders. Disorders involving the pulmonary circulation (e.g., primary pulmonary hypertension, recurrent thromboembolic disease, primary or secondary pulmonary vasculitis) can produce pulmonary vascular hypertension and, eventually, pulmonary heart disease (cor pulmonale) and right heart failure. Persistent hypoxemia produced by any chronic pulmonary disorder also can result in chronic pulmonary hypertension and right heart failure. Chronic infection, caused most frequently by mycobacterial or mycotic organisms, can produce extensive and progressive lung destruction resulting in marked loss of pulmonary function. Some disorders, such as bronchiectasis, cystic fibrosis, and asthma, can be associated with intermittent exacerbations of such frequency and intensity that they produce a disabling impairment, even when pulmonary function during periods of relative clinical stability is relatively well-maintained.

Respiratory impairments usually can be evaluated under these listings on the basis of a complete medical history, physical examination, a chest x-ray or other appropriate imaging techniques, and spirometric pulmonary function tests. In some situations, most typically with a diagnosis of diffuse interstitial fibrosis or clinical findings suggesting cor pulmonale, such as cyanosis or secondary polycythemia, an impairment may be underestimated on the basis of spirometry alone. More sophisticated pulmonary function testing may then be necessary to determine if gas exchange abnormalities contribute to the severity of a respiratory impairment. Additional testing might include measurement of diffusing capacity of the lungs for carbon monoxide or resting arterial blood gases. Measurement of arterial blood gases during exercise is required infrequently. In disorders of the pulmonary circulation, right heart catheterization with angiography and/or direct measurement of pulmonary artery pressure may have been done to establish a diagnosis and evaluate severity. When performed, the results of the procedure should be obtained. Cardiac catheterization will not be purchased.

These listings are examples of common respiratory disorders that are severe enough to prevent a person from engaging in any gainful activity. When an individual has a medically determinable impairment that is not listed, an impairment which does not meet a listing, or a combination of impairments no one of which meets a listing, we will consider whether the individual's impairment or combination of impairments is medically equivalent in severity to a listed impairment. Individuals who have an impairment(s) with a level of severity which does not meet or equal the criteria of the listings may or may not have the residual functional capacity (RFC) which would enable them to engage in substantial gainful activity. Evaluation of the impairment(s) of these individuals will proceed through the final steps of the sequential evaluation process.

B. *Mycobacterial, mycotic, and other chronic persistent infections of the lung.* These disorders are evaluated on the basis of the resulting limitations in pulmonary function. Evidence of chronic infections, such as active mycobacterial diseases or mycoses with positive cultures, drug resistance, enlarging parenchymal lesions, or cavitation, is not, by itself, a basis for determining that an individual has a disabling impairment expected to last 12 months. In those unusual cases of pulmonary infection that persist for a period approaching 12 consecutive months, the clinical findings, complications, therapeutic considerations, and prognosis must be carefully assessed to determine whether, despite relatively well-maintained pulmonary function, the individual nevertheless has an impairment that is expected to last for at least 12 consecutive months and prevent gainful activity.

C. *Episodic respiratory disease.* When a respiratory impairment is episodic in nature, as can occur with exacerbations of asthma, cystic fibrosis, bronchiectasis, or chronic asthmatic bronchitis, the frequency and intensity of episodes that occur despite prescribed treatment are often the major criteria for determining the level of impairment. Documentation for these exacerbations should include available hospital, emergency facility and/or physician records indicating the dates of treatment; clinical and laboratory findings on presentation, such as the results of spirometry and arterial blood gas studies (ABGS); the treatment administered; the time period required for treatment; and the clinical response. Attacks of asthma, episodes of bronchitis or pneumonia or hemoptysis (more than blood-streaked sputum), or respiratory failure as referred to in paragraph B of 3.03, 3.04, and 3.07, are defined as prolonged symptomatic episodes lasting one or more days and requiring intensive treatment, such as intravenous bronchodilator or antibiotic administration or prolonged inhalational bronchodilator therapy in a hospital, emergency room or equivalent setting. Hospital admissions are defined as inpatient hospitalizations for longer than 24 hours. The medical evidence must also include information documenting adherence to a prescribed regimen of treatment as well as a description of physical signs. For asthma, the medical evidence should include spirometric results obtained between attacks that document the presence of baseline airflow obstruction.

D. *Cystic fibrosis* is a disorder that affects either the respiratory or digestive body systems or both and is responsible for a wide and variable spectrum of clinical manifestations and complications. Confirmation of the diagnosis is based upon an elevated sweat sodium concentration or chloride concentration accompanied by one or more of the following: the presence of chronic obstructive pulmonary disease, insufficiency of exocrine pancreatic function, meconium ileus, or a positive family history. The quantitative pilocarpine iontophoresis procedure for collection of sweat content must be utilized. Two methods are acceptable: the "Procedure for the Quantitative Iontophoretic Sweat Test for Cystic Fibrosis" published by the Cystic Fibrosis Foundation and contained in,

"A Test for Concentration of Electrolytes in Sweat in Cystic Fibrosis of the Pancreas Utilizing Pilocarpine Iontophoresis," Gibson, I.E., and Cooke, R.E., *Pediatrics*, Vol. 23: 545, 1959; or the "Wescor Macroduct System." To establish the diagnosis of cystic fibrosis, the sweat sodium or chloride content must be analyzed quantitatively using an acceptable laboratory technique. Another diagnostic test is the "CF gene mutation analysis" for homozygosity of the cystic fibrosis gene. The pulmonary manifestations of this disorder should be evaluated under 3.04. The nonpulmonary aspects of cystic fibrosis should be evaluated under the digestive body system (5.00). Because cystic fibrosis may involve the respiratory and digestive body systems, the combined effects of the involvement of these body systems must be considered in case adjudication.

E. *Documentation of pulmonary function testing.* The results of spirometry that are used for adjudication under paragraphs A and B of 3.02 should be expressed in liters (L), body temperature and pressure saturated with water vapor (BTPS). The reported one-second forced expiratory volume (FEV_1) and forced vital capacity (FVC) should represent the largest of at least three satisfactory forced expiratory maneuvers. Two of the satisfactory spirograms should be reproducible for both pre-bronchodilator tests and, if indicated, post-bronchodilator tests. A value is considered reproducible if it does not differ from the largest value by more than 5 percent or 0.1 L, whichever is greater. The highest values of the FEV_1 and FVC, whether from the same or different tracings, should be used to assess the severity of the respiratory impairment. Peak flow should be achieved early in expiration, and the spirogram should have a smooth contour with gradually decreasing flow throughout expiration. The zero time for measurement of the FEV_1 and FVC, if not distinct, should be derived by linear back-extrapolation of peak flow to zero volume. A spirogram is satisfactory for measurement of the FEV_1 if the expiratory volume at the back-extrapolated zero time is less than 5 percent of the FVC or 0.1 L, whichever is greater. The spirogram is satisfactory for measurement of the FVC if maximal expiratory effort continues for at least 6 seconds, or if there is a plateau in the volume-time curve with no detectable change in expired volume (VE) during the last 2 seconds of maximal expiratory effort.

Spirometry should be repeated after administration of an aerosolized bronchodilator under supervision of the testing personnel if the pre-bronchodilator FEV_1 value is less than 70 percent of the predicted normal value. Pulmonary function studies should not be performed unless the clinical status is stable (e.g., the individual is not having an asthmatic attack or suffering from an acute respiratory infection or other chronic illness). Wheezing is common in asthma, chronic bronchitis, or chronic obstructive pulmonary disease and does not preclude testing. The effect of the administered bronchodilator in relieving bronchospasm and improving ventilatory function is assessed by spirometry. If a bronchodilator is not administered, the reason should be clearly stated in the report. Pulmonary function studies performed to assess airflow obstruction without testing after bronchodilators cannot be used to assess levels of impairment in the range that prevents any gainful work activity, unless the use of bronchodilators is contraindicated. Post-bronchodilator testing should be performed 10 minutes after bronchodilator administration. The dose and name of the bronchodilator administered should be specified. The values in paragraphs A and B of 3.02 must only be used as criteria for the level of ventilatory impairment that exists during the individual's most stable state of health (i.e., any period in time except during or shortly after an exacerbation).

The appropriately labeled spirometric tracing, showing the claimant's name, date of testing, distance per second on the abscissa and distance per liter (L) on the ordinate, must be incorporated into the file. The manufacturer and model number of the device used to measure and record the spirogram should be stated. The testing device must accurately measure both time and volume, the latter to within 1 percent of a 3 L calibrating volume. If the spirogram was generated by any means other than direct pen linkage to a mechanical displacement-type spirometer, the spirometric tracing must show a recorded calibration of volume units using a mechanical volume input such as a 3 L syringe.

If the spirometer directly measures flow, and volume is derived by electronic integration, the linearity of the device must be documented by recording volume calibrations at three different flow rates of approximately 30 L/min (3 L/6 sec), 60 L/min (3 L/3 sec), and 180 L/min (3 L/sec). The volume calibrations should agree to within 1 percent of a 3 L calibrating volume. The proximity of the flow sensor to the individual should be noted, and it should be stated whether or not a BTPS correction factor was used for the calibration recordings and for the individual's actual spirograms.

The spirogram must be recorded at a speed of at least 20 mm/sec, and the recording device must provide a volume excursion of at least 10 mm/L. If reproductions of the original spirometric tracings are submitted, they must be legible and have a time scale of at least 20 mm/sec and a volume scale of at least 10 mm/L to permit independent measurements. Calculation of FEV_1 from a flow-volume tracing is not acceptable, i.e., the spirogram and calibrations must be presented in a volume-time format at a speed of at least 20 mm/sec and a volume excursion of at least 10 mm/L to permit independent evaluation.

A statement should be made in the pulmonary function test report of the individual's ability to understand directions as well as his or her effort and cooperation in performing the pulmonary function tests.

The pulmonary function tables in 3.02 are based on measurement of standing height without shoes. If an individual has marked spinal deformities (e.g., kyphoscoliosis), the measured span between the fingertips with the upper extremities abducted 90 degrees should be substituted for height when this measurement is greater than the standing height without shoes.

F. *Documentation of chronic impairment of gas exchange.*

1. *Diffusing capacity of the lungs for carbon monoxide (DLCO).* A diffusing capacity of the lungs for carbon monoxide study should be purchased in cases in which there is documentation of chronic pulmonary disease, but the existing evidence, including properly performed spirometry, is not adequate to establish the level of functional impairment. Before purchasing DLCO measurements, the medical history, physical examination, reports of chest x-ray or other appropriate imaging techniques, and spirometric test results must be obtained and reviewed because favorable decisions can often be made based on available evidence without the need for DLCO studies. Purchase of a DLCO study may be appropriate when there is a question of whether an impairment meets or is equivalent in severity to a listing, and the claim cannot otherwise be favorably decided.

The DLCO should be measured by the single breath technique with the individual relaxed and seated. At sea level, the inspired gas mixture should contain approximately 0.3 percent carbon monoxide (CO), 10 percent helium (He), 21 percent oxygen (O_2), and the balance nitrogen. At altitudes

above sea level, the inspired O_2 concentration may be raised to provide an inspired O_2 tension of approximately 150 mm Hg. Alternatively, the sea level mixture may be employed at altitude and the measured DLCO corrected for ambient barometric pressure. Helium may be replaced by another inert gas at an appropriate concentration. The inspired volume (VI) during the DLCO maneuver should be at least 90 percent of the previously determined vital capacity (VC). The inspiratory time for the VI should be less than 2 seconds, and the breath-hold time should be between 9 and 11 seconds. The washout volume should be between 0.75 and 1.00 L, unless the VC is less than 2 L. In this case, the washout volume may be reduced to 0.50 L; any such change should be noted in the report. The alveolar sample volume should be between 0.5 and 1.0 L and be collected in less than 3 seconds. At least 4 minutes should be allowed for gas washout between repeat studies.

A DLCO should be reported in units of ml CO, standard temperature, pressure, dry (STPD)/min/mm Hg uncorrected for hemoglobin concentration and be based on a single-breath alveolar volume determination. Abnormal hemoglobin or hematocrit values, and/or carboxyhemoglobin levels should be reported along with diffusing capacity.

The DLCO value used for adjudication should represent the mean of at least two acceptable measurements, as defined above. In addition, two acceptable tests should be within 10 percent of each other or 3 ml CO(STPD)/min/mm Hg, whichever is larger. The percent difference should be calculated as 100×(test 1 − test 2)/average DLCO.

The ability of the individual to follow directions and perform the test properly should be described in the written report. The report should include tracings of the VI, breath-hold maneuver, and VE appropriately labeled with the name of the individual and the date of the test. The time axis should be at least 20 mm/sec and the volume axis at least 10 mm/L. The percentage concentrations of inspired O_2, and inspired and expired CO and He for each of the maneuvers should be provided, and the algorithm used to calculate test results noted. Sufficient data must be provided to permit independent calculation of results (and, if necessary, calculation of corrections for anemia and/or carboxyhemoglobin).

2. *Arterial blood gas studies (ABGS).* An ABGS performed at rest (while breathing room air, awake and sitting or standing) or during exercise should be analyzed in a laboratory certified by a State or Federal agency. If the laboratory is not certified, it must submit evidence of participation in a national proficiency testing program as well as acceptable quality control at the time of testing. The report should include the altitude of the facility and the barometric pressure on the date of analysis.

Purchase of resting ABGS may be appropriate when there is a question of whether an impairment meets or is equivalent in severity to a listing, and the claim cannot otherwise be favorably decided. If the results of a DLCO study are greater than 40 percent of predicted normal but less than 60 percent of predicted normal, purchase of resting ABGS should be considered. Before purchasing resting ABGS, a program physician, preferably one experienced in the care of patients with pulmonary disease, must review all clinical and laboratory data short of this procedure, including spirometry, to determine whether obtaining the test would present a significant risk to the individual.

3. *Exercise testing.* Exercise testing with measurement of arterial blood gases during exercise may be appropriate in cases in which there is documentation of chronic pulmonary disease, but full development, short of exercise testing, is not adequate to establish if the impairment meets or is equivalent in severity to a listing, and the claim cannot otherwise be favorably decided. In this context, "full development" means that results from spirometry and measurement of DLCO and resting ABGS have been obtained from treating sources or through purchase. Exercise arterial blood gas measurements will be required infrequently and should be purchased only after careful review of the medical history, physical examination, chest x-ray or other appropriate imaging techniques, spirometry, DLCO, electrocardiogram (ECG), hematocrit or hemoglobin, and resting blood gas results by a program physician, preferably one experienced in the care of patients with pulmonary disease, to determine whether obtaining the test would presents a significant risk to the individual. Oximetry and capillary blood gas analysis are not acceptable substitutes for the measurement of arterial blood gases. Arterial blood gas samples obtained after the completion of exercise are not acceptable for establishing an individual's functional capacity.

Generally, individuals with a DLCO greater than 60 percent of predicted normal would not be considered for exercise testing with measurement of blood gas studies. The exercise test facility must be provided with the claimant's clinical records, reports of chest x-ray or other appropriate imaging techniques, and any spirometry, DLCO, and resting blood gas results obtained as evidence of record. The testing facility must determine whether exercise testing present a significant risk to the individual; if it does, the reason for not performing the test must be reported in writing.

4. *Methodology.* Individuals considered for exercise testing first should have resting arterial blood partial pressure of oxygen (PO_2), resting arterial blood partial pressure of carbon dioxide (PCO_2) and negative log of hydrogen ion concentration (pH) determinations by the testing facility. The sample should be obtained in either the sitting or standing position. The individual should then perform exercise under steady state conditions, preferably on a treadmill, breathing room air, for a period of 4 to 6 minutes at a speed and grade providing an oxygen consumption of approximately 17.5 ml/kg/min (5 METs). If a bicycle ergometer is used, an exercise equivalent of 5 METs (e.g., 450 kpm/min, or 75 watts, for a 176 pound (80 kilogram) person) should be used. If the individual is able to complete this level of exercise without achieving listing-level hypoxemia, then he or she should be exercised at higher workloads to determine exercise capacity. A warm-up period of treadmill walking or cycling may be performed to acquaint the individual with the exercise procedure. If during the warm-up period the individual cannot achieve an exercise level of 5 METs, a lower workload may be selected in keeping with the estimate of exercise capacity. The individual should be monitored by ECG throughout the exercise and in the immediate post-exercise period. Blood pressure and an ECG should be recorded during each minute of exercise. During the final 2 minutes of a specific level of steady state exercise, an arterial blood sample should be drawn and analyzed for oxygen pressure (or tension) (PO_2), carbon dioxide pressure (or tension) (PCO_2), and pH. At the discretion of the testing facility, the sample may be obtained either from an indwelling arterial catheter or by direct arterial puncture. If possible, in order to evaluate exercise capacity more accurately, a test site should be selected that has the capability to measure minute ventilation, O_2 consumption, and carbon dioxide (CO_2) production. If the claimant fails to complete 4 to 6 minutes of steady state exercise, the testing laboratory should comment on

the reason and report the actual duration and levels of exercise performed. This comment is necessary to determine if the individual's test performance was limited by lack of effort or other impairment (e.g., cardiac, peripheral vascular, musculoskeletal, neurological).

The exercise test report should contain representative ECG strips taken before, during and after exercise; resting and exercise arterial blood gas values; treadmill speed and grade settings, or, if a bicycle ergometer was used, exercise levels expressed in watts or kpm/min; and the duration of exercise. Body weight also should be recorded. If measured, O_2 consumption (STPD), minute ventilation (BTPS), and CO_2 production (STPD) also should be reported. The altitude of the test site, its normal range of blood gas values, and the barometric pressure on the test date must be noted.

G. *Chronic cor pulmonale and pulmonary vascular disease.*

The establishment of an impairment attributable to irreversible cor pulmonale secondary to chronic pulmonary hypertension requires documentation by signs and laboratory findings of right ventricular overload or failure (e.g., an early diastolic right-sided gallop on auscultation, neck vein distension, hepatomegaly, peripheral edema, right ventricular outflow tract enlargement on x-ray or other appropriate imaging techniques, right ventricular hypertrophy on ECG, and increased pulmonary artery pressure measured by right heart catheterization available from treating sources). Cardiac catheterization will not be purchased. Because hypoxemia may accompany heart failure and is also a cause of pulmonary hypertension, and may be associated with hypoventilation and respiratory acidosis, arterial blood gases may demonstrate hypoxemia (decreased PO_2), CO_2 retention (increased PCO_2), and acidosis (decreased pH). Polycythemia with an elevated red blood cell count and hematocrit may be found in the presence of chronic hypoxemia.

P-pulmonale on the ECG does not establish chronic pulmonary hypertension or chronic cor pulmonale. Evidence of florid right heart failure need not be present at the time of adjudication for a listing (e.g., 3.09) to be satisfied, but the medical evidence of record should establish that cor pulmonale is chronic and irreversible.

H. *Sleep-related breathing disorders.*

Sleep-related breathing disorders (sleep apneas) are caused by periodic cessation of respiration associated with hypoxemia and frequent arousals from sleep. Although many individuals with one of these disorders will respond to prescribed treatment, in some, the disturbed sleep pattern and associated chronic nocturnal hypoxemia cause daytime sleepiness with chronic pulmonary hypertension and/or disturbances in cognitive function. Because daytime sleepiness can affect memory, orientation, and personality, a longitudinal treatment record may be needed to evaluate mental functioning. Not all individuals with sleep apnea develop a functional impairment that affects work activity. When any gainful work is precluded, the physiologic basis for the impairment may be chronic cor pulmonale. Chronic hypoxemia due to episodic apnea may cause pulmonary hypertension (see 3.00G and 3.09). Daytime somnolence may be associated with disturbance in cognitive vigilance. Impairment of cognitive function may be evaluated under organic mental disorders (12.02). If the disorder is associated with gross obesity, it should be evaluated under the applicable obesity listing.

3.01 Category of Impairments, Respiratory System.

3.02 *Chronic pulmonary insufficiency.*

A. Chronic obstructive pulmonary disease, due to any cause, with the FEV_1 equal to or less than the values specified in table I corresponding to the person's height without shoes. (In cases of marked spinal deformity, see 3.00E.);

TABLE I

Height without shoes (centimeters)	Height without shoes (inches)	FEV_1 equal to or less than (L, BTPS)
154 or less	60 or less	1.05
155–160	61–63	1.15
161–165	64–65	1.25
166–170	66–67	1.35
171–175	68–69	1.45
176–180	70–71	1.55
181 or more	75 or more	1.65

Or

B. Chronic restrictive ventilatory disease, due to any cause, with the FVC equal to or less than the values specified in Table II corresponding to the person's height without shoes. (In cases of marked spinal deformity, see 2.00E.);

TABLE II

Height without shoes (centimeters)	Height without shoes (inches)	FVC equal to or less than (L, BTPS)
154 or less	60 or less	1.25
155–160	61–63	1.35
161–165	64–65	1.45
166–170	66–67	1.55
171–175	68–69	1.65
176–180	70–71	1.75
181 or more	72 or more	1.85

Or

C. Chronic impairment of gas exchange due to clinically documented pulmonary disease. With:

1. Single breath DLCO (see 3.00F1) less than 10.5 ml/min/mm Hg or less than 40 percent of the predicted normal value. (Predicted values must either be based on data obtained at the test site or published values from a laboratory using the same technique as the test site. The source of the predicted values should be reported. If they are not published, they should be submitted in the form of a table or nomogram); or

2. Arterial blood gas values of PO_2 and simultaneously determined PCO_2 measured while at rest (breathing room air, awake and sitting or standing) in a clinically stable condition on at least two occasions, three or more weeks apart within a 6-month period, equal to or less than the values specified in the applicable table III–A or III–B or III–C:

TABLE III.—A

[Applicable at test sites less than 3,000 feet above sea level]

Arterial PCO_2 (mm. Hg) and	Arterial PO_2 equal to or less than (mm. Hg)
30 or below	65
31	64
32	63
33	62
34	61
35	60
36	59
37	58
38	57
39	56
40 or above	55

TABLE III.—B

[Applicable at test sites 3,000 through 6,000 feet above sea level]

Arterial PCO_2 (mm. Hg) and	Arterial PO_2 equal to or less than (mm. Hg)
30 or below	60

TABLE III.—B—Continued

[Applicable at test sites 3,000 through 6,000 feet above sea level]

Arterial PCO_2 (mm. Hg) and	Arterial PO_2 equal to or less than (mm. Hg)
31	59
32	58
33	57
34	56
35	55
36	54
37	53
38	52
39	51
40 or above	50

TABLE III.—C

[Applicable at test sites over 6,000 feet above sea level]

Arterial PCO_2 (mm. Hg) and	Arterial PO_2 or equal to or less than (mm. Hg)
30 or below	55
31	54
32	53
33	52
34	51
35	50
36	49
37	48
38	47
39	46
40 or above	45

Or

3. Arterial blood gas values of PO_2 and simultaneously determined PCO_2 during steady state exercise breathing room air (level of exercise equivalent to or less than 17.5 ml O_2 consumption/kg/min or 5 METs) equal to or less than the values specified in the applicable table III–A or III–B or III–C in 3.02C2.

3.03 Asthma. With:

A. Chronic asthmatic bronchitis. Evaluate under the criteria for chronic obstructive pulmonary disease in 3.02A;

Or

B. Attacks (as defined in 3.00C), in spite of prescribed treatment and requiring physician intervention, occurring at least once every 2 months or at least six times a year. Each in-patient hospitalization for longer than 24 hours for control of asthma counts as two attacks, and an evaluation period of at least 12 consecutive months must be used to determine the frequency of attacks.

3.04 Cystic fibrosis. With:

A. An FEV_1 equal to or less than the appropriate value specified in table IV corresponding to the individual's height without shoes. (In cases of marked spinal deformity, see 3.00E.);

Or

B. Episodes of bronchitis or pneumonia or hemoptysis (more than blood-streaked sputum) or respiratory failure (documented according to 3.00C), requiring physician intervention, occurring at least once every 2 months or at least six times a year. Each inpatient hospitalization for longer than 24 hours for treatment counts as two episodes, and an evaluation period of at least 12 consecutive months must be used to determine the frequency of episodes;

Or

C. Persistent pulmonary infection accompanied by superimposed, recurrent, symptomatic episodes of increased bacterial infection occurring at least once every 6 months and requiring intravenous or nebulization antimicrobial therapy.

TABLE IV

[Applicable only for evaluation under 3.04A—cystic fibrosis]

Height without shoes (centimeters)	Height without shoes (inches)	FEV_1 equal to or less than (L, BTPS)
154 or less	60 or less	1.45
155–159	61–62	1.55
160–164	63–64	1.65
165–169	65–66	1.75
170–174	67–68	1.85
175–179	69–70	1.95
180 or more	71 or less	2.05

3.05 [Reserved]

3.06 *Pneumoconiosis* (demonstrated by appropriate imaging techniques). Evaluate under the appropriate criteria in 3.02.

3.07 *Bronchiectasis* (demonstrated by appropriate imaging techniques). With:

A. Impairment of pulmonary function due to extensive disease. Evaluate under the appropriate criteria in 3.02;

Or

B. Episodes of bronchitis or pneumonia or hemoptysis (more than blood-streaked sputum) or respiratory failure (documented according to 3.00C), requiring physician intervention, occurring at least once every 2 months or at least six times a year. Each in-patient hospitalization for longer than 24 hours for treatment counts as two episodes, and an evaluation of at least 12 consecutive months must be used to determine the frequency of episodes.

3.08 *Mycobacterial, mycotic, and other chronic persistent infections of the lung* (see 3.00B). Evaluate under the appropriate criteria in 3.02.

3.09 *Cor pulmonale secondary to chronic pulmonary vascular hypertension.* Clinical evidence of cor pulmonale (documented according to 3.00G) with:

A. Mean pulmonary artery pressure greater than 40 mm Hg;

Or

B. Arterial hypoxemia. Evaluate under the criteria in 3.02C2;

Or

C. Evaluate under the applicable criteria in 4.02.

3.10 *Sleep-related breathing disorders.* Evaluate under 3.09 (chronic cor pulmonale), 9.09 (obesity), or 12.02 (organic mental disorders).

* * * * *

4. Part B of appendix 1 (Listing of Impairments) of subpart P is amended by revising 103.00, Respiratory System, to read as follows:

Part B

* * * * *

103.00 Respiratory System

A. *Introduction.* The listings in this section describe impairments resulting from respiratory disorder based on symptoms, physical signs, laboratory test abnormalities, and response to a regimen of treatment prescribed by a treating source. Respiratory disorders, along with any associated impairment(s) must be established by medical evidence. Evidence must be provided in sufficient detail to permit an independent reviewer to evaluate the severity of the impairment. Reasonable efforts should be made to ensure evaluation by a program physician specializing in childhood respiratory impairments or a qualified pediatrician.

Many children, especially those who have listing-level impairments, will have received the benefit of medically prescribed treatment. Whenever there is such evidence, the longitudinal clinical record must include a description of the treatment prescribed by the treating source and response, in addition to information about the nature and severity of the impairment. It is important to document any prescribed treatment and response because this medical management may have improved the child's functional status. The longitudinal record should provide information regarding functional recovery, if any.

Some children will not have received ongoing treatment or have an ongoing relationship with the medical

community, despite the existence of a severe impairment(s). A child who does not receive treatment may or may not be able to show an impairment that meets the criteria of these listings. Even if a child does not show that his or her impairment meets the criteria of these listings, the child may have an impairment(s) equivalent in severity to one of the listed impairments or be disabled because of a substantial reduction in the ability to function independently, appropriately, and effectively in an age-appropriate manner. Unless the claim can be decided favorably on the basis of the current evidence, a longitudinal record is still important because it will provide information about such things as the ongoing medical severity of the impairment, the level of the child's functioning, and the frequency, severity, and duration of symptoms. Also, the asthma listing specifically includes a requirement for continuing signs and symptoms despite a regimen of prescribed treatment.

Evaluation should include consideration of adverse effects of respiratory impairment in all relevant body systems, and especially on the child's growth and development or mental functioning, as described under the growth impairment (100.00), neurological (111.00), and mental disorders (112.00) listings.

It must be remembered that these listings are only examples of common respiratory disorders that are severe enough to prevent a child from functioning independently, appropriately, and effectively in an age-appropriate manner. When a child has a medically determinable impairment that is not listed, an impairment which does not meet a listing, or a combination of impairments no one of which meets a listing, we may make an equivalence determination on medical or functional grounds. Also, with respect to children claiming SSI benefits under title XVI of the Act who have an impairment(s) with a level of severity which does not meet or equal (medically or functionally) the criteria of the listings, we will determine whether the impairment(s) is of comparable severity to one that would disable an adult. In these cases, we will perform an individualized functional assessment to determine whether the child is disabled.

B. *Documentation of Pulmonary Function Testing.* The results of spirometry that are used for adjudication, under the 103.02 A and B, 103.03, and 103.04 of these listings should be expressed in liters (L), body temperature and pressure saturated with water vapor (BTPS). The reported one-second forced expiratory volume (FEV_1) and forced vital capacity (FVC) should represent the largest of at least three satisfactory forced expiratory maneuvers. Two of the satisfactory spirograms should be reproducible for both pre-bronchodilator tests and, if indicated, post-bronchodilator tests. A value is considered reproducible if it does not differ from the largest value by more than 5 percent or 0.1 L, whichever is greater. The highest values of the FEV_1 and FVC, whether from the same or different tracings, should be used to assess the severity of the respiratory impairment. Peak flow should be achieved early in expiration, and the spirogram should have a smooth contour with gradually decreasing flow throughout expiration. The zero time for measurement of the FEV_1 and FVC, if not distinct, should be derived by linear back-extrapolation of peak flow to zero volume. A spirogram is satisfactory for measurement of the FEV_1 if the expiratory volume at the back-extrapolated zero time is less than 5 percent of the FVC or 0.1 L, whichever is greater. The spirogram is satisfactory for measurement of the FVC if maximal expiratory effort continues for at least 6 seconds, or if there is a plateau in the volume-time curve with no detectable change in expired volume (VE) during the last 2 seconds of maximal expiratory effort.

Spirometry should be repeated after administration of an aerosolized bronchodilator under supervision of the testing personnel if the pre-bronchodilator FEV_1 value is less than the appropriate reference value in table I or III, as appropriate. If a bronchodilator is not administered, the reason should be clearly stated in the report. Pulmonary function studies should not be performed unless the clinical status is stable (e.g., the child is not having an asthmatic attack or suffering from an acute respiratory infection or other chronic illness). Wheezing is common in asthma, chronic bronchitis, or chronic obstructive pulmonary disease and does not preclude testing. Pulmonary function studies performed to assess airflow obstruction without testing after bronchodilators cannot be used to assess levels of impairment in the range that prevents a child from performing age-appropriate activities, unless the use of bronchodilators is contraindicated. Post-bronchodilator testing should be performed 10 minutes after bronchodilator administration. The dose and name of the bronchodilator administered should be specified. The values in 103.02 and 103.04 must only be used as criteria for the level of ventilatory impairment that exists during the child's most stable state of health (i.e., any period in time except during or shortly after an exacerbation).

The appropriately labeled spirometric tracing, showing the child's name, date of testing, distance per second on the abscissa and distance per liter (L) on the ordinate, must be incorporated into the file. The manufacturer and model number of the device used to measure and record the spirogram should be stated. The testing device must accurately measure both time and volume, the latter to within 1 percent of a 3 L calibrating volume. If the spirogram was generated by any means other than direct pen linkage to a mechanical displacement-type spirometer, the spirometric tracing must show a recorded calibration of volume units using a mechanical volume input such as a 3 L syringe.

If the spirometer directly measures flow, and volume is derived by electronic integration, the linearity of the device must be documented by recording volume calibrations at three different flow rates of approximately 30 L/min (3 L/6 sec), 60 L/min (3 L/3 sec), and 180 L/min (3 L/sec). The volume calibrations should agree to within 1 percent of a 3 L calibrating volume. The proximity of the flow sensor to the child should be noted, and it should be stated whether or not a BTPS correction factor was used for the calibration recordings and for the child's actual spirograms.

The spirogram must be recorded at a speed of at least 20 mm/sec and the recording device must provide a volume excursion of at least 10 mm/L. If reproductions of the original spirometric tracings are submitted, they must be legible and have a time scale of at least 20 mm/sec and a volume scale of at least 10 mm/L to permit independent measurements. Calculation of FEV_1 from a flow volume tracing is not acceptable, i.e., the spirogram and calibrations must be presented in a volume-time format at a speed of at least 20 mm/sec and a volume excursion of at least 10 mm/L to permit independent evaluation.

A statement should be made in the pulmonary function test report of the child's ability to understand directions, as well as his or her efforts and cooperation in performing the pulmonary function tests.

Purchase of a pulmonary function test is appropriate only when the child is capable of performing reproducible forced expiratory maneuvers. This capability usually occurs around age 6. Purchase of a pulmonary function test may be appropriate when there is a

question of whether an impairment meets or is equivalent in severity to a listing, and the claim cannot otherwise be favorably decided.

The pulmonary function tables in 103.02 and 103.04 are based on measurement of standing height without shoes. If a child has marked spinal deformities (e.g., kyphoscoliosis), the measured span between the fingertips with the upper extremities abducted 90 degrees should be substituted for height when this measurement is greater than the standing height without shoes.

C. *Documentation of chronic impairment of gas exchange.*

1. *Arterial blood gas studies (ABGS).* An ABGS performed at rest (while breathing room air, awake and sitting or standing) should be analyzed in a laboratory certified by a State or Federal agency. If the laboratory is not certified, it must submit evidence of participation in a national proficiency testing program as well as acceptable quality control at the time of testing. The report should include the altitude of the facility and the barometric pressure on the date of analysis.

Purchase of resting ABGS may be appropriate when there is a question of whether an impairment meets or is equivalent in severity to a listing, and the claim cannot otherwise be favorably decided. Before purchasing resting ABGS, a program physician, preferably one experienced in the care of children with pulmonary disease, must review the clinical and laboratory data short of this procedure, including spirometry, to determine whether obtaining the test would present a significant risk to the child.

2. *Oximetry.* Pulse oximetry may be substituted for arterial blood gases in children under 12 years of age. The oximetry unit should employ the basic technology of spectrophotometric plethysmography as described in Taylor, M.B., and Whitwain, J.G., "Current Status of Pulse Oximetry," "Anesthesia," Vol. 41, No. 9, pp. 943–949, 1986. The unit should provide a visual display of the pulse signal and the corresponding oxygen saturation. A hard copy of the readings (heart rate and saturation) should be provided. Readings should be obtained for a minimum of 5 minutes. The written report should describe patient activity during the recording, i.e., sleep rate, feeding, or exercise. Correlation between the actual heart rate determined by a trained observer and that displayed by the oximeter should be provided. A statement should be made in the report of the child's effort and cooperation during the test.

Purchase of oximetry may be appropriate when there is a question of whether an impairment meets or is equivalent in severity to a listing, and the claim cannot otherwise be favorably decided.

D. *Cystic fibrosis* is a disorder that affects either the respiratory or digestive body systems or both and may impact on a child's growth and development. It is responsible for a wide and variable spectrum of clinical manifestations and complications. Confirmation of the diagnosis is based upon an elevated sweat sodium concentration or chloride concentration accompanied by one or more of the following: the presence of chronic obstructive pulmonary disease, insufficiency of exocrine pancreatic function, meconium ileus, or a positive family history. The quantitative pilocarpine iontophoresis procedure for collection of sweat content must be utilized. Two methods are acceptable: the "Procedure for the Quantitative Iontophoretic Sweat Test for Cystic Fibrosis," published by the Cystic Fibrosis Foundation and contained in, "A Test for Concentration of Electrolytes in Sweat In Cystic Fibrosis of the Pancreas Utilizing Pilocarpine Iontophoresis," Gibson, L.E., and Cooke, R.E., "Pediatrics," Vol 23: 545, 1959; or the "Wescor Macroduct System." To establish the diagnosis of cystic fibrosis, the sweat sodium or chloride content must be analyzed quantitatively using an acceptable laboratory technique. Another diagnostic test is the "CF gene mutation analysis" for homozygosity of the cystic fibrosis gene. The pulmonary manifestations of this disorder should be evaluated under 103.04. The nonpulmonary aspects of cystic fibrosis should be evaluated under the listings for the digestive system (105.00) or growth impairments (100.00). Because cystic fibrosis may involve the respiratory and digestive body systems, as well as impact on a child's growth and development, the combined effects of this involvement must be considered in case adjudication.

E. *Bronchopulmonary dysplasia (BPD).* Bronchopulmonary dysplasia is a form of chronic obstructive pulmonary disease that arises as a consequence of acute lung injury in the newborn period and treatment of hyaline membrane disease, meconium aspiration, neonatal pneumonia and apnea of prematurity. The diagnosis is established by the requirement for continuous or nocturnal supplemental oxygen for more than 30 days, in association with characteristic radiographic changes and clinical signs of respiratory dysfunction, including retractions, rales, wheezing, and tachypnea.

103.01 Category of Impairments, Respiratory System

103.02 Chronic pulmonary insufficiency. With:

A. Chronic obstructive pulmonary disease, due to any cause, with the FEV_1 equal to or less than the value specified in Table I corresponding to the child's height without shoes. (In cases of marked spinal deformity, see 103.00B.);

TABLE I

Height without shoes (centimeters)	Height without shoes (inches)	FEV_1 equal to or less than (L, BTPS)
119 or less	46 or less	0.65
120–129	47–50	0.75
130–139	51–54	0.95
140–149	55–58	1.15
150–159	59–62	1.35
160–164	63–64	1.45
165–169	65–66	1.55
170 or more	67 or more	.165

Or

B. Chronic restrictive ventilatory disease, due to any cause, with the FVC equal to or less than the value specified in table II corresponding to the child's height without shoes. (In cases of marked spinal deformity, see 103.00B.);

TABLE II

Height without shoes (centimeters)	Height without shoes (inches)	FEV equal to or less than (L, BTPS)
119 or less	46 or less	0.65
120–129	47–50	0.85
130–139	51–54	1.05
140–149	55–58	1.25
150–159	59–62	1.45
160–164	63–64	1.65
165–169	65–66	175
170 or more	67 or more	205

Or

C Frequent need for:

1. Mechanical ventilation; or

2. Nocturnal supplemental oxygen as required by persistent or recurrent episodes of hypoxemia;

Or

D. The presence of a tracheostomy in a child under 3 years of age;

Or

E. Bronchopulmonary dysplasia characterized by two of the following:

1. Prolonged expirations; or

2. Intermittent wheezing or increased respiratory effort as evidenced by retractions, flaring and tachypnea; or

3. Hyperinflation and scarring on a chest radiograph or other appropriate imaging techniques; or

4. Bronchodilator or diuretic dependency; or

5. A frequent requirement for nocturnal supplemental oxygen; or

6. Weight disturbance with:

a. An involuntary weight loss (or failure to gain weight at an appropriate rate for age) resulting in a fall of 15 percentiles from established growth curve (on standard growth charts) which persists for 2 months or longer; or

b. An involuntary weight loss (or failure to gain weight at an appropriate rate for age) resulting in a fall to below the third percentile from established growth curve (on standard growth charts) which persists for 2 months or longer;

Or

F. Two required hospital admissions (each longer than 24 hours) within a 6-month period for recurrent lower respiratory tract infections or acute respiratory distress associated with:

1. Chronic wheezing or chronic respiratory distress; or

2. Weight disturbance with:

a. An involuntary weight loss (or failure to gain weight at an appropriate rate for age) resulting in a fall of 15 percentiles from established growth curve (on standard growth charts) which persists for 2 months or longer; or

b. An involuntary weight loss (or failure to gain weight at an appropriate rate for age) resulting in a fall to below the third percentile from established growth curve (on standard growth charts) which persists for 2 months or longer;

Or

G. Chronic hypoventilation ($PaCO_2$ greater than 45 mm Hg) or chronic cor pulmonale as described under the appropriate criteria in 104.02;

Or

H. Growth impairment as described under the criteria in 100.00.

103.03 Asthma. With:

A. FEV_1 equal to or less than the value specified in Table I of 103.02A;

Or

B. Attacks (as defined in 3.00C), in spite of prescribed treatment and requiring physician intervention, occurring at least once every 2 months or at least six times a year. Each inpatient hospitalization for longer than 24 hours for control of asthma counts as two attacks, and an evaluation period of at least 12 consecutive months must be used to determine the frequency of attacks;

Or

C. Persistent low-grade wheezing between acute attacks or absence of extended symptom-free periods requiring daytime and nocturnal use of sympathomimetic bronchodilators with one of the following:

1. Persistent prolonged expiration with radiographic or other appropriate imaging techniques evidence of pulmonary hyperinflation or peribronchial disease; or

2. Short courses of corticosteroids that average more than 5 days per month for at least 3 months during a 12-month period;

Or

D. Growth impairment as described under the criteria in 100.00.

103.04 Cystic fibrosis. With:

A. An FEV_1 equal to or less than the appropriate value specified in Table III corresponding to the child's height without shoes. (In cases of marked spinal deformity, see 103.00B.);

Or

B. For children in whom pulmonary function testing cannot be performed, the presence of two of the following:

1. History of dyspnea on exertion or accumulation of secretions as manifested by repetitive coughing or cyanosis; or

2. Persistent bilateral rales and rhonchi or substantial reduction of breath sounds related to mucous plugging of the trachea or bronchi; or

3. Radiographic evidence of extensive disease, such as thickening of the proximal bronchial airways or persistence of bilateral peribronchial infiltrates;

Or

C. Persistent pulmonary infection accompanied by superimposed, recurrent, symptomatic episodes of increased bacterial infection occurring at least once every 6 months and requiring intravenous or nebulization antimicrobial treatment;

Or

D. Episodes of bronchitis or pneumonia or hemoptysis (more than blood-streaked sputum) or respiratory failure (documented according to 3.00C), requiring physician intervention, occurring at least once every 2 months or at least six times a year. Each inpatient hospitalization for longer than 24 hours for treatment counts as two episodes, and an evaluation period of at least 12 consecutive months must be used to determine the frequency of episodes;

Or

E. Growth impairment as described under the criteria in 100.00.

TABLE III

[Applicable only for evaluation under 103.04A—cystic fibrosis]

Height without shoes (centimeters)	Height without shoes (inches)	FEV_1 equal to or less than (L, BTPS)
119 or less	46 or less	0.75
120–129	47–50	0.85
130–139	51–54	1.05
140–149	55–58	1.35
150–159	59–62	1.55
160–164	63–64	1.85
165–169	65–66	2.05
170 or more	67 or more	2.25

* * * * *

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

Subpart I—[Amended]

1. The authority citation for Subpart I continues to read as follows:

Authority: Secs. 1102, 1614(a), 1619, 1631(a) and (d)(1), and 1633 of the Social Security Act; 42 U.S.C. 1302, 1382c(a), 1382(h), 1383(a) and (d)(1), and 1383b.

2. Paragraphs (d)(3) and (d)(12) of § 416.926a are revised to read as follows:

§ 416.926a Equivalence for children.

* * * * *

(d) *Examples of impairments of children that are functionally equivalent to the listings.* * * *

* * * * *

(3) Frequent need for a life-sustaining device (e.g., central venous alimentation catheter), at home or elsewhere.

* * * * *

(12) Gastrostomy in a child who has not attained age 3.

* * * * *

[FR Doc. 93–24238 Filed 10–6–93; 8:45 am]

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federal register

Thursday
October 7, 1993

Part III

Department of Education

Federal Perkins Loan Program; Notice

DEPARTMENT OF EDUCATION

Federal Perkins Loan Program

AGENCY: Department of Education.

ACTION: Notice of deadline for submission of institutional agreement for participation in the Federal Perkins Loan Program Expanded Lending Option.

SUMMARY: "Dear Colleague Letter CB–93–12(LD)," dated August 1993, announced the Expanded Lending Option of the Federal Perkins Loan Program and transmitted, to all eligible institutions, the "Institutional Agreement For Participation In The Federal Perkins Loan Program Expanded Lending Option (ELO)" (ELO Participation Agreement). This notice establishes the deadline for submission of the ELO Participation Agreement by those eligible institutions that elect to participate in the Federal Perkins Loan Program ELO in the 1993–94 award year (the period from July 1, 1993 through June 30, 1994).

SUPPLEMENTARY INFORMATION: The Federal Perkins Loan Program provides low-interest loans to financially needy students attending institutions of higher education to help them pay their educational costs. The Higher Education Amendments of 1992 created the ELO as part of the Federal Perkins Loan Program, making the ELO available for the 1993–94 award year for institutions of higher education that participate in the Federal Perkins Loan Program.

To be eligible to participate in the Federal Perkins Loan Program ELO for 1993–94, an institution must have a Federal Perkins Loan default rate of 7.5 percent or less as of June 30, 1992 and must have participated in the Federal Perkins Loan Program for the two previous award years (1991–92 and 1992–93). In addition, an institution must enter into a special ELO participation agreement with the Secretary. An institution that elects to participate in the ELO must complete, sign, date and submit the ELO Participation Agreement by the closing date to obtain approval.

Institutions that become Federal Perkins Loan Program ELO participants will be required to increase the Institutional Capital Contribution (ICC) to at least a dollar-for-dollar match with any portion of the 1993–94 award year Federal Capital Contribution (FCC) received. Only new FCC received on or after July 1, 1993, would be matched at the increased rate. Institutions would not match funds received prior to July 1, 1993, at the higher rate. Institutions receiving no new FCC for the 1993–94 award year may still elect to participate in the Federal Perkins Loan Program ELO.

Institutions that become Federal Perkins Loan Program ELO participants may make loans to eligible students at higher maximum annual and aggregate limits than is the case with nonparticipating institutions. ELO participating institutions that do not ultimately make any loans at the higher ELO levels for the 1993–94 award year must still honor the ELO Participation Agreement to deposit in the Federal Perkins Loan Program Fund an ICC at least equal to the 1993–94 award year FCC deposited into the Fund. All other administrative procedures would remain the same as for institutions not participating in the Federal Perkins Loan Program ELO.

Closing Date for Transmittal of ELO Participation Agreement: To ensure participation in the Federal Perkins Loan Program ELO in the 1993–94 award year, an eligible institution that elects to participate, must submit its ELO Participation Agreement by November 8, 1993.

ELO Participation Agreement Delivered By Mail: An ELO Participation Agreement delivered by mail must be addressed to the U.S. Department of Education, Office of Student Financial Assistance, Campus-Based Programs, Financial Management Division, 400 Maryland Avenue, SW., room 4621, Regional Office Building 3, Washington, DC 20202–5452.

An institution must show proof of mailing its ELO Participation Agreement by the closing date. Proof of mailing consists of one of the following: (1) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service, (2) a legibly dated U.S. Postal Service postmark, (3) a dated shipping label, invoice, or receipt from a commercial carrier, or (4) any other proof of mailing acceptable to the U.S. Secretary of Education.

If an ELO Participation Agreement is sent through the U.S. Postal Service, the Secretary does not accept either of the following as proof of mailing: (1) A private metered postmark, or (2) a mail receipt that is not dated by the U.S. Postal Service. An Institution should note that the U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, an institution should check with its local post office. An institution is encouraged to use certified or at least first-class mail.

ELO Participation Agreement Delivered by Hand: An ELO Participation Agreement delivered by hand must be delivered to the U.S. Department of Education, Office of Student Financial Assistance, Campus-Based Programs, Financial Management Division, 7th and D Streets, SW., room 4621, Regional Office Building 3, Washington, DC.

Hand-delivered ELO Participation Agreements will be accepted between 8 a.m. and 4:30 p.m. daily (Eastern Daylight Time), except Saturdays, Sundays, and Federal holidays. An ELO Participation Agreement that is hand-delivered will not be accepted after 4:30 p.m. on the closing date.

Applicable Regulations: The following regulations apply to this program:

Student Assistance General Provisions, 34 CFR part 668.

Federal Perkins Loan Program, 34 CFR part 674.

Federal Work-Study Program, 34 CFR part 675.

Federal Supplemental Educational Opportunity Grant Program, 34 CFR part 676.

Institutional Eligibility Under the Higher Education Act of 1965, as amended, 34 CFR part 600.

Federal Family Educational Loan Program, 34 CFR part 682.

New Restrictions on Lobbying, 34 CFR part 82.

Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants), 34 CFR part 85.

FOR FURTHER INFORMATION CONTACT: For information concerning designation of eligibility, contact Robert Coates, Director Campus-Based Programs, Financial Management Division, Office of Postsecondary Education, 400 Maryland Avenue, SW., (Room 4621, ROB–3), Washington, DC 20202–5452. Telephone: 202–708–4664.

For technical assistance concerning the Federal Perkins Loan Program ELO, contact Susan Morgan, Chief, Campus-Based Loan Programs Section, Division of Policy Development, Student Financial Assistance Programs, Office of Postsecondary Education, U.S. Department of Education, Telephone: 202–708–8242 or Gwendolyn Dockett-Morris, Program Specialist, Telephone: 202–708–8242. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

(Catalog of Federal Domestic Assistance Numbers: 84.038, Federal Perkins Loan Program)

Dated: September 30, 1993.

William L. Moran,

Acting Assistant Secretary for Postsecondary Education.

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