SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404 and 416

[Regulations Nos. 4 and 16]

RIN 0960–AB01

Revised Medical Criteria for Determination of Disability, Musculoskeletal System and Related Criteria

AGENCY: Social Security Administration (SSA).

ACTION: Final rules with request for comments.

SUMMARY: We are revising the criteria in the Listing of Impairments (the listings) that we use to evaluate musculoskeletal impairments in adults and children who claim Social Security or Supplemental Security Income (SSI) benefits based on disability under titles II and XVI of the Social Security Act (the Act). The revisions reflect advances in medical knowledge, treatment, and methods of evaluating musculoskeletal impairments.

When the final rules become effective, we will apply them to new applications filed on or after the effective date of the rules and to other claims described in the preamble. Individuals who currently receive benefits will not lose eligibility as a result of these final rules.

Also, although some individuals with musculoskeletal impairments will not meet the requirements of these final listings, they may still be found disabled at a later step in the sequential evaluation process based on their functional limitations.

DATES: These regulations are effective February 19, 2002. Comments must be received on or before January 18, 2002.

ADDRESSES: You may give us your comments via: our Internet site facility (i.e., Social Security Online) at *http://www.ssa.gov/regulations/index.htm;* e-mail to *regulations@ssa.gov;* telefax to (410) 966–2830; or, letter to the Commissioner of Social Security, P.O. Box 17703, Baltimore, Maryland 21235–7703. You may also deliver them to the Office of Process and Innovation Management, Social Security Administration, L2109 West Low Rise Building, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, between 8:00 a.m. and 4:30 p.m. on regular business days. Comments are posted on our Internet site, or you may inspect them on regular business days by making arrangements with the contact person shown in this preamble.

FOR FURTHER INFORMATION CONTACT: Suzanne DiMarino, Social Insurance Specialist, Office of Process and Innovation Management, 2109 West Low Rise, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, (410) 965–1769 or TTY (410) 966–5609 for information about these rules. For information on eligibility, claiming benefits, or coverage of earnings, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit our Internet web site, Social Security Online, at www.ssa.gov.

SUPPLEMENTARY INFORMATION: We are revising and making final the rules we proposed in the Notice of Proposed Rulemaking (NPRM) published in the **Federal Register** on December 21, 1993 (58 FR 67574). Although we are publishing these regulations as final rules, we also are providing the public with the opportunity to provide us with comments on the changes we have made in these final rules. Although this is not our usual practice when we issue final rules, we are providing an opportunity to comment on these changes for two reasons. First, we recognize that there is significant public interest in the listings that we use to adjudicate musculoskeletal impairments, since impairments of the musculoskeletal system represent a high percentage of cases that we adjudicate under the listings. Second, we are committed to ensuring that the listings for the musculoskeletal body system continue to reflect appropriate advances in medical knowledge, treatment and methods of evaluating musculoskeletal impairments. In light of the advances in medical knowledge with respect to the treatment and evaluation of musculoskeletal impairments, we have determined that the most appropriate way to ensure that the requirements of these listings continue to reflect current medical knowledge is to request public comments on the changes we are making in these final rules.

We provide a summary of the provisions of the final rules below. A more detailed explanation of the provisions of the final rules and the changes we have made from the text in the NPRM follows in the section, ''Revisions to Appendix 1.'' We then provide a summary of the public comments and our reasons for adopting or not adopting the recommendations in the summaries of the comments in the section, ''Public Comments.'' The final rule language follows the comment section.

Background

The Act provides, in title II, for the payment of disability benefits to individuals insured under the Act. Title II also provides child's insurance benefits based on disability and widow's and widower's insurance benefits for disabled 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 adults under both the title II and title XVI programs and for persons claiming child's insurance benefits based on disability under the title II program, ''disability'' means that an impairment(s) results in an inability to engage in any substantial gainful activity. For a child claiming SSI benefits based on disability, ''disability'' means that an impairment(s) causes marked and severe functional limitations. Under both title II and title XVI, disability must be the result of a medically determinable physical or mental impairment(s) 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.

The listings contain examples of some of the most frequently encountered 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 person from doing any gainful activity, or in the case of a child claiming SSI benefits under title XVI of the Act, an impairment that causes marked and severe functional limitations. The listings help to ensure that determinations and decisions regarding disability have a sound medical basis, that claimants receive equal treatment through the use of specific criteria, and that people who are disabled can be readily identified and awarded benefits if all other factors of entitlement or eligibility are met.

The listings contained in appendix 1 to subpart P of part 404 are referenced in subpart I of part 416. The listings are divided into part A and part B. The criteria in part A are applied in evaluating impairments of persons age 18 or over. The criteria in part A may also be applied in evaluating impairments in children (persons under age 18) if the disease processes have a similar effect on adults and children. In evaluating disability for children using the listings, we first use the criteria in part B and, if the criteria in part B do not apply, we use the criteria in part A. See §§ 404.1525 and 416.925. We use the criteria in the listings only to make favorable determinations or decisions regarding disability. We never deny a claim or find that an individual's disability has ceased because an impairment(s) does not meet or medically equal a listing. When an

individual has a severe impairment(s) that does not meet or medically equal a listing, we may still find him or her disabled (or still disabled) based on other rules. For more information about our sequential evaluation processes for adults and children, see §§ 404.1520, 416.920, and 416.924 of our regulations regarding initial claims and §§ 404.1594, 416.994, and 416.994a of our regulations regarding continuing disability reviews.

When the musculoskeletal listings were revised and published in the **Federal Register** on December 6, 1985 (50 FR 50068), we indicated that medical advances in disability evaluation and treatment and program experience would require that we periodically review and update the medical criteria in the listings. Accordingly, we published termination dates ranging from 4 to 8 years for each of the specific body system listings. These dates currently appear in the introductory text of the listings. We published the latest extension for part A and part B of the musculoskeletal listings, until July 2, 2003, in the **Federal Register** on June 28, 2001 at 66 FR 34361. We are now updating the listings for the musculoskeletal system in 1.00 (part A) and 101.00 (part B). These regulations will expire 7 years after the effective date unless revised and issued again or extended.

We published these regulations in the **Federal Register** on December 21, 1993 (58 FR 67574) as an NPRM. We gave members of the public a period of 60 days in which to comment. The comment period ended on February 22, 1994. Thirty-four commenters provided comments on the NPRM. We have carefully considered all the comments submitted and we respond below to those comments that were substantive. In addition, we discuss the significant differences between the final rules and the proposed rules and the changes we have made in response to the public comments.

Explanation of the Effective Date

As we noted in the ''Date'' section of this preamble, these final rules will be effective February 19, 2002. Under the provisions of 5 U.S.C. 801ff, for certain rules, we must provide an effective date of no less than 60 days after the later of the date the rule is published in the **Federal Register** or the date on which we sent them to Congress for review. There are also extensive changes in these final rules, and we need additional time to provide training and instructions to all of our adjudicators. For these reasons, we have provided that the rules will not be effective until 90 days after the date on which we published them. In addition, we will carefully consider any comments we receive in order to determine whether any changes in these rules are necessary. We will then respond to the comments we receive and publish any necessary revisions as final rules.

We will continue to apply the current rules until the effective date of these final rules. When the final rules become effective, we will apply them to new applications filed on or after the effective date of the rules. Individuals who currently receive benefits will not lose eligibility solely as a result of these listings going into effect.

When we conduct reviews to determine whether an individual's disability continues, we do not find that disability has ended based only on these changes in the listings. Our regulations explain that we continue to use our prior listings when we review the cases of people who receive disability benefits or SSI payments because we found that their impairments met or equaled those listings. In these cases, we determine whether the individual has experienced medical improvement, and if so, whether the medical improvement is related to the ability to work. If the individual's impairment still meets or equals the same listing section that we used to make our most recent favorable determination or decision, we will find the medical improvement is not related to the ability to work. If the individual's condition has medically improved so that he or she no longer meets or equals the prior listing, we engage in further evaluation to determine whether the individual is currently disabled. We may find that such an individual is currently disabled, depending on the full circumstances of his or her case. See 20 CFR 404.1594(c)(3)(i), 416.994(b)(2)(iv)(A). We follow a similar rule when we decide whether a child who is eligible for SSI payments has experienced medical improvement in his or her condition. 20 CFR 416.994a(b)(2).

As is our usual practice when we make changes to our regulations, we will apply these final rules to the claims of applicants for benefits that are pending at any stage of our administrative review process, including those claims that are pending administrative review after remand from a Federal court. With respect to claims in which we have made a final decision, and that are pending judicial review in Federal court, we expect that the court's review of the Commissioner's final decision would be made in accordance with the rules in effect at the time of the final decision. If the court determines that the Commissioner's final decision is not supported by substantial evidence, or contains an error of law, we would expect that the court would reverse the final decision, and remand the case for further administrative proceedings pursuant to the fourth sentence of section 205(g) of the Act, except in those few instances in which the court determines that it is appropriate to reverse the final decision and award benefits, without remanding the case for further administrative proceedings. In those cases decided by a court after the effective date of the rules, where the court vacates the Commissioner's final decision and remands the case for further administrative proceedings, on remand, we will apply the provisions of these final rules to the entire period at issue in the claim.

Explanation of the Final Rules

For clarity, we refer to the changes we are making here as ''final'' rules and to the rules that will be changed by these final rules as the ''current'' rules. These final rules update our regulations to reflect advances in the medical treatment and methods of evaluating musculoskeletal impairments since we published the current rules. We explain the reasons for these changes in more detail below. Because these final rules provide listing-level criteria that reflect advances in medical science and technology, some individuals with musculoskeletal impairments who would meet the criteria of the current listings will not meet the requirements of these final listings. Although these individuals may not have their claims allowed at the third step of our sequential evaluation process, depending on their residual functional capacity and age, education and past work experience, they may be found disabled at a later step in the sequential evaluation process.

It must be remembered that these final rules do not go into effect until February 19, 2002. Therefore, the current rules remain in effect until that date.

A claimant with a musculoskeletal impairment, as a claimant with any other impairment(s), may be found disabled without considering age, education, and work experience, if his or her impairment(s) meets or equals one of the sets of medical criteria in the listings. We do not deny any adult's claim solely because his or her impairment(s) does not meet or equal in severity the requirements of any listing. Under the sequential evaluation process set out in §§ 404.1520 and 416.920 of our regulations, for every adult claimant whose severe impairment or combination of impairments does not

meet or equal in severity a listing, we assess his or her residual functional capacity to determine what he or she can still do despite his or her limitations. This individualized assessment of the individual's functioning considers all relevant evidence. Using the residual functional capacity assessment, we determine whether the person retains the capacity to perform his or her past relevant work; if not, we determine if any other work exists in significant numbers in the national economy, considering the individual's residual functional capacity, age, education, and work experience. Thus, we do not deny any adult's claim of disability on the sole basis that the individual's musculoskeletal impairment or any other impairment(s) does not meet or equal in severity the criteria of a listing.

For children claiming SSI benefits based on disability, the impairment(s) must cause marked and severe functional limitations as defined in § 416.906 following a sequential evaluation process for children set out in § 416.924. If the child has a severe impairment that does not meet or medically equal the requirements of a listed impairment, we will determine if the child's impairment(s) functionally equals listing-level severity (see § 416.926a.) If the child's impairment(s) does not meet or medically or functionally equal the requirements of the listings, we will find that he or she is not disabled.

The final rules stress a finding of disability under the musculoskeletal listings on the basis of how the individual is functioning. This factor, especially as it relates to the individual's ability to ambulate and perform fine and gross movements effectively on a sustained basis, drew the greatest number of comments, both positive and negative. For reasons that we will explain in detail below, we have kept with some minor modifications the sections on ability to ambulate and perform fine and gross movements effectively, because we continue to believe that these represent appropriate benchmarks for deciding whether the majority of musculoskeletal impairments are of listing-level severity. We believe these functional criteria represent an appropriate method to evaluate listing-level severity in individuals with musculoskeletal impairments. We will carefully monitor these musculoskeletal listings to ensure that they continue to meet program intent as part of our ongoing review of our criteria in the Listing of Impairments for evaluating musculoskeletal impairments.

As we stated earlier, current beneficiaries will not lose eligibility solely as a result of these listings going into effect. If the beneficiary's impairment(s) does not meet or medically equal the requirements of a listing, we may still find him or her disabled based on other rules. For more information about our sequential evaluation processes for adults and children, see §§ 404.1520, 416.920, and 416.924 of our regulations regarding initial claims, and §§ 404.1594, 416.994, and 416.994a of our regulations regarding continuing disability reviews.

The following is a summary of the provisions of the final rules and the changes we have made from the text of the NPRM published on December 21, 1993 (58 FR 67574) and the comments we received on it. A more detailed discussion of the changes made and why we made them follows in the section discussing public comments. The changes in the proposed rules ''Technical Revisions to Medical Criteria for Determinations of Disability'' that we published in the **Federal Register** on February 11, 2000 (65 FR 6929), and the comments we received in response to that NPRM are not addressed here.

Revisions to Appendix 1

We revised item 2 in the second paragraph of the introductory text to Appendix 1 to show that the part A and part B musculoskeletal system listings will expire 7 years after the effective date of the final regulations.

Revisions to Part A of Appendix 1

1.00 Musculoskeletal System

We reorganized and revised 1.00, the introductory section of the musculoskeletal listings, to bring it up to date and to reflect the new listings. To facilitate use of the new listings, we have provided sub-section headings for the text in this section.

1.00A Disorders of the Musculoskeletal System

This is a new, brief introductory section which describes the pathologic processes that may cause musculoskeletal impairments.

1.00B Loss of Function

We redesignated the section on loss of function from 1.00A in the current rules to 1.00B and have expanded the section to provide more information about the causes of, and ways to evaluate, loss of function resulting from musculoskeletal impairments. The opening section (final 1.00B1) expands the first sentence of current 1.00A to include a wider range of causes for musculoskeletal dysfunction than in the current rule, which mentions only amputation and deformity. The final rules include the following impairments that have been in the listings for some time: Bone or joint deformity or destruction due to any cause, miscellaneous disorders of the spine with or without radiculopathy or other neurological deficits, amputation, and fractures or soft tissue injuries, including burns, requiring prolonged periods of immobility or convalescence. The additions make the list of possible causes of functional loss due to musculoskeletal impairments correspond to the listed impairments.

We expanded the guidance about musculoskeletal ''deformity'' to clarify that the term refers to joint deformity due to any cause. In a nonsubstantive editorial change, we clarified the second sentence of the first paragraph of proposed 1.00B to cross-refer to final 14.00B6 instead of final listing 14.09. We also clarified the language to better express our intent. This will clarify in the final rules that individuals with inflammatory arthritis that does not meet the requirements of final listing 14.09 are to be evaluated under final listing 1.02 or under any other body system listing that is appropriate. In response to a comment, we added a new sentence at the end of final 1.00B1 to make it clear that impairments with neurological causes are to be evaluated under the appropriate neurological listings (11.00ff).

The second section (final 1.00B2) is based in part on current 1.00A, but it also contains new material. It explains that, regardless of the cause(s) of a musculoskeletal impairment, the functional loss that must result from certain listed impairments is defined in terms of ''the inability to ambulate effectively on a sustained basis for any reason, including pain associated with the underlying musculoskeletal impairment, or the inability to perform fine and gross movements effectively on a sustained basis for any reason, including pain associated with the underlying musculoskeletal impairment.'' The terms represent new criteria we use to measure loss of function in several of the listings. Because we intend these listings to emphasize the impact of the impairment(s) on a person's ability to function, and thereby to perform gainful activity, these criteria clarify the degree of musculoskeletal functional limitations required to establish listing-level severity in adults and make clear that the inability to ambulate effectively or the inability to perform fine and gross movements effectively must have lasted, or be expected to last for at least 12

months. We use the same basic standards in part B, because they establish an appropriate benchmark for determining whether a child has ''marked and severe functional limitations'' necessary to establish disability under the SSI program; i.e., an ''extreme'' limitation in functioning. We also clarified in these sections that we will determine whether an individual can ambulate effectively or can perform fine and gross movements effectively based on the medical and other evidence in the case record, generally without developing additional evidence about the individual's ability to perform the specific activities that we list as examples in this section.

These criteria are measurements to be considered from a physical standpoint alone. The functional limitations resulting from a mental impairment(s) are to be considered under the mental disorders criteria in 12.00ff.

Sections 1.00B2b and 1.00B2c (B1, paragraph 2, and B2 in the NPRM) define what we mean by ''inability to ambulate effectively'' and ''inability to perform fine and gross movements effectively.'' Both sections describe ''extreme'' functional loss. In response to a public comment, we expanded the first sentence in each section to better explain what we mean by an ''extreme'' loss of function when we talk about an inability to ambulate effectively and an inability to perform fine and gross movements effectively. In final 1.00B2b and 1.00B2c we define an ''extreme'' loss in terms of the individual's ability to independently initiate, sustain, or complete activities. We believe that this phrase better describes what we mean later on in 1.00B2b(1) and 1.00B2c when we explain that the individual must have an extreme limitation in ''the ability to carry out activities of daily living.'' It clarifies that an individual may have an ''extreme'' limitation when he or she has a very serious limitation in any one of these abilities: the ability to independently initiate activities (e.g., because of frequent need for assistance from somebody else), or sustain activities (e.g., because of pain), or complete activities (e.g., because of muscle fatigue).

The phrase also helps to clarify that an individual does not have to be completely unable to walk or to use his or her upper extremities. We recognize that, even though individuals may have functional limitations of such severity that they are unable to engage in any gainful activity, they may still have some residual ability to function in their daily activities.

The phrase is also consistent with the definition of ''extreme'' in our rules for assessing ''functional equivalence'' in SSI childhood cases (§ 416.926a(e)(3)). In this way, the term will have the same meaning throughout our rules. For this reason, we made the same changes in part B of these final listings.

Final 1.00B2b addresses only an individual's ability to walk, not the ability to stand. This is because standing as a functional measure is a presupposed condition for walking; that is, before a person can walk, he or she must be able to stand. Furthermore, standing is not an accurate gauge of functioning for purposes of assessing listing-level severity. Even profoundly impaired individuals can often stand for a period of time, although they may not be able to walk effectively.

In response to public comments, we added ''the inability to walk without the use of a walker, two crutches or two canes'' as one example of an inability to ambulate effectively. For reasons explained in the section that deals with public comments, we do not consider required use of one cane or crutch to automatically exclude all gainful activity. However, if someone who uses one cane or crutch is otherwise unable to effectively ambulate, the impairment(s) might still meet or equal a listing. In addition, if an adult's impaired ability to ambulate does not meet or equal any listing, this does not mean that, upon further consideration at later steps in the sequential evaluation process, the claim could not be allowed.

We also made several other changes in final 1.00B2c (1.00B2 in the NPRM) in response to public comments. We revised the second sentence to clarify that loss of function of one arm (including amputation of the arm), but continued excellent use of the other arm would not satisfy the definition. We also deleted the example of ''intermittent assistance'' in buttoning and tying shoes in the last sentence of the proposed rule because of public comments that indicated it was not clear.

Finally, we made two minor editorial changes to sections 1.00B2b and 1.00B2c in the final rules (1.00B1 and B2 in the NPRM) to make the sentences read less awkwardly and to make them more ''user-friendly.'' The phrase, ''to afford them the ability to,'' which appeared in both paragraphs of the NPRM, now reads, ''to be able to.''

In final 1.00B2d (1.00B3 in the NPRM), we clarified the statement about pain in the second sentence of current 1.00A. Our intention is to make sure that no one has the erroneous impression that there must be objective medical findings that directly support the severity of a person's pain. The new language, which is consistent with our rules for the evaluation of symptoms, including pain, in §§ 404.1525(f), 404.1529 and §§ 416.925(f) and 416.929, clarifies that there need only be medical signs or laboratory findings that show the existence of a medically determinable impairment which could reasonably be expected to cause pain or other symptoms for these symptoms to be found to affect an individual's ability to perform basic work activities. It also explains the importance of evaluating the intensity and persistence of an individual's pain or other symptoms to determine their impact on functioning in the new musculoskeletal listings, whenever appropriate.

1.00C Diagnosis and Evaluation

As in the NPRM, final 1.00C expands the guidance in the third sentence of current 1.00A. In response to comments and to make the provisions easier to read, we divided the proposed section into three numbered paragraphs.

The first sentence of final 1.00C1 (the first paragraph of proposed 1.00C) corresponds to the current rule. We expanded the section to say that both the evaluation and the diagnosis of musculoskeletal impairments should be supported, as applicable, by detailed clinical and laboratory findings. Although the severity level of the new listings is generally met with functional limitations, diagnosis may be important for predicting the duration of the impairment, including expected response to any treatment an individual may be receiving. Chronic conditions must be differentiated from short-term, reversible disorders, and it is sometimes necessary to be able to predict response to current treatment.

We also revised the references to x-ray evidence to include other, modern imaging. Requirements for x-ray evidence appear in numerous places in the current listings. Because there have been significant medical advances in imaging techniques, such as computerized axial tomography (CAT scan) and magnetic resonance imaging (MRI), we expanded the criteria in final 1.00C1 and throughout the introductory text and listings to include all medically acceptable imaging. In these final rules we added language to make clear that not only must the imaging be medically acceptable, but that it must also be ''appropriate'' to ensure that the technique used is the proper one to support the evaluation and diagnosis of the impairment. In response to public comments, we added myelography to the list of examples of appropriate medically acceptable imaging.

Final 1.00C2 and 1.00C3 correspond to the second paragraph of proposed

1.00C. Both the proposed and final language are based on the seventh paragraph in current 1.00B, but the final rules are expanded to respond to public comments. We added final 1.00C2 to address CAT scans, MRIs, myelography, and similar tests. The final rule clarifies that we will not routinely purchase expensive tests such as CAT scans and MRIs, and that we will not order myelograms and other invasive tests that may involve significant risk to the claimant. However, we also include a reminder of our longstanding policy that we will consider the results of these tests when they are part of the existing evidence we have in the case record.

Final 1.00C3 now addresses only electrodiagnostic procedures. It is otherwise substantially the same as the current and proposed rules. We included the paragraph in this section because it fits more appropriately with the discussion of evaluation techniques in 1.00C.

We made one other minor change from the NPRM in final 1.00C1. The parenthetical examples of condition of the musculature in the first sentence of this section are just that, examples. Thus, the correct term to use is ''e.g.,'' not ''i.e.,'' as shown in the NPRM.

1.00D The Physical Examination

Final 1.00D draws extensively from the fourth and fifth paragraphs of current 1.00B. These paragraphs are included in current 1.00B under the heading, ''Disorders of the spine,'' even though much of the information they contain is relevant to examinations for any musculoskeletal impairment. We created a new section headed, ''The physical examination,'' to make clear that these criteria are not confined to disorders of the spine. We moved parts of the fourth paragraph of current 1.00B that are relevant only to examinations of the spine to what is now 1.00E, ''Examination of the spine.'' In addition, we made a number of nonsubstantive editorial changes for clarity and precision.

In the next-to-the-last sentence of 1.00D in the final rules, which corresponds to the third sentence of the fifth paragraph of current 1.00B, we changed the reference from ''a record of ongoing treatment'' to ''a record of ongoing management and evaluation.'' Not all individuals with musculoskeletal impairments receive treatment even though they may be seen by a medical source. In some cases, the abnormalities may temporarily, or even permanently, improve with the passage of time, even if the individual is not receiving treatment; in others, there may not be any formal treatment, only such conservative measures as bed rest, curtailed activities, or over-the-counter medications. The provision is also meant to underscore the need for a longitudinal record because musculoskeletal impairments are often characterized by exacerbations and remissions, whether there is treatment or not.

We also included the last sentence from the third paragraph of current 1.00B as the last sentence of final 1.00D. We believe that a correlation of examination findings with an individual's daily activities is important not only for evaluation of pain, as the current rule may suggest, but also for the assessment of the individual's overall ability to function.

1.00E Examination of the Spine

As pointed out in the explanation for 1.00D, we retained the portions of the sentences from the fourth paragraph of current 1.00B that pertain only to examinations of the spine in the new section that describes examinations for disorders of the spine, now 1.00E. In 1.00E1 we also defined more precisely how measurements of motion of the spine and straight-leg raising are to be made, based on guidance in the ''Guides to the Evaluation of Permanent Impairment'' published by the American Medical Association. Since publishing the NPRM, we added that straight-leg raising should be reported together with any other appropriate tension signs. In response to public comments, we added that muscle spasm should be reported when present. We also added guidance for measuring muscle strength in conjunction with findings of atrophy in response to comments that pointed out that atrophy in itself may not provide sufficient information about functioning of the muscle.

The last sentence of final 1.00E2 (the second paragraph of 1.00E in the NPRM) is based on the last sentence of the second paragraph of current 1.00B, which explains that neurological impairments are to be evaluated under the neurological listings in 11.00ff. The reference to ''neurological abnormalities'' in the old paragraph is not a general reference to all neurological abnormalities that may not completely subside after treatment or with the passage of time. Rather, it is a reference to neurological abnormalities of such severity that they could be considered to meet or equal the severity of a neurological listing. We, therefore, clarified the statement and have indicated in parentheses the two types of neurological conditions that would be evaluated under the neurological listings. We removed the second and third sentences of the second paragraph of current 1.00B because they would be redundant in the context of the new rules.

Final 1.00F (Proposed 1.00N) Major Joints

We redesignated this section from 1.00N, as it appeared in the NPRM, to final 1.00F. It corresponds to current 1.00D. Current 1.00D explains that the wrist and hand are considered together as one major joint, but there was no provision for the ankle and foot. Instead, it referred only to the ankle and did not mention the foot. The new section corrects this inadvertent omission.

Although we do not use the term ''major joint'' in these final rules, we are defining it in final 1.00F to point out a difference between our rules and the ordinary use of the term. In the final rule, we make explicit that we are referring to major peripheral joints, as opposed to other peripheral joints (e.g., the joints of the hand or forefoot) or axial joints (i.e., the joints of the spine.) Further, and in response to comments, we explain that we consider the ankle and foot separately for evaluation of weight bearing under final listings 1.02A and 1.03.

Final 1.00G (Proposed 1.00O) Measurements of Joint Motion

Final 1.00G was proposed 1.00O in the NPRM and it corresponds to current 1.00E. We revised this section to bring it up-to-date and to broaden its scope. We removed the reference in the current rules to the ''Joint Motion Method of Measuring and Recording'' published by the American Academy of Orthopedic Surgeons because it has not been revised or updated since 1965. For the measurement of joint motion, therefore, the final rule refers only to the ''Guides to the Evaluation of Permanent Impairment,'' which is used throughout the country by physicians and surgeons. The final rule does not include a date of publication but instead refers to the ''current edition'' in order to ensure that only the most current standards are used in the future.

Final 1.00H (Proposed 1.00F) Documentation

We added a new 1.00H, based on 1.00F of the NPRM, ''Duration of Impairment.'' The final section explains that musculoskeletal impairments frequently improve with time or treatment and provides guidance on the evidence we need to establish a longitudinal record. In the final rules, we revised the heading to better reflect

these provisions, which were not only about duration.

We made several revisions in the final rule in response to comments. The final rule now contains four numbered paragraphs. In final 1.00H1, we clarified what we mean by a ''longitudinal clinical record.'' We deleted the requirement that there must usually be a longitudinal clinical record covering at least 3 months of management and evaluation in response to public comments. However, we continue to stress in final 1.00H1 that a longitudinal clinical record is important for the assessment of severity and expected duration of an impairment unless the claim can be decided favorably on the basis of current evidence.

In final 1.00H2, we provide a reminder that we will consider evidence of treatment when it is available. In final 1.00H3, we added guidance to explain what we will do when an individual does not have a record of ongoing treatment. The guidance is identical to guidance we provide in the introductory text in some of the other body system listings.

In final 1.00H4, we added a reminder that individuals whose impairments do not meet the listings may still be found disabled based on a finding of medical equivalence or an assessment of residual functional capacity, age, education, and work experience. This language is also identical to provisions in the introductory text to other body system listings.

Final 1.00I (Proposed 1.00G) Effects of Treatment

Final 1.00I (1.00G in the NPRM) discusses the effects of treatment, including surgery. It explains the importance of considering a person's treatment because treatment can have beneficial effects or adverse side effects that in themselves can cause limitations. The section explains that some people can experience full or partial improvement of their conditions with a given treatment, while others may experience little or no improvement with the same treatment. Even though some treatments may result in improvement in a condition, their beneficial effects may be counterbalanced by adverse side effects, such as in the case of pain medication that relieves the symptom of pain but causes symptoms of drowsiness, dizziness, or disorientation that compromises the individual's ability to function.

In response to a public comment, we added the phrase, ''or judgment about future functioning,'' to the end of the last sentence of final 1.00I3 to make clear our concern with how treatment affects or will affect the individual's ability to function.

Final 1.00J (Proposed 1.00H) Orthotic, Prosthetic, or Assistive Devices

Another new section, 1.00J (1.00H in the NPRM), discusses how orthotic, prosthetic, or assistive devices are to be considered in evaluating musculoskeletal impairments.

In response to comments, we revised and clarified this section and removed the phrase ''medically necessary.'' In final 1.00J2 (orthotics) and 1.00J3 (prosthetics) we explain that it is unnecessary to routinely evaluate an individual's ability to function without the orthotic or prosthetic device in place. In 1.00J2 (orthotics) we explain that we would not expect an examination without an orthotic device unless the individual with a lower extremity impairment has difficulty with, or cannot use, the device. In this situation, the examination should include information on how the individual ambulates without the device. However, we do not expect a physician to examine the individual without the device if contraindicated by medical judgment.

In final 1.00J3 (prosthetics) we explain that it is necessary to evaluate an individual's medical ability to use a prosthetic device to ambulate effectively. However, it is unnecessary to evaluate an individual's ability to walk without the device. This is because we recognize that individuals with the type of lower extremity amputation described in final listing 1.05B, will have an inability to ambulate effectively, as defined in 1.00B2b, when they are not using a prosthesis. This would be true whether they do not use a prosthesis because they cannot afford one, because a prosthesis has not been prescribed for them, or for other reasons. However, the condition of the stump should be evaluated without the prosthesis in place.

Also, in final 1.00J4 (hand-held assistive devices) we explain the importance of an evaluation with and without a hand-held assistive device. We explain that it is important to document the medical basis for the hand-held assistive device.

We expect that the medical basis for an orthotic, prosthetic or hand-held assistive device will be confirmed by a physician who has treated or examined the individual.

Final 1.00K (Proposed 1.00I) Disorders of the Spine

Final 1.00K (1.00I in the NPRM) revises current 1.00B. We reorganized and expanded the current rules.

The first sentence of final 1.00K corresponds to the first sentence of current 1.00B. In this sentence of the final rules and in the next sentence, we explain that various abnormalities may result in nerve root impingement (including impingement on those in the cauda equina) or impingement on the spinal cord, from a herniated nucleus pulposus (1.00K1), spinal arachnoiditis (1.00K2), or lumbar spinal stenosis resulting in pseudoclaudication (1.00K3). We expanded the second sentence of 1.00K to include other causes of limitations that should be evaluated under final listing 1.04. However, we do not describe every possible impairment that can cause neurological involvement because the effects of some of the impairments are identical to those we have described.

The third sentence of 1.00K corresponds to the last sentence of the second paragraph in current 1.00B, and is a brief restatement of current 1.00B and 1.00E. We clarified the language in the third sentence of final 1.00K from the way it appeared in the NPRM, because the original language was possibly ambiguous. It also is consistent with the statements added to final 1.00B1 about how to evaluate neurological impairments. No substantive change is intended from the current rule or the NPRM.

Final sections 1.00K1 through 1.00K4 describe the various impairments we refer to in 1.00K: herniated nucleus pulposus (1.00K1), spinal arachnoiditis (1.00K2), lumbar spinal stenosis (1.00K3), and other miscellaneous conditions (1.00K4). In these sections, we provide information about the causes of the conditions, the findings one should look for on clinical and laboratory examination, and the functional effects of the impairments. We also provide guidance about certain conditions, such as spinal dysrhaphism (e.g., spinal bifida), diastematomyelia, and tethered cord syndrome, that are more appropriately evaluated under the neurological listings.

We made a minor revision to the first sentence of 1.00K1 to make it clear that herniated nucleus pulposus is a common disorder ''frequently'' associated with the impingement of a nerve root since this is not an absolute; that is, the two are not always associated. We have made a very minor syntactical change to the final sentence of 1.00K3 because the original language

was awkward and possibly unclear. We have deleted the word ''obvious'' in the penultimate sentence of 1.00K4 and have combined this sentence with the last sentence, revising the syntax to be more compatible with the statement added to final 1.00B1 about where to evaluate neurological impairments.

Final 1.00L (Proposed 1.00J) Abnormal Curvatures of the Spine

We designated a new section as 1.00L (1.00J in the NPRM) to discuss evaluation of abnormal curvatures of the spine. We revised the language of the NPRM in response to comments, the first revision being to the first sentence. We no longer cite scoliosis, kyphosis, and kyphoscoliosis as examples of spinal curvature. Rather, we specify that these are the types of curvature we are considering under this section. The new section focuses on the impact of the abnormal curvature on the individual's ability to function, in keeping with our approach in revising the current listings. Thus, we explain in the final rule that abnormal curvatures may impair a number of functions and we cite as examples impaired ability to ambulate, restricted breathing, cardiac difficulties, and disfigurement resulting in withdrawal or isolation. When abnormal curvature of the spine results in impaired ambulation, evaluation of equivalence should be done by reference to final listing 14.09A, which describes impaired ambulation resulting from a deformed spine. When abnormal curvature of the spine results in symptoms related to fixation of the dorsolumbar or cervical spine, evaluation of equivalence should be done by reference to final listing 14.09B. When there is respiratory or cardiac involvement, or an associated mental disorder, evaluation should be done by reference to the respiratory listings, the cardiovascular listings, or the mental disorder listings, as appropriate.

Final 1.00M (Proposed 1.00K) Under Continuing Surgical Management

We added final 1.00M (1.00K in the NPRM) to explain what we mean by the term ''under continuing surgical management,'' which is a term we use in final listings 1.07 and 1.08 and in current listing 1.12. The new provision explains that ''surgical management'' includes more than the surgery itself. It includes various post-surgical procedures, complications of surgery, infections, or other medical complications, and other factors associated with surgery that delay the individual's attainment of maximum benefits from surgery.

Final 1.00N (Proposed 1.00L) After Maximum Benefit From Therapy Has Been Achieved

Final 1.00N (1.00L in the NPRM), which discusses evaluation after the achievement of maximum benefit from surgery or other medical therapy in certain situations, corresponds to current 1.00C. We revised and expanded the current provision to clarify our policy that an individual can have an impairment that meets the criteria of current listings 1.12 and 1.13 (final listings 1.07 and 1.08) because of functional limitations resulting from the impairment itself and because of the effects of the surgery or other medical management, including recovery time following intervention and any complications from the intervention. In response to comments, we revised the language from that in the NPRM, as discussed in more detail in the discussion of public comments that follows.

Final 1.00O Major Function of the Face and Head

As the result of public comments, we added a new section describing what we mean by major function of the face and head for purposes of listing 1.08. We also added a cross-reference to this new section in final listing 1.08.

Final 1.00P (Proposed 1.00M) When Surgical Procedures Have Been Performed

Final 1.00P (1.00M in the NPRM) is substantively the same as the sixth paragraph of current 1.00B. It states that the documentation should include a copy of operative notes and available pathology reports when surgery has been performed.

Final 1.00Q Effects of Obesity

Final 1.00Q (current 1.00F) is a new section that was not in the NPRM. On August 24, 1999, we published in the **Federal Register** (64 FR 46122) final rules to remove prior listing 9.09, ''Obesity.'' The rules became effective October 25, 1999. At that time, we added a paragraph (1.00F) to the introductory text of the musculoskeletal body system listing to provide guidance about the evaluation of claims for benefits involving obesity. Final 1.00Q is the same as current 1.00F.

1.01 Category of Impairments, Musculoskeletal

We removed the criteria for rheumatoid arthritis previously in listing 1.02 and have established new listing 14.09 in the Immune System listings. Rheumatoid arthritis is a connective tissue disorder that should be grouped with other connective tissue disorders. Final listing 14.09 will cover all the inflammatory arthritides, including rheumatoid arthritis. In addition to moving current listing 1.02 to 14.09, we removed two other listings. We removed the criteria in current listing 1.05B, which would be met if an individual had generalized osteoporosis with pain, limitation of motion, paravertebral muscle spasm, and vertebral fracture. As we stated in the NPRM, our experience showed that the listing was unclear. Moreover, our experience has shown that the number of applicants alleging disability on the basis of osteoporosis is small and no longer justifies a specific listing.

The final listings include criteria to evaluate individuals who have osteoporosis of listing-level severity by adding ''vertebral fractures'' in the list of examples of conditions that are included under final listing 1.04, for disorders of the spine resulting in compromise of a nerve root or the spinal cord.

Final listing 1.02A will cover the situations in which there is hip involvement resulting in inability to ambulate effectively, a situation that is not included in the current listing.

We also removed current listing 1.08, ''Osteomyelitis or septic arthritis.'' Again, as we explained in the NPRM, advances in treatment have made both osteomyelitis and septic arthritis much rarer than they were when we last issued these listings. More importantly, fundamental advances in antibiotic therapy have meant that, when they do occur, these conditions are not usually expected to last for 1 year. Therefore, we believe that cases of osteomyelitis and septic arthritis must be evaluated on a case-by-case basis to determine whether they are equivalent in severity to a listed impairment or result in a finding of disability at later steps in the sequential evaluation process for adults, and will meet the 12-month duration requirement. Residuals of these impairments may also result in disability. Any residuals (such as a fused hip or knee joint in a poor anatomic position) may be evaluated under the appropriate listings, or later in the sequential evaluation process for adults. As we stated earlier, current beneficiaries will not lose eligibility solely as a result of the removal of this listing. We may find these individuals disabled based on this listing section or other rules.

Septic arthritis that is associated with human immunodeficiency virus (HIV) infection is listed separately in our existing rules, under listing 14.08M.

1.02 Major Dysfunction of a Joint(s) (due to any cause)

As the result of a public comment, we changed the title of this listing from the proposed ''Deficit of musculoskeletal function of a major joint(s) (due to any cause)'' to ''Major dysfunction of a joint(s) (due to any cause).''

This final listing consolidates into one listing current listing 1.03A, ''Arthritis of a major weight-bearing joint (due to any cause),'' and current listing 1.04, ''Arthritis of one major joint in each of the upper extremities (due to any cause),'' because both listings describe gross anatomical deformities. We also have expanded the scope of the listing to include deficits of musculoskeletal function from residual deformity due to any cause, not just arthritis. Current listing 1.03B, for reconstructive surgery or surgical arthrodesis of a major weight-bearing joint, has been retained as a separate listing 1.03, described below.

In keeping with the overall functional approach in our listings, the final listing encompasses any musculoskeletal condition that involves a major peripheral joint in one lower extremity and results in an inability to ambulate effectively (listing 1.02A), or that involves a major peripheral joint in each of the upper extremities, and results in an inability to perform fine and gross movements effectively (listing 1.02B). As in the current rules, the listing requires gross anatomical deformity, such as subluxation, contracture, bony or fibrous ankylosis, or instability, and chronic joint pain and stiffness with signs of limitation of motion of the affected joints. We removed the example of ''ulnar deviation'' because it is no longer germane in this context.

We broadened the criteria used to evaluate disability under final listing 1.02, for reasons similar to those that apply to the evaluation of disability under final listing 14.09, explained below. Diagnosis may be necessary to resolve duration issues, but the basis for finding that the listing is met or equaled is whether the medical condition causes functional limitations that are of listing-level severity.

Because final listing 1.02 is based on a criterion for gross anatomical deformity, it would also replace some of the criteria of current listing 1.09. Current listing 1.09 is met with amputation ''or anatomical deformity'' of both hands (current listing 1.09A), both feet (current listing 1.09B), or one hand and one foot (current listing 1.09C). In current listings 1.09B and 1.09C, the anatomic reference to the foot means the entire foot, to include the hindfoot which, as part of the ankle joint, is weight bearing. Final listing 1.02A requires gross anatomical deformity of one major peripheral weight-bearing joint and, therefore, replaces the requirement for deformity of two feet now in listing 1.09B with a less anatomically based, more functionally based criterion. The final criterion does not require involvement of both lower extremities or even specifically of the feet.

Final listing 1.02B replaces the requirement for involvement of both hands with a requirement for involvement of any major joint in each upper extremity and, again, is a functionally based criterion. There is no provision to correspond to current listing 1.09C, however, because we believe that individuals who have deformities of one hand and one foot should have their claims evaluated on a case-by-case basis. Such individuals do not always have impairments that would preclude the ability to do any gainful activity, and to determine if they are disabled, we may have to assess their residual functional capacity and consider their age, education, and work experience.

As already noted, under final 1.00F (proposed 1.00N in the NPRM), we clarified that major joints refers to the major peripheral joints. We also further defined the ankle-foot as a major peripheral joint and stated that the ankle is a major weight-bearing joint for purposes of final listing 1.02A. As throughout these listings, we updated the criterion for x-ray evidence by replacing it with a reference to ''appropriate medically acceptable imaging.'' Throughout the final rules we have added that the medically acceptable imaging must be ''appropriate.''

We also removed the term ''significant,'' used to describe the amount of joint space narrowing or bony destruction caused by the arthritis in current listings 1.03A and 1.04A, because there is a relative lack of correlation between findings on imaging and function of the joint. Furthermore, since final listing 1.02 would ultimately be met because of functional limitations resulting from the arthritis or any other condition, the term ''significant'' is unnecessary in the revised rule. We believe that the objective requirement for gross anatomical deformity and the other requirements in the listing are sufficient in themselves.

1.03 Reconstructive Surgery or Surgical Arthrodesis of a Major Weight-Bearing Joint

Final listing 1.03 corresponds to current listing 1.03B. The current listing describes individuals who have undergone reconstructive surgery or surgical arthrodesis of a major peripheral weight-bearing joint, and return to full weight-bearing status did not occur, or is not expected to occur within 12 months of onset. The final listing would change the criterion for failure to return to ''full weight-bearing status'' to the criterion for inability to ambulate effectively used in final listing 1.02 and other final listings. As we explained in the NPRM, with advances in surgical techniques and post-surgical treatment, some individuals who are not able to bear full weight on a lower extremity nevertheless have sufficient ability to ambulate to be able to work.

1.04 Disorders of the Spine

This final listing corresponds to current listing 1.05C, which we use for evaluating impairments like herniated nucleus pulposus and lumbar spinal stenosis. We have expanded the list of examples in the opening sentence to show that other conditions are also included, such as spinal arachnoiditis, osteoarthritis, degenerative disc disease, facet arthritis and vertebral fractures, which are all examples of conditions that may compromise nerve roots (including the cauda equina) or the spinal cord. As already stated, we also describe several—though not all—of these conditions and their effects in final 1.00K (1.00I in the NPRM). We have not described every possible impairment that can cause neurological involvement because the effects of some of the impairments are identical to those we have described.

Consistent with the discussions in final 1.00K, we have named three separate sets of criteria under listing 1.04, for nerve root compression (final listing 1.04A), spinal arachnoiditis (final listing 1.04B), and lumbar spinal stenosis resulting in pseudoclaudication (final listing 1.04C). Spinal arachnoiditis and lumbar spinal stenosis with pseudoclaudication are listed separately because they present different signs and symptoms than nerve root compression (which has many causes, including spinal stenosis) and neither condition is adequately covered by the current rules.

Final listing 1.04A corresponds most closely to current listing 1.05C. We replaced the examples in the current rule with the examples in final listing 1.04 and the discussions in final 1.00K.

We also added a criterion for positive straight-leg raising in the sitting and supine positions when there is involvement of the lower back. We also removed the requirement for muscle spasm in current listing 1.05C because the finding usually reflects an acute condition that will not persist for a year. Moreover, because spasm is often an intermittent finding, it may not be present on a given examination even though an individual might otherwise be significantly limited.

We also removed the requirement in current listing 1.05C that limitation of motion of the spine be ''significant.'' The requirement is imprecise. More importantly, we would consider any limitation of motion to be significant if it were accompanied by the other requirements of the final listing. Under the final listing, we no longer require anatomic or radicular distribution of both sensory and reflex abnormalities as required under the current listing, but require only that one or the other be present. This is because sensory and reflex abnormalities are not concurrent in all cases of nerve root compression that would nonetheless be disabling at the listing level. Depending on the level of the compression, both sensory and reflex abnormalities may not occur anatomically. However, the final listing does require a ''neuro-anatomic distribution'' of pain to make clear that the nerve root compression would have to be reasonably expected to cause the pain. This final requirement is consistent with our evaluation of pain and other symptoms pursuant to §§ 404.1529 and 416.929 of our rules. We also clarified in final 1.00E1 what we mean by ''motor loss''—that is, atrophy with associated muscle weakness, or muscle weakness alone. Atrophy in the absence of muscle weakness is not evidence of motor loss. We explain in final 1.00E, discussed earlier, what we require to show atrophy.

Final listing 1.04A does not contain the criteria in current listing 1.05C for persistence of signs and symptoms ''for at least 3 months despite prescribed therapy'' and that they be ''expected to last 12 months.'' This is because we no longer require that there must invariably be a record of at least 3 months. Instead we require that there be a longitudinal clinical record sufficient to assess the severity and expected duration of an impairment, as explained in final 1.00H. In final 1.00H we explain that when there is no longitudinal clinical record the evaluation will be based on all the available evidence.

Final listings 1.04B, for spinal arachnoiditis, and 1.04C, for lumbar spinal stenosis resulting in pseudoclaudication, list the characteristic signs and symptoms of their respective impairments and require appropriate limitations of function. Thus, final listing 1.04B describes severe burning or painful dysesthesia resulting in the need for frequent changes in position or posture, and final listing 1.04C describes chronic nonradicular pain and weakness resulting in an inability to ambulate effectively. In response to a public comment, final listing 1.04B contains a more precise description of what we mean by frequent changes in position or posture. The final rule states that the changes in position or posture must be more than once every 2 hours.

1.05 Amputation (due to any cause)

As the result of a public comment, we changed the title of this listing from ''Amputation,'' to ''Amputation (due to any cause),'' to make clear that impairments due to amputations, including amputations due to vascular disease, diabetes mellitus, or any other cause, may be evaluated under final listing 1.05.

We combined the two current listings that deal with amputations, 1.09 and 1.10, into a single listing 1.05. As stated earlier, the ''anatomical deformity'' criterion of current listing 1.09 will be evaluated under final listing 1.02.

Final listing 1.05A, amputation of both hands, corresponds to current listing 1.09A, and is unchanged.

We replaced the listings that previously included a criterion for amputation of the foot (current listings 1.09B and 1.09C) with listings based on inability to ambulate effectively. We also removed one listing that provides a criterion for amputation ''at or above the tarsal region'' as a result of peripheral vascular disease or diabetes mellitus (current listing 1.10B). Since we last published these listings, significant refinements in surgical techniques (e.g., development of improved soft tissue flaps) to cover the bone stump have been made. This has resulted in more durable stumps. Engineering advances have produced prosthetic devices which minimize and distribute stress so that some individuals wearing artificial limbs after amputation above the tarsal level for any reason (including diabetes mellitus, and vascular and arterial disease) are able to work. Although some individuals with these impairments will, of course, be disabled, the final revisions recognize that this is not a certainty and that we must assess the impairments of such individuals and how well these individuals are able to adapt to their impairments on a case-by-case basis.

Accordingly, final listing 1.05B replaces current listings 1.09B (amputation of both feet) and 1.10B and 1.10C (amputation of one lower extremity at or above the tarsal region due to peripheral vascular disease or diabetes mellitus, or inability to use a prosthesis effectively) with a requirement for stump complications resulting in medical inability to use a prosthetic device to ambulate effectively, regardless of the cause of the amputation, the level of the amputation (at or above the tarsal region,) or whether there is amputation of one or both limbs. In the final rule we removed the phrase ''from onset'' which appeared in the NPRM and is in current listing 1.10C3 to make clear that for purposes of final listing 1.05B, the stump complications resulting in medical inability to use a prosthetic device to ambulate effectively have to last or be expected to last for at least 12 months. Similarly, final listing 1.05C replaces current listing 1.09C (amputation of one hand and one foot) with a requirement for amputation of one hand and one lower extremity at or above the tarsal region resulting in an inability to ambulate effectively without an obligatory hand-held assistive device. (We also added an exception to the definition of ''inability to ambulate effectively'' in final 1.00B2b to take this listing into account since individuals with amputation of a hand will not generally use bilateral upper limb assistance.)

Final listing 1.05C corresponds to current listing 1.09C (amputation of one hand and one foot) with a requirement for amputation of one hand and one lower extremity at or above the tarsal region resulting in an inability to ambulate effectively. In final listing 1.05C we deleted the phrase ''without an obligatory hand-held assistive device,'' which we had included in the NPRM. The change is not substantive, but only for clarity. The phrase was unnecessary since section 1.00B2b(1) defines ''ineffective ambulation'' as the inability to ambulate independently without the use of a hand-held assistive device(s).

In the NPRM, proposed listing 1.05D, hemipelvectomy or hip disarticulation also required that there be an amputation of the other lower extremity at or above the tarsal region. In response to public comment, we agree that, despite advances in treatment and technology, a hemipelvectomy or hip disarticulation is still, in itself, sufficient to establish the existence of an impairment of listing-level severity.

Therefore, we are not changing the criteria. Final listing 1.05D, for hemipelvectomy or hip disarticulation, corresponds to current listing 1.10A.

1.06 Fracture of the Femur, Tibia, Pelvis or One or More of the Tarsal Bones

Final listing 1.06 corresponds to current listing 1.11. We have revised the criterion requiring an inability to return to full weight-bearing status within 12 months of onset to a criterion requiring an inability to ambulate effectively for an expected 12 months or longer. This is essentially the same requirement as for final listing 1.03 (current listing 1.03B). Internal fixation devices (such as intramedullary rods) and external fixators can in some cases return an individual to effective ambulation even though the lower extremity is not fully weight bearing.

Because of the above revision, we restructured the listing for clarity. We are also changing the reference to the ''tarsal bone'' in the heading of the listing to ''one or more tarsal bones'' for technical reasons. There are a number of tarsal bones.

In final listing 1.06A we deleted the phrase ''when such determination is feasible,'' which we had included in the NPRM. The change is not substantive, but only for clarity. The phrase was clearly unnecessary since we would not make any determination or decision that was not ''feasible.''

1.07 Fracture of an Upper Extremity

Final listing 1.07 is identical to current listing 1.12 except for minor editorial changes.

1.08 Soft Tissue Injury (e.g., Burns) of an Upper or Lower Extremity, Trunk, or Face and Head

Final listing 1.08 corresponds to current listing 1.13. We revised the heading to make clear that the listing is appropriate for the evaluation of burns. We expanded the scope of the rule to include soft tissue injuries to the trunk or to the face and head. The criteria for ''surgical management'' are the same as in final listing 1.07. Therefore, we would no longer require surgical procedures to be ''staged.'' The surgical procedures required to restore function in injuries of the type covered by this listing are not always planned in advance and are, therefore, not necessarily ''staged.'' For further clarity, a reference to final listing 1.08, has been added to final 1.00M.

14.00 Immune System

For reasons explained above, we moved the criteria in current 1.00 that address rheumatoid arthritis and other inflammatory arthritides to the immune system listings so that these conditions can be grouped together with the other connective tissue disorders. We, therefore, established new sections in the introductory text to 14.00 and a new listing 14.09 which corresponds to current listing 1.02. We are also revising and broadening our criteria, as explained below.

14.00B

The fourth paragraph of final 14.00B is changed to include the inflammatory arthritides in the impairments mentioned therein.

We changed final 14.09D as the result of public comments.

We changed the term ''severe'' in the first sentence of the paragraph to ''serious.'' We also took the opportunity to correct a preexisting syntactical error in the same sentence. The phrase, ''loss of function in,'' as it appeared in two places in the sentence has been changed to ''loss of function because of disease affecting'' because an organ(s) of the body does not lose function in the manner we intended by our narrow definition of the term. It is the individual's ability to function about which we are concerned in the listings, and not whether an organ(s) is functioning from a medical standpoint.

14.00B6 Inflammatory Arthritis

Final 14.00B6 is a new section we added to address the inflammatory arthritides; it has no counterpart in current 1.00. Even though the primary feature of these disorders is joint involvement, they are connective tissue disorders, like systemic lupus erythematosus and scleroderma, and they cause extra-articular manifestations that may be disabling, just as the other connective tissue disorders do.

Final 14.00B6 provides examples of some of the disorders that affect the spine (inflammatory spondyloarthropathies). It also provides examples of disorders that affect the peripheral joints. The first group of disorders includes ankylosing spondylitis, Reiter's syndrome, Behiet's disease and other conditions. The second group includes rheumatoid arthritis, Sjgren's syndrome, psoriatic arthritis and other conditions.

We made a number of changes in this section in response to comments that asked us to clarify the provisions of proposed listing 14.09. The changes in final 14.00B6 respond to those comments as well. We provide a description of some of the factors that can cause functional deficits and clarify that their combined effects may produce serious functional limitations. In addition, we clarified the reminder in the rule that, when the conditions are quiescent but have caused persistent musculoskeletal deformity, it is still appropriate to use final listing 1.02, which describes gross anatomical deformity due to any cause, or final listing 1.03, which describes reconstructive surgery or surgical arthrodesis of a major peripheral weight-bearing joint, when such deformities are the dominant feature.

We added the word ''persistent'' to the last sentence in the opening paragraph to further emphasize this point.

We also deleted the fourth sentence of this paragraph from the NPRM. That sentence discussed chronic forms of the diseases and is no longer necessary because of the other clarifications we made in the paragraph and in final listing 14.09.

In the subsections of final 14.00B6, we provide explanations to make clear that the provisions in listing 14.09 use the same terms and definitions that are in the final musculoskeletal listings. Thus, the terms ''major joints,'' ''inability to ambulate effectively,'' and ''inability to perform fine and gross movements effectively'' have the same meaning as they do in final 1.00. Accordingly, we indicated in final 14.00B6a that the term ''major joints'' refers to major peripheral joints and have explained that because only the ankle joint is crucial to weight-bearing, the ankle and foot are considered separately for evaluation of weight-bearing. In final 14.00B6b we make clear that the inability to ambulate effectively or the inability to perform fine and gross movements effectively must have lasted, or be expected to last for at least 12 months. In final 14.00B6c, we do not provide a functional criterion for ankylosing spondylitis and other ankylosing spondyloarthropathies (final listing 14.09B), because the medical findings in that listing would invariably cause such functional limitations. Thus, once the requisite objective medical findings are established, we expect the individual will have functional limitations that result in an impairment of listing-level severity.

In final 14.00B6d, we provide guidance about establishing the existence of an impairment of listing-level severity based upon extra-articular features. We also provide examples of kinds of extra-articular features that may be seen with the inflammatory arthritides in the different body systems. Although many of the extra-articular features are the same as those that may be seen in other medical disorders, some (such as keratoconjunctivitis sicca,

which is seen in Sjögren's syndrome, and amyloidosis of the kidney, which is seen in rheumatoid arthritis) are specific to the disorders in listing 14.09. The term ''extra-articular features'' has replaced ''extra-articular findings'' in the NPRM. We also made syntactical changes to final 14.00B6d to clarify the listings as requested by commenters.

Final 14.00B6e is a new section added for consistency between the adult and childhood rules. The section, which corresponds to final rule 114.00E6, explains why steroid dependence in and of itself is insufficient to establish an impairment of listing-level severity.

14.09 Inflammatory Arthritis

For reasons explained above, we redesignated current listing 1.02 as final listing 14.09. We also changed its heading from ''Active rheumatoid arthritis and other inflammatory arthritis'' to ''Inflammatory arthritis'' to emphasize that we include a host of syndromes characterized by joint inflammation, not just rheumatoid arthritis. The final change also emphasizes the functional consequences of joint inflammation as a determinant of a disabling impairment rather than focusing on specific etiologic diagnoses. The final change recognizes that, although etiologic diagnosis is needed to distinguish chronic disorders from short-term disorders, as well as from other connective tissue disorders that are listed elsewhere, it is joint inflammation and its sequelae, and other symptoms and signs of these disorders, not etiologic diagnosis, that result in work-related functional limitations.

The final rule provides several methods for determining whether an impairment is of listing-level severity. It advances the concept of graded levels of severity of the diseased joint (i.e., articular process), which can result in disability because of the severity of the joint involvement itself, or because of joint involvement coupled with major signs and symptoms produced by the extra-articular features which together impair an individual's functioning to the degree described in these final listings. Thus, final listings 14.09A and 14.09B would be met with articular findings that are of such severity that they alone result in inability to ambulate effectively or to perform fine and gross movements effectively. Final listings 14.09C, 14.09D, and 14.09E would be met with less severe joint involvement than in final listings 14.09A and 14.09B, but with extra-articular features that establish the existence of an impairment of listing-level severity.

Final listing 14.09A replaces current listing 1.02A. It describes inflammatory arthritis of the major peripheral joints (i.e., the hip, knee, shoulder, elbow, wrist-hand, and ankle-foot) which is of such severity that in itself it results in disability. We clarified and simplified the current provisions and replaced the requirement in current listing 1.02A for involvement of ''multiple'' major joints with the more precise requirement for ''two or more'' major joints. Consistent with other final listings, we replaced the current criterion for ''significant restriction of function of the affected joints'' with the more precise standard of inability to ambulate effectively or inability to perform fine and gross movements effectively. We removed the requirement for the listed findings despite prescribed therapy for at least 3 months and clinical activity expected to last at least 12 months from final listing 14.09A. This is because the third paragraph of current 14.00B already provides a general requirement for these findings, applicable to all of the connective tissue disorder listings.

In final listings 14.09A, C, and D, we removed the requirements in current listing 1.02B for corroboration of the existence of the impairment by specific laboratory tests. We retained the requirement for appropriate medically acceptable imaging in final listings 14.09B and E, as the imaging is necessary to document the impairment.

We made these changes because inflammatory arthritis with the findings described in final listing 14.09 is sufficient to establish the existence of an impairment of listing-level severity. Moreover, the laboratory findings described under current listing 1.02B are neither specific for diagnosis nor indicators of a level of functional limitation.

Ankylosing spondylitis, currently evaluated under listing 1.05A, will be evaluated under final listing 14.09B, which lists ''ankylosing spondylitis or other spondyloarthropathy.'' In the NPRM (proposed listing 14.09B) we inadvertently required fixation of both the dorsolumbar and cervical spine. In the final rule we corrected this. Consistent with the current rules, final listing 14.09B requires fixation of either the dorsolumbar or cervical spine. Because the emphasis in these final listings is on function, the final listing does not require the extensive x-ray evidence of calcification of spinal ligaments and abnormal apophyseal articulations, and bilateral ankylosis of the sacroiliac joints required in current listing 1.05A. Rather, the final listing provides for a degree of ankylosis of the cervical or dorsolumbar spines that correlates with an inability to ambulate effectively. We also broadened the current criterion for a finding of bilateral sacroiliac ankylosis to include those disorders that are characterized by either unilateral or bilateral sacroiliitis.

Final listing 14.09C is based on the other connective tissue disorders listings in 14.00, and provides for a finding of disability when an extra-articular feature of any inflammatory arthritis is disabling, as shown by reference to listings in other body systems. The final listing is similar to current listing 14.06, ''Undifferentiated connective tissue disorder,'' which cross-refers to the list of body systems established in current listing 14.02A so that repetition of that long list is unnecessary.

Final listing 14.09D is a listing for the inflammatory arthritides that affect the peripheral joints which would be met with less severe joint findings than in listing 14.09A and less severe extra-articular features than in listing 14.09C. It provides criteria similar to those in listings 14.02B, 14.03B, 14.04B, and 14.06; that is, significant, documented constitutional symptoms and signs with involvement of at least two other organs/body systems. To reflect the symptoms and signs of these particular disorders, the final rule calls for a history of joint pain, swelling, tenderness, and inflammation, which we included in 14.09D. As a result of public comments, in the final rule we removed the requirement in the NPRM for morning stiffness of at least 2 hours' duration, as we recognize that there is no reliable way to document a claimant's allegation of morning stiffness.

Similarly, final listing 14.09E is a listing for inflammatory spondyloarthropathies that do not meet the deformity requirements of final listing 14.09B or the extra-articular requirements of final listing 14.09C. The final rule calls for the extra-articular features described in 14.09D, which is more appropriate than the NPRM requirements for ''the extra-articular findings described in 14.09D.''

Revisions to Part B of Appendix 1

101.00 Musculoskeletal System

We reorganized, revised, and expanded 101.00, the introductory text to part B of the musculoskeletal listings, to be consistent with the final revisions in part A. When changes have been made from the NPRM for adults and parallel criteria existed in the NPRM for children, we have made the same changes in final part B for the same reasons as in final part A. However, we

also established additional criteria in final 101.00 to give appropriate consideration to the particular effects of the disease processes in children. For example, in 101.00B2b and 101.00B2c, we created specific definitions of the terms ''inability to ambulate effectively'' and ''inability to perform fine and gross movements effectively'' for infants and young children in terms that are appropriate to these children. Thus, final 101.00B2b(2) defines ineffective ambulation for children who would not yet be expected to walk in terms of a failure to achieve skills or performance involving the lower extremities at no greater than one-half of age-appropriate expectations based on an overall developmental assessment. Extreme limitations on use of the upper extremities is defined by reference to the descriptions of motor dysfunction in the listing for multiple body dysfunction, listing 110.07A.

In other instances, we altered in part B the criteria in final part A to address children, in order to underscore the importance of the criteria in childhood cases and to eliminate any question about their applicability to children.

As in part A, we moved current listing 101.02, for juvenile rheumatoid arthritis, to the immune system listings in 114.00. For this reason, we removed current 101.00A, which addresses the documentation of juvenile rheumatoid arthritis. We have not moved it into the introductory text of 114.00 because it explains that the documentation of the diagnosis of juvenile rheumatoid arthritis should be made according to an established protocol, such as that published by the Arthritis Foundation, and we have expanded the listings to address all forms of inflammatory arthritis in children. As in the final adult rules, final listing 114.09A includes the findings of joint pain, swelling, tenderness, and inflammation noted in current 101.00A, but goes on to address the functional impact of any form of severe inflammatory arthritis by acknowledging that it may result in the inability to ambulate effectively or the inability to perform fine and gross movements effectively with the upper extremities.

We also removed the discussion currently in 101.00C. This section of the current rules explained that degenerative arthritis may be the end stage of many skeletal diseases and conditions. The discussion, though correct, has no special relevance to the final rules, which are functionally based.

101.01 Category of Impairments, Musculoskeletal

We removed current listings 101.05B, 101.05C, and 101.08 for the reasons set forth below.

We removed listing 101.05B, ''Scoliosis,'' and listing 101.05C, ''Kyphosis or lordosis,'' and added to the introductory text a new 101.00L, ''Abnormal curvatures of the spine,'' which corresponds to final 1.00L in the adult rules. We have removed the criteria for a spinal curve measuring 60° or greater in current listing 101.05B1 and for kyphosis or lordosis measuring 90° or greater in current listing 101.05C because these measurements do not focus on the functional impact of the abnormal curvature. We instead included a provision which parallels the provision for the adult listings, and focuses evaluation on the functional impact of abnormal curvatures; i.e., impaired ambulation, ventilatory restriction, cardiac difficulties, or disfigurement resulting in withdrawal or isolation. As in the final adult rules, we now make reference to listing 114.09A when the spinal deformity is so severe that it results in ineffective ambulation; the reference is to the respiratory listings in 103.00ff when there is restricted breathing because of the deformity, to the cardiovascular listings in 104.00ff when there is cardiac involvement and to the mental disorder listings in 112.00ff when there is an associated mental disorder.

We removed current listing 101.05B2, which provides that a child will be considered disabled for 1 year from the time of surgery based on a spinal fusion of six or more levels, because improvements in medical technology have shortened the period of recuperation following spinal fusion to less than a year. As a result, it is no longer possible to assume that the duration requirement will be met in all cases. Improved techniques with internal fixation devices (e.g., Harrington rods, Cotrel-Dubousset, and other fixation devices) have eliminated the need for turnbuckle casts and lengthy immobilization in plaster following spinal fusion. With the use of these improved techniques, a return to age-appropriate activities can now be expected in less than 1 year following spinal fusion.

The removal of current listing 101.05B will also correct a printing error. The current listing provided for ''FEV (vital capacity)'' of 50 percent or less of predicted normal. The abbreviation ''FEV,'' however, does not stand for ''vital capacity,'' but for ''forced expiratory volume,'' a measurement of obstructive lung disease, not of restrictive dysfunction. Our intent has always been to measure the restrictive breathing dysfunction that may be caused by the musculoskeletal deformity, the vital capacity or VC.

Finally, consistent with the revisions to the listings in part A, we also removed listing 101.08, ''Chronic osteomyelitis.'' We provide our reasons for this in the explanation under part A for the removal of current listing 1.08.

Final listings 101.02 through 101.08 are in most instances the same as the corresponding final adult rules explained above. Final listings 101.03 and 101.05 through 101.08 are new, and are the same as the corresponding final adult listings, 1.03 and 1.05 through 1.08. These listings will maintain structural and content consistency with the adult listings. The following is an explanation of final listings 101.02 and 101.04, which have revised current listings 101.03 and 101.05.

101.02 Major Dysfunction of a Joint(s) (Due to Any Cause)

This final listing corresponds to current listing 101.03, ''Deficit of musculoskeletal function.'' The final rule is the same as the corresponding adult rule. As in the adult rule, the proposal would broaden the listing to include deficit of functioning due to any cause, with involvement of either one major peripheral weight-bearing joint or one major peripheral joint in each upper extremity.

The functional limitations in the final listing encompass the criteria of current listings 101.03A, 101.03B, and 101.03C, and provide a uniform functional measure which applies to all children within their respective age-appropriate functional expectations. We believe the listing will be easier to use with the better-defined term ''inability to ambulate effectively.'' Current listing 101.03A (''Walking is markedly reduced in speed or distance despite orthotic or prosthetic devices'') and current listing 101.03B (''Ambulation is possible only with obligatory bilateral upper limb assistance * * *'') have been subsumed under the definition of ''inability to ambulate effectively.'' Current listing 101.03C (''Inability to perform age-related personal self-care activities * * *'') has been subsumed under the definition of ''inability to perform fine and gross movements effectively.''

101.04 Disorders of the Spine

This final listing corresponds to current listing 101.05. Final listing 101.04 focuses on disorders that involve compromise of a nerve root(s)

(including the cauda equina) or the spinal cord. Although the listing is consistent with the final adult listing, it does not include criteria for spinal arachnoiditis or lumbar spinal stenosis resulting in pseudoclaudication. These conditions generally develop over time and with age and are rarely seen in children. Should a child need to be evaluated for spinal arachnoiditis or lumbar spinal stenosis, the part A listings should be used.

We removed current listing 101.05A, for fracture of a vertebra with spinal cord involvement, because it describes a spinal cord injury and is more appropriately a neurological disorder than a musculoskeletal disorder. Current listing 111.06 describes the limitations resulting from such an injury.

114.00 Immune System

For reasons we have given under the explanation of the corresponding adult rules, 14.00 of the introductory text to the immune system listings in part A and final listing 14.09, we changed the heading of listing 114.09 (formerly 101.02) from ''Juvenile rheumatoid arthritis'' to ''Inflammatory arthritis.'' This revision provides a more comprehensive consideration of the features and functional impact of any of the inflammatory arthritides and moves all of the criteria for juvenile rheumatoid arthritis and the inflammatory arthritides into 114.00. In final 114.00E, we provide essentially the same provision for children that we provide for the inflammatory arthritides for adults, with appropriate changes to address the particular presentation and effects of the disorders in children. The difference in numbering of the sections in part A and part B reflects the differences between the current part A and part B sections. Final 114.00E1, however, has no counterpart in final part A. Final 114.00E1 explains the importance of differentiating the inflammatory arthritides from other connective tissue disorders in children and of determining whether the disorder is chronic or short-term, because children may have more limited antigenic exposure and immune reactivity than adults.

For reasons we explain below, we removed current listing 101.02B, which provides that a child with rheumatoid arthritis who is dependent on steroids meets the listing. In final 114.00E6, we explain why steroid dependence in and of itself is insufficient to establish an impairment of listing-level severity.

We revised 114.00B, which currently refers to the descriptions of the connective tissue disorders in 14.00B, to add a cross-reference to final 114.00E. We made technical revisions to 114.00B so that it will parallel 14.00B. The changes bring conformity to the two sections, but do not substantively change the rules. Rather, they remove any question that might arise from our using slightly different language in two sections that are intended to say the same thing.

We added a new second sentence in 114.00C2, which describes growth impairments resulting from connective tissue disorders. The new provision explains that children with inflammatory arthritides have growth impairments because of the diseases' effects on the immature skeleton, open epiphyses, and young cartilage and bone. In the final rule, we deleted the ''many'' as a modifier as we are not certain that this is a true reflection of the incidence of growth impairment as a result of the inflammatory arthritides.

The final listing criteria in 114.09 are the same as the corresponding adult listing in part A and replace the criteria in current listing 101.02A. Again, changes we made to final 114.00E and 114.09 that are identical to changes made in the corresponding part A sections that were not in the NPRM have been made for the same reasons.

As noted above, we removed current listing 101.02B, which provided that a child with rheumatoid arthritis who is dependent on steroids meets the listing. Although this was an appropriate listing when we first published it, advances in treatment have made the listing obsolete. Advances in the administration of steroids have corrected some of the previously disabling consequences of continuous steroid use, and it is no longer appropriate to assume that every child who is dependent on steroids will have an impairment of listing-level severity. Moreover, there are few instances when systemic corticosteroids are used in the long-term management of children with inflammatory arthritis. When steroid treatment is indicated, it is usually given only on a short-term basis, with the drug dosage being gradually reduced and discontinued within a few weeks or months.

Other Changes

Because current listing 1.10B in part A (amputation at or above the tarsal region due to peripheral vascular disease or diabetes mellitus) has been removed, we also removed the listings with similar criteria in other body systems, listing 4.12C (''Amputation at or above the tarsal region due to peripheral vascular disease'') and listing 9.08C (''Amputation at, or above, the tarsal region due to diabetic necrosis or peripheral arterial disease'') to be consistent with our approach that assesses disability on the basis of how the individual is functioning. Our experience has shown that many individuals who have undergone amputation at or above the tarsal level for vascular disease or diabetes mellitus are able to return successfully to gainful work. Those individuals who are unable to ambulate effectively due to stump complications may still have their impairments evaluated under final listing 1.05B. Current listing 9.08D has become listing 9.08C. We believe that these cases must be evaluated on a case-by-case basis to determine whether they are equivalent in severity to a listed impairment or result in a finding of disability at later steps in the sequential evaluation process for adults, and will meet the 12-month duration requirement. As we stated earlier, current beneficiaries will not lose eligibility solely as a result of this listing being removed. We may find these individuals disabled based on this listing section or other rules.

In addition, we made a technical change to the current listing for systemic lupus erythematosus. Current listing 14.02A provides cross-references to ten body systems in which impairments of listing-level severity that result from the primary condition are described. We inadvertently omitted from this list an eleventh possibility, hematologic disorders, which would be evaluated under the listings in 7.00ff.

As we explain in current 14.00B1, systemic lupus erythematosus frequently results in anemia, leukopenia, and thrombocytopenia, and it is, therefore, possible that an individual would have an impairment of listing-level severity based on a hematologic disorder. We added a reference to the hemic and lymphatic body system. In keeping with the format of listing 14.02A, which lists the body systems in their order of appearance in appendix 1, the new provision has become listing 14.02A8. For this reason, we redesignated current listings 14.02A8 through 14.02A10 as listings 14.02A9 through 14.02A11.

No similar change is required in part B. Current listing 114.02A includes a reference to the hemic and lymphatic listings.

For consistency, in the final rules, we also made changes in two of the examples in § 416.926a(m), ''Examples of impairments that functionally equal the listings.'' In the second example, the requirement for ''a series of staged surgical procedures,'' has been changed to a requirement for ''continuing

surgical management.'' As explained above, we no longer require surgical procedures to be ''staged.'' We have also made a small change in the fourth example to make clear that it is the inability to maintain effective ambulation that makes a condition functionally equivalent to a listed impairment.

Also for consistency, in the final rules we made technical changes in §§ 416.933, ''How we make a finding of presumptive disability or presumptive blindness,'' and 416.934, ''Impairments which may warrant a finding of presumptive disability or presumptive blindness,'' based on our change in assessing disability on how the individual is functioning. In § 416.933 we have amended the second sentence by removing ''amputation of extremities'' as an example of a readily observable impairment upon which we can find an individual disabled without medical or other evidence. In § 416.934 we have removed current impairment categories (a) and (h). Our experience has shown that we can no longer presume that an individual who has undergone amputation of two limbs (impairment category (a)) or an individual with diabetes who has undergone amputation of a foot (impairment category (h)) would be unable to successfully perform gainful work.

Throughout the final rules, we made nonsubstantive editorial changes from the NPRM. For example, in several places in final 101.00, we deleted the words, ''given age ranges'' from the phrase ''given normal developmental expectations for given age ranges'' because ''developmental expectations'' already implies consideration of age. Deleting the words does not change the meaning of the statement. In the NPRM, we used ''motor deficit'' and ''motor loss'' interchangeably. For consistency, throughout the final rules we use ''motor loss.''

Public Comments

Subsequent to the publication of the NPRM in the **Federal Register** (58 FR 67574) on December 21, 1993, we mailed copies to national medical organizations and professionals whose responsibilities and interests provide them with some expertise in the evaluation of musculoskeletal impairments. We also sent copies to Federal and State agencies (including the State agencies that make disability determinations for us) interested in the administration of the title II and title XVI disability programs. As part of our outreach efforts, we invited comments from advocacy groups, as well as from legal service organizations.

We received 34 letters and telefaxes containing comments pertaining to the changes we proposed. We carefully considered all of the comments and adopted many of the recommendations. A number of the comments were quite long and detailed. Of necessity, we have had to condense, summarize, or paraphrase them. Nevertheless, we have tried to present all views adequately and to respond to all of the relevant issues raised by the commenters. We provide our reasons for adopting or not adopting the recommendations in the summaries of the comments and our responses below.

General Comments

Emphasis on Function

Comment: A number of commenters expressed general approval of the proposed listings. One commenter stated that the changes are reasonable and probably necessary in light of the fact that there have been advances in medical knowledge and diagnoses since changes were last considered several years ago. Other commenters specifically praised the emphasis on function, on the results of physical examination rather than on diagnosis, and on a longitudinal picture of the claimant's impairment in the proposed listings. These commenters were impressed generally with the expansion of the introductory text to the proposed listings to include definitions of terms and examples. One of these commenters stated that the definitions of ambiguous terms and examples would promote uniformity of decisionmaking. These commenters had no specific suggestions.

Response: We agree with the commenter who stated that the changes are reasonable and necessary in light of the fact that there have been advances in medical knowledge, diagnosis, and treatment. In the past, it may have been reasonable to assume that individuals with particular diagnoses were disabled once the diagnoses were objectively established. However, with state-of-the-art medicine, we can no longer reach the same conclusions. It is more important now to determine how an individual is functioning with treatment and use of technological advances in such devices as prostheses than it is to know the diagnosis of the individual.

Proposed Listings More Restrictive Than Past Listings

Comment: Some commenters, however, expressed concerns about the functional aspects of the proposals. Several commenters noted that the proposed revisions reflect the trend to write listings which rely on the assessment of function, rather than on diagnosis, to determine if a listing is met. While all of these commenters did not necessarily disagree with this trend, there were various concerns, such as that the proposed listings are possibly more restrictive than past listings and that with an emphasis on function comes the potential need for detailed development of activities of daily living on a larger number of cases. In the view of some commenters, the proposed listings require or at least imply the need for a more extreme level of functional loss to meet the listings than did prior listings.

Response: The proposed and final listings describe a level of impairment severity that represents the inability to perform any gainful activity. We believe the new listings describe this level of impairment severity more clearly and will therefore promote greater consistency in decisionmaking. Furthermore, if an individual does not have an impairment that meets a listing, this does not mean that the claim will be denied. This is because we do not make a determination or decision regarding disability based solely on whether or not an individual's impairment(s) meets a listing. The impairment(s)also could be found to equal a listing. If the severity of an adult claimant's impairment(s) does not meet or medically equal the severity of an impairment in the medical listings, the claimant can be found disabled at a later step in the sequential evaluation process. (In the case of a child claiming benefits under title XVI of the Act, the impairment(s) must cause marked and severe functional limitations as defined in § 416.906.)

Proposed Listings May Result In More Documentation and Delays

Comment: Some commenters stated that the listing changes could lead to more decisions at steps four and five of the sequential evaluation process for adults than at step three. Based on a premise that more documentation is required at these later steps of the sequential evaluation process, these commenters also thought the proposed listings may require more development and longer case processing time.

One commenter also stated that the proposed listings will require more documentation because they emphasize the need for and reliance on existing medical evidence, and the course of an impairment must be documented with a longitudinal clinical record covering at least 3 months of management and

evaluation. This commenter pointed out that the expanded criteria included the need to look at ''surgical management,'' not just ''staged surgical treatment,'' which, in the commenter's view, also will require more documentation of such things as information regarding various procedures post-surgery, complications of surgery, infections, and other factors associated with surgery, which adjudicators will need in order to determine functional limitations.

Response: We are not convinced that, even if there are more decisions at steps four and five of the sequential evaluation process, this will result in more development and increased processing time. The intent of the listings is to identify impairments that preclude the ability to perform any gainful activity (or, in the case of a child applying for SSI benefits based on disability, results in marked and severe functional limitations). Several of the current listings already include criteria based on functioning, and a degree of functioning has always been implicit in the other listings. Furthermore, we believe that if there are any increases in required documentation or processing time, they will be counterbalanced by the positive impact of the clarifications made in the new listings and the resulting uniformity of determinations and decisions. This will help ensure that the correct decision is made as early in the adjudicative process as possible, thereby reducing the number of appeals. However, in response to these comments, we added language in final 1.00B2a and 101.00B2a to make clear that we are not requiring additional documentation about the individual's ability to perform the specific activities that we list as examples in this section.

Although we disagree with the comment that the requirement for a longitudinal clinical history of management and evaluation for at least 3 months after alleged onset of the impairment in many cases would have resulted in more documentation and delays, we adopted the comment and deleted the 3-month requirement in favor of more general language on the need to establish a longitudinal history. In final 1.00H we make clear that, while a longitudinal clinical record is generally important for the assessment of severity and expected duration of an impairment, it is not always required.

''Level of Proof'' Needed To Show Loss of Function

Comment: One commenter suggested that we should define the ''level of proof'' needed in order for a physician to reach a conclusion regarding a condition and its effect on function. Physicians generally are asked if something is ''possible,'' ''probable,'' (more likely than not) or beyond a reasonable doubt. The commenter stated that there are a variety of references throughout this text which need this clarification. The same commenter was concerned that the proposed listings may not clearly show how physicians should determine functional ability. This commenter voiced the opinion that there is no more difficult determination that physicians have to make than to objectively evaluate functional capacity. Another commenter stated, ''If the intent is to make a more functional evaluation, then a more objective standard should be utilized.''

Response: We believe the ''level of proof'' issue, that is a better definition of how physicians will determine functional loss, is comprehensively discussed in our existing regulations at §§ 404.1512(b)(2) through (6), 404.1513(b)(1), (4), and (5), 404.1528(b) and (c), 404.1529, 416.912(b)(2) through (6), 416.913(b)(1), (4), and (5), 416.928(b) and (c), and 416.929. These sections stress that there must be objective medical evidence of a medically determinable impairment, and what is meant by objective medical evidence and other evidence. They also emphasize how we will consider all such evidence in determining how an impairment and related symptoms will be considered in determining their impact on an individual's ability to function. Regarding the concern that the listings do not teach physicians how to determine functional ability, the listings are not intended as a vehicle for training physicians. Rather, the listings provide guidelines for evaluating disability claims and provide an administrative means for screening in obviously disabled individuals. However, we do provide information on functional assessments as part of our professional relations outreach at medical conventions, forums, etc. We believe this is a more appropriate and effective approach to educating doctors and other medical professionals than using the regulatory process.

We agree that it is difficult for physicians to reach conclusions about an individual's functional ability. As we stress in §§ 404.1527 and 416.927, a physician's medical opinion on an individual's functional ability should be based on the medical signs and laboratory findings, the individual's symptoms, diagnosis and prognosis and the physician's own observations of the individual. However, the ultimate decision about a claimant's residual functional capacity (RFC) and whether the individual is disabled is reserved to the Commissioner of Social Security.

Muscle Spasm as an Indication of Impairment

Comment: One commenter suggested that the regulations should still require that muscle spasm be reported when it is present in back impairments, even if the finding may not be constantly present, because it helps to establish a severe impairment.

Response: We agree and have added language to final 1.00E and 101.00E that muscle spasm, when present, should be reported. We trust it is clear that, because muscle spasm is not always present in severe back impairments and is often a transient finding when it occurs, it need not be present to support a finding of disability. This is stated in our policy on pain and other symptoms at §§ 404.1529(c)(2) and 416.929(c)(2). This is also why sections 1.00D and 101.00D discuss the need for establishing a record of such intermittent findings as muscle spasm over a period of time, whenever possible.

Medical History

Comment: One commenter stated that the introductory text to the listings contains no guidance or requirement that a standard medical history be taken, nor does it include a description of the elements that should be included in the history. The commenter would add a section that discusses specific elements that the history should contain. The commenter suggested that the introduction should discuss acceptable methods of obtaining information regarding functioning, and that it should clarify that information regarding function should be obtained through a medical history, which may be supplemented by information obtained directly from claimants or third parties by adjudicators. The commenter also suggested that, when appropriate, the history should specify why treatment is not commensurate with the claimant's alleged level of symptoms to better address issues of credibility.

Response: We have not adopted this comment because most of the suggested revisions are covered adequately in other sections of the existing regulations and Social Security Rulings (SSRs), which are better vehicles for issues such as relating claimants' medical histories to their levels of functioning and addressing credibility. Current §§ 404.1512(d), 404.1513(b), 416.912(d), and 416.913(b) stress the need for a medical history in all medical reports, regardless of the nature of the

impairment, and state that we will make every reasonable effort to obtain this history. The suggestion that information regarding functioning should be obtained through a medical history supplemented by non-medical evidence need not be included in these rules because this is already required by §§ 404.1545(a) and 416.945(a).

We believe the suggestion that adjudicators should obtain information that explains why a claimant has not sought treatment commensurate with his or her allegations is already required in the regulations at §§ 404.1529 and 416.929. These regulations require adjudicators to consider, among other things, the type, dosage, effectiveness, and side effects of any medication the claimant takes or has taken to alleviate pain or other symptoms; treatment other than medication that the claimant receives or has received to relieve symptoms; any other measures used to relieve symptoms; and other factors concerning the claimant's functional limitations and restrictions due to symptoms. The regulations go on to state that in determining the extent to which symptoms affect the claimant's ability to perform basic work activities, we will evaluate the claimant's statements in relation to the objective medical evidence and other evidence in reaching a conclusion concerning disability. Further, we will consider whether there are any inconsistencies in the evidence and the extent to which there are any conflicts between the claimant's statements and the rest of the evidence. To make sure that adjudicators fully understand how to consider the level of a claimant's treatment in assessing his or her credibility, we published SSR 96–7p, ''Titles II and XVI: Evaluation of Symptoms in Disability Claims: Assessing the Credibility of an Individual's Statements,'' on July 2, 1996 (61 FR 34483), to further clarify the intent of these regulations.

We do not see further need to specify what goes into a history taken by an examining physician. Sections 1.00B2d–1.00E2 and 101.00B2d–101.00E2 include statements about what is needed to evaluate an impairment under these listings, and this includes the elements of a complete musculoskeletal history.

Proposed Obsolescence of Listing for Osteomyelitis

Comment: Another commenter stated that the listing for osteomyelitis and septic arthritis should be retained because she indicated that she knows of some individuals who continue to meet this listing.

Response: As we stated above and in the NPRM, advances in antibiotic therapy and in treatment have made osteomyelitis and septic arthritis rare occurrences, and cases that would last or be expected to last 12 months are even rarer. This does not mean that we would never find an individual disabled based on these conditions. It simply means that their occurrence is sufficiently rare that we can no longer justify a specific listing just for the occasional case we may encounter. As we stated in the NPRM, individual occurrences should be handled on a case-by-case basis to determine if they are equivalent in severity to a listed impairment or if they reduce RFC sufficiently to result in an allowance at a later step of the sequential evaluation process.

An individual who has been found disabled because of a listing for osteomyelitis or septic arthritis would not be disadvantaged because we later removed the listing. We do conduct periodic ''continuing disability reviews'' of individuals on the rolls to determine whether they are still disabled. However, when we conduct continuing disability reviews, we do not find that disability has ended solely based on a change in the listing. In most cases, we must show that an individual's impairment(s) has medically improved and that any medical improvement is ''related to the ability to work.'' If an individual's impairment(s) has not medically improved, we will generally find that the individual is still disabled. Even if the impairment has medically improved, our regulations provide that the improvement is not ''related to the ability to work,'' if the impairment(s) continues to meet or equal the ''same listing section used to make our most recent favorable decision.'' This is true even if, as in these final rules, we have removed the listing section that we used to make the most recent favorable decision. See §§ 404.1594(c)(3)(i) and 416.994(b)(2)(iv)(A) of our regulations. (A similar provision for continuing disability reviews for children eligible for SSI based on disability appears in § 416.994a(b)(2).) In a case where we find that medical improvement is not related to the ability to work (or the impairment still meets or equals the prior listing, in the case of an individual under age 18), we will find that disability continues, unless an exception to medical improvement applies.

Need for Training/Education

Comment: Some commenters thought that any change in listings such as these will require re-education of the medical community and disability adjudicators. As one commenter noted, there may be an initial slowing of adjudication because of requests for clarification of the doctors' reports. This should be only temporary, however, and should be resolved in a relatively short time. Another commenter strongly recommended that SSA involve itself in the process of educating the medical community and motivating them to provide timely, complete information.

Response: Any changes in policy raise some issues during transition, but as always, we will train our adjudicators on the final regulations so that they will be familiar with the new criteria. We would expect physicians in the community who are involved with the program to learn about the changes through the usual channels provided under our auspices (e.g., public relations forums and meetings with professional relations officers).

1.00A Disorders of the Musculoskeletal System

Comment: A commenter asked (apparently for informational purposes) if hemophilic arthritides are also included under this section of the listings, but did not ask for any changes to the listings.

Response: Joint problems in people with hemophilia are caused by either acute bleeding into the joints or chronic changes related to prior joint bleeding. Because this is not a true inflammatory or infectious process, the term ''arthrosis'' rather than ''arthritis'' is actually more technically correct. Children, as well as adults, are affected by this condition, although children more frequently present with acute problems and adults more frequently present with chronic problems. Thus, hemophilic arthrosis would be included in the general conditions considered under 1.00A and 101.00A, and the effects of this condition generally would be considered under the listings that follow. Occasionally, chronic septic arthritis can occur in a hemophiliac with joint bleeding from frequent needle withdrawal of fluid from the joints. If this occurs, then the resulting impairment would be evaluated under listings 14.09 or 114.09.

1.00B Loss of Function

Comment: One commenter asked, ''Since these functional criteria are similar to 11.04B, shouldn't there be a referral to Listing 11.00ff if the restriction is due to a neurological problem?''

Response: We agree with this suggestion and have added statements

to this effect to final 1.00B1 and 101.00B1.

Terminology Used in 1.00B

Comment: One commenter called the term ''sustained basis'' an open-ended term that could use further definition. Several other commenters believed that the terms ''inability to ambulate effectively'' and ''inability to perform fine and gross movements effectively'' need clarification because they are open to interpretation and may make consistency of decisionmaking and review difficult. In addition, a commenter suggested that we need to provide some guidance on how to verify the degree to which a claimant's ability to ambulate is diminished. Another commenter suggested that the ''term 'extreme' is nonspecific and will not provide appropriate guidance to decision makers.'' Still another commenter suggested that the criteria for inability to ambulate provide more specific examples than the inability to perform fine and gross movements, and an explanation of how much or to what extent the ability or inability to reach, push and/or pull has in determining severity is needed. The commenter also stated that further explanation about intermittent assistance in buttoning and tying should be included. Similarly, another commenter suggested that we need to define exactly what we mean by intermittent assistance.

Response: We disagree, but we clarified the rules in response to these comments. We believe that it is clear from the examples cited in 1.00B2b, 1.00B2c, 101.00B2b, and 101.00B2c what we mean by ''the inability to ambulate effectively on a sustained basis or the inability to perform fine and gross movements effectively on a sustained basis.'' Further, we do not believe that assessing a claimant's ability to ambulate will be any different from any other assessment of the individual's ability to function. Thus, no further ''verification'' should be necessary.

The term ''extreme'' is not a new one to our disability adjudicators and is, in fact, defined, as it relates to children, in § 416.926a(e)(3) of our regulations. We disagree that the examples for inability to ambulate are any more specific than the examples for inability to perform fine and gross movements.

However, in response to these and other comments, we made several changes in final 1.00B2 and 101.00B2 that we believe will help clarify our intent. In 1.00B2b, 1.00B2c, 101.00B2b, and 101.00B2c we expanded the first sentence to better explain what we mean by an ''extreme'' loss of function when we talk about the ''inability to ambulate effectively'' and the ''inability to perform fine and gross movements effectively.'' In response to the comments indicating that the example of ''intermittent assistance'' in buttoning and tying shoes was not clear, we deleted this example.

In final 101.00B2b(2) we have made an additional modification of the first sentence to make it clear that consideration of function in children too young to walk independently must be based on assessment of the limitations in the ability to perform comparable age-appropriate activities with the lower extremities, given normal developmental expectations. This makes it clear that ''extreme'' levels of limitation will not necessarily mean a complete inability to do age-appropriate activities. We made a similar change in final 101.00B2c(2) regarding limitations in the ability to perform fine and gross movements for very young children.

Comment: Without making a specific recommendation, two commenters asked for clarification of the second sentence of 1.00B1 in the NPRM (final 1.00B2b). They wondered why the definition would require limitations to both upper extremities if a hand-held assistive device were required for adequate ambulation. They also asked if a cane would qualify under this section. Furthermore, would holding a device in one hand with only minimal assistance of the other hand constitute functional limitations of both upper extremities, or must the hand-held device require limitations of both hands (i.e., crutches, walker, etc.).

Response: We believe that the sentence is clear in its intent that an individual with one hand free while using an assistive device in walking would not meet the definition if he or she were otherwise ambulating effectively as defined in final 1.00B2b. As we repeatedly stress, the criteria expressed in the listings are intended to define limitations that prevent any gainful activity. A claimant requiring a cane or other device in only one hand to effectively ambulate might be severely impaired and could possibly be allowed at a later step of the sequential evaluation process, but he or she would not necessarily be unable to perform any gainful activity.

Comment: In related comments, two respondents implied that the required limitations to both upper extremities if a hand-held assistive device is required for adequate ambulation is a restatement of our policy. One of the two indicated that the proposed criteria are too restrictive, while the other believed the change is a good idea but would require training of adjudicators.

Response: We believe that the change is consistent with the intent of all listings regardless of the body system (i.e., as stated in the previous response, the listings are intended to define limitations that they would prevent any gainful activity.) Some individuals who walk reasonably well with a cane might be capable of some jobs and would need to be evaluated at later steps of the sequential evaluation process. To the degree that these changes require training for our adjudicators, we will provide such training just as we do with all new listings. Furthermore, the change is consistent with SSR 96–9p, ''Titles II and XVI: Determining Capability to Do Other Work—Implications of a Residual Functional Capacity for Less Than a Full Range of Sedentary Work'' (61 FR 34478 (1996)), which deals with evaluating the vocational impact of using a hand-held assistive device.

Comment: Three commenters were opposed to the new criteria because they were apparently of the impression that we will now require individuals to use an assistive device with both hands to meet the criteria, which they, in turn, seem to equate with disability. One commenter stated, ''It has been my experience in working with disability claimants who have musculoskeletal impairments that would require the use of a hand held assistive device for ambulation, that even in the most extreme cases, an individual does not necessarily use a hand held assistive device that limits the functioning of both upper extremities.'' Another stated, ''The new proposal requiring the use of an ambulatory aid which uses both hands to be classified as the 'inability to ambulate effectively' is unjustified and absurd. By this proposal you are saying that a person who needs a cane to safely and effectively get around is not disabled.'' This individual also wanted to know how a case would be handled ''if a person has no use of an upper extremity because of C[erebral] V[ascular] A[ccident] or amputation.'' The third commenter suggested that, unless a claimant were in a wheelchair, he or she would not meet the ambulatory criteria, and that ''the slightest ability to ambulate would, in effect, rule out your meeting and/or equalling [sic]'' the musculoskeletal listings.

Response: We believe that these comments stem from a misinterpretation of the criteria. The criteria do not require an individual to use an assistive device of any kind. The first sentence of final 1.00B2b stresses that ''[i]nability to

ambulate effectively means an extreme limitation of the ability to walk.'' The ensuing explanation and examples should make it clear that this applies to anyone who cannot walk adequately. The explanation is intended to mean that individuals who can only walk with the aid of hand-held assistive devices requiring the use of both upper extremities would meet the definition of inability to ambulate effectively. In addition, anyone with an ineffective gait who cannot use assistive devices would also meet the definition of inability to ambulate effectively. An individual who can walk adequately with a cane or other device that affects only one upper extremity cannot be considered as incapable of any gainful activity, but such an individual might well be found disabled at later steps of the sequential evaluation process.

Thus, we recognize that individuals with extreme inability to ambulate do not necessarily use assistive devices. Furthermore, we recognize that an individual who uses a cane may be disabled. In addition, we state in the explanations at 1.00B2b and 101.00B2b(1) that listings 1.05C and 101.05C are exceptions to the general rule because an individual evaluated under these listings would have only one upper extremity. If an individual, for any reason, could only use a cane and no other assistive device and could not effectively ambulate, he or she would meet the criteria. Furthermore, we hope it is clear that the criteria are not intended to exclude all but those confined to wheelchairs. We believe that the language in final 1.00B2b and 101.00B2b(1) clarifies confusing language in the current listings.

Comment: One commenter stated that proposed 1.00B (final 1.00B2b) ''is contrary to the intent of the S[ocial] S[ecurity] Act, which defines a listed impairment as any impairment in which medical factors alone are presumed to preclude substantial gainful activity.'' The commenter suggested that we change the language to reflect that an individual would be disabled with the ''ability to walk only short distances (e.g., a city block) before resting,'' or the ''ability to walk only with the use of any ambulatory aid (e.g., one cane or crutch), as long as the other criteria of the Listings (e.g., joint pain, swelling, tenderness, and signs of inflammation or deformity on current physical examination in 14.09) are met.''

Response: We do not believe that the criteria in any way conflict with the Act. The Act does not, in fact, make any provision for the listings at all. The listings are an administrative convenience established by regulation to identify obviously disabled individuals. Furthermore, we believe the final criteria better identify obviously disabled individuals than would the suggested criteria. The suggestion might result in erroneous awards of benefits to individuals who could perform substantial gainful activity.

Comment: Another two commenters indicated that the introductory text should provide a definition and or example of what constitutes ''reasonable pace.'' One of the two wanted to know if it is having the ability to walk for one block on uneven surfaces in 5 minutes.

Response: We do not believe that ''reasonable pace'' can be easily limited to a particular distance in a specific amount of time. Disability determinations and decisions require a certain amount of judgment, no matter how specifically we define our terminology. The total medical and other evidence, including, but not limited to, what is learned about the individual's activities of daily living, and third party observations, must be utilized. By providing specific examples, we believe that we are providing adjudicators with sufficiently defined terms to make reasonable and consistent determinations and decisions.

Comment: One commenter disagreed with our decision not to consider the ability to stand in the definition for ambulation. The commenter stated, ''This section addresses only an ability to walk, not the ability to stand because standing is 'not an accurate gauge of functioning.' Standing is often a frequent function of many jobs, whereas, walking may only be occasional. For example, most assembly line workers stand a majority of the day in one spot, with minimal walking.'' The commenter further stated that standard SSA vocational documentation forms ''list walking and standing as separate physical activities when describing job duties.''

Response: The commenter has taken issue with the explanatory section of the draft regulations, and we agree that this explanation may have been confusing. We did not mean to imply that standing is not considered in an individual's ability to function. The primary intention for not including standing as a measure of function in final 1.00B2b (1.00B1 in the NPRM) is because, as we state in the explanation, ''profoundly impaired individuals can often stand for a period of time, although they may not be able to walk effectively.'' By including standing as a criterion, we might have incorrectly denied some claims by individuals who are disabled. A focus on ambulation rather than on standing does not mean that an individual who cannot stand for a period of time would not be disabled. Such an individual could quite possibly be unable to ambulate effectively. If an adult's impairment(s) did not meet or equal the requirements of the listings because the individual could walk without much difficulty but was unable to stand for long periods of time, as in the case of an individual with a back impairment who must alternate standing and sitting, the claim would be evaluated at the later steps of the sequential evaluation process.

Comment: Another commenter stated that in proposed 1.00B1, inability to ambulate effectively is defined as needing a hand-held assistive device that limits the functioning of both upper extremities, i.e., the claimant cannot walk without two canes or crutches, but the second paragraph of this section appears to describe a severe impairment, but less severe than the need for two assistive devices. The commenter suggested that either we change the first paragraph or we state that ineffective ambulation means the claimant needs two hand-held assistive devices and omit the rest of the description. Another commenter suggested that the regulations should include one other example of inability to ambulate effectively, the inability to walk without the use of a walker or two canes.

Response: We do not want to say that a claimant needs two hand-held assistive devices in order to exhibit inability to ambulate effectively because this would mean that people who cannot walk at all or who do not use any device but still cannot ambulate effectively would not meet the definition. The definition requires only that the claimant not be able to ambulate effectively and that effective ambulation would not occur if the only way an individual could get around would be with an assistive device that requires use of both upper extremities. Nonetheless, we have adopted the second suggestion, which may also satisfy the first commenter's concerns.

Comment: Two commenters believed there were additional inconsistencies within the definitions themselves. One commenter suggested that the first example listed in proposed 1.00B1 and 101.00B1, ''inability to climb,'' seems to be significantly more stringent than a later example, ''inability to use standard public transportation.'' Because most commuter trains and subways involve climbing up/down one or more flights of stairs, the commenter reasoned that inability to use public transit will

include many more people than those who are unable to climb ''a few steps.'' Asking if these examples are to be considered ''comparable'' in the level of severity, the commenter suggested that perhaps additional examples would help illustrate the level intended.

The other commenter believed that the second sentences of proposed 1.00B2 and 101.00B2, which stated, in part, that ''to use their upper extremities effectively, individuals must be capable of sustaining reasonable use of both upper extremities,'' could be interpreted to mean that individuals who can use only one upper extremity for pushing, pulling, grasping and fingering would have an impairment of listing-level severity because they do not have reasonable use of both upper extremities. The commenter believed this interpretation is inconsistent with a finding that an individual with a total amputation of one arm but no restriction in the use of the other arm would not meet any listing. The commenter recommended that the section be revised to indicate that individuals who are unable to perform such functions as reaching, pushing, and pulling with either upper extremity are not capable of sustaining reasonable use of the upper extremities.

Response: We added one example in connection with the previous comment, which may also help to clear up any concerns about inequities in final 1.00B2b and 101.00B2b. Nevertheless, we do not believe there is a problem with these sections. We do not intend the examples to be equivalent to each other, but to illustrate that even ''extreme'' limitation represents a range of severity. We list other examples and we make clear in final 1.00B2b and 101.00B2b that inability to ambulate effectively is not limited to these examples. For this reason, we did not change the example of inability to use ''standard public transportation.''

We did not agree with the commenter's suggestion that any individual who has lost, or lost the use of, an upper extremity should be found to meet a listing even if he or she has no other functional limitation. However, the comment made us realize that proposed 1.00B2 and 101.00B2 could have been misinterpreted. Therefore, in response to this comment we revised final 1.00B2c and 101.00B2c to make it clear that an individual must be unable to sustain such functions as reaching, pushing, pulling, grasping and fingering, regardless of whether he or she has the use of one or both upper extremities.

Comment: One commenter wanted to know how the examples in proposed 1.00B1 and 2 are to be developed and applied. The commenter wanted to know if some examples are ''critical'' to a decision of disability and how a claim would be decided if the claimant met some of the criteria but not others.

Response: Because the criteria mentioned are intended as examples of what would be extreme loss of function and not as individual requirements of a listing, it is not intended that some are more ''critical'' to a decision than others, any more than that some should be construed as more ''stringent'' than others. A claimant's loss of function may be evident through some other description than is found in any of the examples. This is why we are careful to state that these are examples and inability to ambulate or use the upper extremities is not limited to these examples.

Documentation Issues

Comment: Some commenters questioned how adjudicators should obtain the documentation required to meet the proposed 1.00B or 101.00B criteria, specifically inquiring whether adjudicators should attempt to get the evidence from physicians who treat or examine the individual or from lay sources, such as spouses, relatives, neighbors, or claimants, themselves. This led to the concern that getting the documentation might necessitate purchasing more examinations. One commenter stated that the ''emphasis on 'effective ambulation' will be very difficult to document objectively, since it will depend on the claimant's description of their activities.''

Response: As we noted in response to a prior comment, we added language in final 1.00B2a and 101.00B2a to explain that we are not requiring additional documentation about the individual's ability to perform the specific activities that we list as examples in final 1.00B2 and 101.00B2. In obtaining the evidence necessary to determine whether a claimant has an extreme loss of ability to ambulate or to use the upper extremities, adjudicators should follow the rules of evidence in §§ 404.1512 through 404.1513 and 416.912 through 416.913. Thus, we do not see this as an ''either/or'' question. Rather, we would consider statements from both medical sources and lay sources to assess the claimant's ability to do these things, ascribing appropriate weight to the statements as explained in these rules. We do not believe that the new rules will result in the purchase of more examinations or in the need for increased documentation. Even when documentation is insufficient to establish listing-level severity, many adults' claims may be allowed at a succeeding step in the sequential evaluation process.

We do not see lack of objectivity as an issue. A claimant's own statements about his or her functioning have always been factored into a decision, because symptoms are the claimant's statements about how an impairment affects the individual. We base disability determinations and decisions on all of the evidence in file, objective and subjective, and we consider whether there are any conflicts between the objective evidence and the claimant's own statements.

Pain or Other Symptoms

Comment: One commenter considered it problematic to include pain as a reason for loss of function, stating that with regard to the definitions of inability to ambulate and inability to perform fine and gross movements, including pain could create problems. The commenter indicated that this language might blur the lines between assessing the impairment severity based on objective findings, and then subsequently evaluating symptoms to see if there is a further reduction in function. Another commenter suggested we clarify the pain standard in this section. Still another commenter was concerned that this section will require the purchase of more consultative examinations.

Response: Under final 1.00B2d and 101.00B2d, we stress that in order for pain or other symptoms to be found to affect an individual's ability to perform work activities, there must first be objective medical evidence to support the existence of a medically determinable impairment that could reasonably be expected to produce the symptom. Considering pain as a factor in an individual's loss of function is consistent with §§ 404.1529 and 416.929 on evaluation of symptoms, including pain. Because the language in these final regulations is consistent with the current regulatory language regarding pain and other symptoms, it should not affect documentation requirements or practices, nor do we see any need for further clarification of the pain standard.

1.00C Diagnosis and Evaluation

Comment: Two commenters questioned whether this section might lead to purchase of extremely expensive tests. To avoid unnecessary purchase of such tests, one suggested it might be useful to include an explanation of the limitations inherent in using electromyography to assess impairment severity or functional limitations, and

that the section should specifically state that tests such as computerized axial tomography (CAT) scan or magnetic resonance imaging (MRI) should be reserved for difficult cases. Also, the commenter wanted to know if it would be possible to address the role of such newer testing as thermography. The other commenter asked, ''Since diagnosis and evaluation will be supported by medically acceptable imaging techniques such as CAT scan, MRI and radionuclear bone scans, will SSA be considering purchase of these techniques, if not part of the medical evidence of record?''

Response: SSA has never routinely purchased the types of tests mentioned in proposed 1.00C and 101.00C, nor do we see these sections as endorsing such a purchase. Rather, we will consider the results of such tests when they are part of the existing evidence in the case record. Such evidence normally would not be necessary because of the functional aspects of the revised listings. The ultimate degree of impairment severity is determined by how the claimant is functioning. Thus, although the types of tests mentioned are useful, they are usually not required for establishing a diagnosis and are rarely required for evaluating function. Nevertheless, in order to avoid unnecessary purchase of expensive tests, we have provided clarification in final 1.00C2 and 101.00C2 that we do not routinely purchase certain types of tests which are expensive and do not order other tests, such as myelograms, which are invasive and may pose significant risk to the claimant. In final 1.00C1 and 101.00C1 we have also explained that the medically acceptable imaging must be ''appropriate'' to ensure that the technique is one which can support the evaluation and diagnosis of an impairment.

A discussion of such newer techniques as thermography is not necessary since the tests mentioned are examples and not an exhaustive list. Tests such as electromyography, which are generally accepted by health care professionals as useful in establishing a diagnosis, would be acceptable to SSA. We state in final 1.00C3, with a minor clarification of the NPRM, that electrodiagnostic procedures may be useful in establishing the clinical diagnosis, but do not provide evidence which can be used to assess function for purposes of listing 1.04.

Comment: One commenter asked, ''Why is myelography (with or without post-myelographic CAT) not considered an acceptable imaging study? Are not the 'acceptable' imaging studies diagnostic procedures in the same vein and only helpful in establishing (supporting) the history of symptoms and physical signs?''

Response: This commenter seems to have misinterpreted the intent of the section. We do not state that these tests are not ''acceptable.'' We state that they may be ''useful'' in establishing diagnosis. However, because they do not, in and of themselves, measure functional ability they are not a substitute for the other requirements of the listings. The commenter is correct in noting that myelography is a form of medically acceptable imaging. We have added myelography to the list of examples in final 1.00C1 and 101.00C1. However, as explained above, this is an invasive procedure which may involve significant risk to the claimant. Therefore, we will consider the results of this testing when it is in the evidence in the case record, but we will never order the test.

1.00D The Physical Examination

Comment: One commenter suggested that ''[t]his section requires 'alternative' testing methods'' be used to verify abnormal findings'' and wanted to know, if alternate methods are not reported, would additional development be required to obtain them. Another commenter stated that use of alternative testing methods could result in apparent conflicts and delays in claims processing to resolve these conflicts. However, the commenter added that the provision recognizing that musculoskeletal impairments may be intermittent is a positive one.

Response: In response to the first commenter's concern, 1.00D does not require alternative testing methods in all cases. In some cases disability might be so obvious that alternative tests would not be needed. An adjudicator would only delay adjudication of a case if alternative methods were specifically required. Such a decision would be made on a case-by-case basis. We do not see such a need as a frequent occurrence because alternative tests are routinely performed in a general examination. The main reason why we included straight-leg raising in both the supine and the sitting positions as an example in this section is that these two versions of this test are routinely done to verify findings on examination. We should add that the language about which the commenters have expressed concern was not new to the NPRM. Rather, it is longstanding policy, having been part of current 1.00B.

We agree with the second commenter that in the event of a conflict, further investigation may be necessary. This, too, is consistent with longstanding policy. We believe that the type of thorough examination in which such cross-checks are performed will help ensure sound determinations and decisions and will in no way disadvantage disabled individuals. The statement that recognizes the intermittent nature of the presenting signs and symptoms of some impairments has been in the introduction to the musculoskeletal listings for some time and is there to safeguard the rights of disabled individuals. Current 1.00B contains an almost identical statement to the one in the proposed and final rule.

1.00E Examination of the Spine

Comment: Several commenters presented suggestions and concerns regarding the specificity needed for findings of muscle atrophy, motor abnormalities, and ranges of motion. One commenter suggested that a straight-leg raising test is meaningless if simply reported as ''positive,'' and that if pain is produced during straight-leg raising, it is necessary to know the location, pattern, and character of the pain. Another commenter suggested the listings should request that examining and treating physicians provide the Lasegue's sign. Some commenters also questioned the value of physicians merely reporting atrophy. One commenter suggested that a slight asymmetry of comparative circumference measurements may be unrelated to strength and could even be the result of errors in methods of measurement. Similarly, other commenters suggested that general statements regarding loss of muscle strength are of limited value and suggested the need for standard guidelines for measuring muscle strength. One commenter suggested the commonly used ratings of 0–5 with 5 representing normal muscle strength. Concerning ranges of motion, one commenter asked whether they should be given quantitatively, while another asked if anything less than the normal values listed in the ''Guides to the Evaluation of Permanent Impairment'' (the Guides) be considered a limitation of motion. He stated, ''For example the normal range of motion for flexion of the shoulder is listed as 180o. The rule should clarify what degree of flexion of the shoulder, e.g., 175o or 179o, is to be considered as a limitation of motion.''

Response: We agree that a statement of positive straight-leg raising alone is insufficient, which is why we request that it be reported in degrees and why we prefer that it be reported from both the supine and sitting positions (cf. 1.00D). We agree that the Lasegue's sign,

or any other appropriate tension signs, be provided, and we have added a phrase to this effect to final 1.00E1. We believe that this addition, together with the statement that observations of the individual during the examination should be reported, will be adequate to determine the significance of pain on straight-leg raising, especially because we already consider the location, pattern, and character of any pain under our regulations at §§ 404.1529(c)(3) and 416.929(c)(3). Furthermore, listing 1.04A, to which this discussion of straight-leg raising refers, calls for a ''neuro-anatomic distribution of pain.''

We also agree that measurement of muscle strength via the 5-point scale would be useful in conjunction with reports of atrophy for assessing motor function. Therefore, we have added language to final 1.00E1 and 101.00E1 that a report of atrophy should be accompanied by some form of measurement of the strength of the muscle(s) in question, and that we suggest that the 0 to 5 scale be used.

Concerning ranges of motion, experience in the past has shown that the criteria in the Guides have been sufficient for proper adjudication of musculoskeletal impairments. No further descriptions are really needed. Anything less than normal range of motion is clearly defined in the Guides and should be considered a limitation of motion.

Comment: One commenter thought that residual neurological deficit after surgery or other resolution of the underlying problem should be able to satisfy listing 1.04.

Response: As we stated in the explanation of the proposed rules in the NPRM, the second paragraph of proposed 1.00E (final 1.00E2), which is the section in question, is a clarification of the language in the current listings. As such, it represents a longstanding policy. Because the listing presupposes certain complications, such as significant disability due to pain, caused by active compromise of a nerve root, it is sound and logical from a medical standpoint to evaluate residual impairment under the more appropriate neurological listings once the compromise has been alleviated.

Proposed 1.00F (Final 1.00H) Documentation

Comment: Two commenters indicated that the section on Duration of Impairment (1.00F in the NPRM) needed clarification because it implied that 3 months of treatment history is needed in all cases. One commenter suggested that ''[t]here are many musculoskeletal impairments in which we do not need to have a record of at least 3 months of management and evaluation,'' while the other was concerned that ''the impression is that musculoskeletal conditions all improve with time.'' The latter suggested rewording the phrase, ''musculoskeletal impairments frequently improve with time or respond to treatment'' to ''musculoskeletal impairments frequently improve or respond to treatment within a three-month period after onset; degree of improvement can vary, and some impairments ultimately result in progressive disability.'' Two additional commenters were concerned that the 3-month requirement could result in delays and increased expense, and one of the two asked for clarification of what we mean by a favorable decision because if ''favorable'' means ''fully favorable'' and all other cases require a 3-month history, this would delay development of the majority of cases. Another commenter asked for clarifying language on how to handle this requirement when there is no treating source.

Response: As already noted, we deleted the requirement for a 3-month history in response to these and other comments, although we continue to stress the importance of a longitudinal history. In final 1.00H, we explain that, in the absence of a longitudinal clinical record, we will make a determination based on all the available evidence.

In responding to these comments, we also realized that the heading of the section was inaccurate because the section was not exclusively about ''Duration.'' In final 1.00H (and final 101.00H) we have changed the title to ''Documentation,'' which better describes the provisions in this section.

The fact that an individual may not have a treating or other medical source does not mean that we cannot establish a longitudinal clinical record. If necessary, we may purchase a consultative examination for comparison with earlier evidence. Also, we made several changes in response to this and other comments. We clarified final 1.00H and 101.00H by stating that a longitudinal picture of the individual's impairment(s) in terms of medical severity, functioning, and symptomatology is important even when the individual has not received ongoing treatment. We also added final 1.00H3 and 101.00H3, ''When there is no record of ongoing treatment.'' The language is taken from the introductory texts to other body systems; see, e.g., 4.00A, third paragraph, in the cardiovascular system. It only repeats our longstanding policy. In both the NPRM and final 1.00H and 101.00H, we state that it is not necessary to defer a determination or decision when the evidence establishes that the claimant is disabled.

Proposed 1.00G (Final 1.00I) Effects of Treatment

Comment: One commenter wanted to know how the issue of duration figures into the positive or negative effects of pain medication, while another asked how the impact of adverse side effects should be documented or evaluated.

Response: We believe that these issues are adequately addressed in the regulations on pain and other symptoms found in §§ 404.1529 and 416.929. The effects of any medications used for symptoms are considered together with all medical and other evidence in determining the severity and expected duration of an impairment. Findings that medication relieves pain only sporadically or that side effects are long lasting and particularly debilitating would impact adversely on the claimant's overall ability to function for extended periods, while extended periods of relief with few side effects might improve ability to function. However, the regulations do not intend that the effects of medication be considered alone. Rather, these effects should be considered with a number of factors outlined in §§ 404.1529(c)(3) and 416.929(c)(3), as well as the objective medical evidence and all other available evidence, in measuring the total impact of symptoms on the ability to function. Nevertheless, we added the phrase, ''or judgment about future functioning,'' to the end of the last sentence of final 1.00I3 and 101.00I3 to make clear that we are ultimately concerned with how treatment, be it medication, surgery, or any other measures, affects or will affect the individual's ability to function.

Proposed 1.00H (Final 1.00J) Orthotic, Prosthetic, or Assistive Devices

Comment: One commenter questioned the logic for assessing an individual without the aid of a hand-held device, especially because it has already been deemed ''medically'' necessary. Another commenter liked the concept, but together with a third commenter, foresaw practical difficulties with getting the information. The former suggested that it is unlikely that claimants will voluntarily relinquish their devices, and he doubted that consulting physicians will remove them forcibly. The other commenter stated, ''The new listings require information as to exactly what function a person has without the device if one is usually used, including how far he/she can ambulate without it, and on what kind

of surfaces. Not all claimants are treated by specialists prepared to provide such details.''

Response: In response to these comments we have removed the phrase, ''medically necessary'' and have restructured the section to clarify when an examination with or without an orthotic, prosthetic, or assistive device is important.

We explain in final 1.00J4 (hand-held assistive devices), the importance of an evaluation with and without a hand-held assistive device, and why it is important to document the need for the device. We would not require an examination without the assistive device if such an examination is contraindicated by the medical judgment of a physician who has treated or examined the individual.

In final 1.00J2 (orthotics) we explain that it is unnecessary to routinely evaluate an individual's ability to function without the orthosis in place. If an individual with an impairment of a lower extremity or extremities cannot use an orthotic device, the examination should include information on how the individual ambulates without the device. However, we do not expect a physician to examine the individual without the device if contraindicated by medical judgment.

In final 1.00J3 (prosthetics) we explain that the examination should be with the prosthetic device in place. We make clear that where an amputation involves a lower extremity or extremities, we do not require an evaluation of an individual's ability to walk without the prosthesis, but we do require an evaluation of the individual's medical ability to use a prosthetic device to ambulate effectively as defined in 1.00B2b. We also explain that the condition of the stump should be evaluated without the prosthesis in place.

We expect that the appropriate medical need for an orthotic, prosthetic, or hand-held assistive device will be confirmed by a physician who has treated or examined the individual.

Proposed 1.00I (Final 1.00K) Disorders of the Spine

Comment: One commenter suggested that arachnoiditis can be determined through CAT and MRI scans, rather than only through surgery and subsequent pathology report. Another was concerned that this section does not mention scarring from surgery, which is one of the most common causes of arachnoiditis. A third commenter indicated that the listings for impairments such as spinal arachnoiditis and lumbar stenosis call for a description of pain sufficiently detailed to determine whether or not it follows the required anatomical distribution and persists despite prescribed therapy. By implication, the commenter seemed to be suggesting that this would lead to increased documentation of claims.

Response: We agree with the first commenter and believe this is adequately covered by our statement in final 1.00K2b that arachnoiditis can be confirmed by ''appropriate medically acceptable imaging.'' Concerning the second comment, we do not list any causes of arachnoiditis but only that it may be related to certain factors. In fact, we specifically stated in 1.00K2 of the NPRM that ''the cause of spinal arachnoiditis often remains obscure.'' In the event that this language may have been ambiguous, we have revised the sentence to indicate that ''[a]lthough the cause of spinal arachnoiditis is not always clear, it may be associated with chronic compression or irritation of nerve roots (including the cauda equina) or the spinal cord.'' We have also revised the last sentence of 1.00K2b to make it clear that it is particularly arachnoiditis of the lumbosacral spine that generally makes it difficult for an individual to sustain a given position or posture for more than a short period of time due to pain.

We do not believe that the description of pain required to document either spinal arachnoiditis or lumbar stenosis deviates in any way from longstanding policy set forth in the regulations at §§ 404.1529 and 416.929. The regulations require that any symptom(s) must be reasonably expected to be produced by the impairment. Generally, if a symptom is a criterion of a listing, the symptom need only be present along with the other requisite criteria. It is usually not necessary to determine whether there is functional loss associated with the symptom. It is the interrelationship of the set of medical findings, not the individual criteria, that establishes listing-level severity. Information about the nature of the pain, its intensity, persistence or limiting effects is appropriate in certain listings to establish the required level of severity. Thus, we do not believe that the requirements under proposed 1.00I and final 1.00K will affect the way claims are documented.

Proposed 1.00J (Final 1.00L) Abnormal Curvatures of the Spine

Comment: One commenter suggested that we include ''outside parameters'' of degrees of curvature, even though the primary focus of the listings is on functioning.

Response: We did not adopt the comment. As the commenter noted, the emphasis of this section is on functioning, and we do not think it would be practical to set a level of curvature beyond which we would presume the appropriate degree of functional limitation.

Comment: One commenter referred to our statement in the NPRM that marked disfigurement may result in emotional withdrawal and isolation. This commenter asked whether such a mental impairment should be evaluated separately since any marked deformity could have a similar impact. Another commenter suggested that we expand our list of examples to include ''cardiac, gastrointestinal, neurologic, and immune system compromise'' in addition to ''pulmonary complications'' and ''disfigurement with emotional withdrawal or isolation.''

Response: We revised the rules to address these comments, although the first comment was not entirely clear to us. We expanded the section to provide guidance about other impairments an individual with abnormal curvature of the spine may have.

We provide guidance in this section about the potential emotional effects of disfigurement to remind our adjudicators to be alert to this possibility when they evaluate the effects of the impairment on each individual. However, as in the NPRM, we also provide that associated mental disorders may be evaluated separately under the mental disorders listings, consistent with the suggestion in the first comment.

Proposed 1.00K (Final 1.00M) Under Continuing Surgical Management

Comment: One commenter asked us to clarify this section. Essentially, the inquirer wanted to know if ''continuing surgical management'' meant only surgery or if other treatment modalities, such as closed reduction, casting, bracing, bone stimulation, etc., with nonunion of the radius or ulna lasting more than 12 months, would satisfy the criteria for listing 1.07.

Response: The types of alternatives to surgery mentioned in the question would satisfy the requirements of the listings, as we believe is made clear by the language in 1.00M. This is why we use such terms as ''surgical procedures and any other associated treatments,'' ''other medical complications,'' and ''related treatments'' in our discussion of what we mean by surgical management. In our explanation of changes we did state that ''surgical management'' means more than surgery itself.

Proposed 1.00L (Final 1.00N) After Maximum Benefit From Therapy Has Been Achieved

Comment: There were three separate suggestions for clarification of this section. One suggestion was that the section should make some mention of how to apply the guides when the 12-month duration period has already been met, not merely when there has been no surgical intervention for 6 months. Another commenter was concerned that ''[a]s written, this section would require multiple surgical procedures. Is this the intent or could the listing be met with more conservative treatment without surgical intervention?'' The third commenter was concerned about how to apply the medical improvement review standard in §§ 404.1594 and 416.994 when surgeries ''appeared to be in progress at the time of the initial allowance'' but no further surgery was done and no ''substantial increase in function has occurred.'' This commenter recommended adding language to proposed 1.00L to address this situation.

Response: We do not see the need to discuss how to address duration if a condition has lasted at listing-level for at least 12 months and then stabilized following surgical or medical intervention during this period. If this were the situation, we believe it is obvious that the claimant's impairment would be disabling for at least a closed period, and any further finding of disability would depend on how the individual's demonstrable residuals affect him or her, using the guidelines set forth in proposed 1.00L (final 1.00N).

We did not intend for 1.00L (final 1.00N) to exclude more conservative treatment, as evidenced by our phrase approximately midway through the proposed and final sections, ''surgical or medical intervention.'' To clarify our intent, we have added a similar phrase to the first sentence of final 1.00N. What once read, ''last definitive surgical procedure,'' in this sentence, now reads ''last definitive surgical procedure or other medical intervention.''

We revised the language of the last two sentences in final 1.00N and 101.00N to attempt to clear up any ambiguities that might have arisen. We believe the revised text addresses the third commenter's concern.

Proposed 1.00M (Final 1.00P) When Surgical Procedures Have Been Performed

Comment: A commenter wanted to know if we really mean to state that a copy of operative notes and available pathology reports ''should'' be included or do we mean that they ''must'' be included. If it is not imperative that they be included, the commenter suggested that a summary of the surgery, usually included in hospitalization summaries, would be sufficient and that a statement to this effect should be added.

Response: In most cases, the operative notes and pathology reports would be preferred, but we recognize that they are not always available. If a summary is sufficiently detailed and the actual report is either not provided or unavailable, we would not require the actual report. The proposed language is nearly identical to the statement in 1.00B it has replaced, and there have been no adjudicative problems associated with this language in the past. We believe that our adjudicators can use sound judgment in applying this guideline in case situations.

Proposed 1.00N (Final 1.00F) Major Joints

Comment: One commenter suggested that this section and 1.00O be placed more logically after 1.00E and that 101.00N and 101.00O be placed after 101.00E. Another suggested that the ''ankle'' joint is so crucial to the ability to ambulate, it should be considered a major weight-bearing joint without being combined with the foot. A third inquirer wanted to know if the fact that we consider the wrist and hand to be a major joint requires impairment of both the wrist and hand and whether an impairment of the fingers alone can be considered a major joint.

Response: We agree with the first suggestion and have redesignated all affected sections accordingly. We also agree that for purposes of weight bearing, the ankle and foot should be considered separately for the reasons stated by the commenter, and we have reworded this section and listing 1.02A to reflect this change. In the final rules we clarified that ''major joints'' as used in 1.00F and 101.00F and in listings 1.02 and 101.02 refers to major peripheral joints as opposed to other peripheral joints, (e.g., the joints of the hand or forefoot) or axial joints (i.e., the joints of the spine). For purposes of meeting the ''listings test'' for disability, we must consider the hand and wrist as a major joint. Impairment of either the hand (including fingers) or wrist, alone, would not be of listing-level severity. However, this does not mean that an adult could not be disabled at a later step of the sequential evaluation process with only impairment to the fingers, hand, or wrist.

1.02 Major Dysfunction of a Joint(s) (Due to Any Cause)

Comment: One commenter wanted to know if any degree of limitation of motion will satisfy the requirements of the listing.

Response: Yes. As we stated in our response to a similar inquiry involving 1.00E, anything less than normal range of motion is clearly defined in the ''Guides to the Evaluation of Permanent Impairment'' and should be considered a limitation of motion.

Comment: Another commenter proposed adding another subsection to the listing requiring involvement of one hand and one foot, with less severe restrictions than are required in A and B.

Response: As we stated in other responses, the listings are intended to define such extreme limitations that they would prevent any gainful activity. Although we agree with the commenter that the suggested impairment would likely be severe, and might prevent many types of gainful activity, we do not think that such an impairment with fewer limitations than are contemplated by either listing 1.02A or B would necessarily prevent any gainful activity. Therefore, we have not added the suggested listing. Rather, in adult claims, we would continue to evaluate any severe impairment that falls short of listing-level severity at later steps of the sequential evaluation process.

Comment: A physician commented that the title of this listing is confusing and should be changed to ''Major Joint Dysfunction.'' He also stated that the listing is too rigid and requires too many physical findings. Because the A and B sections of the listing require extreme loss of function, the commenter suggested that requiring such extensive physical findings could result in delays of decisions and unnecessary development to attempt to obtain missing findings, when all that is really required is that an individual have a medically determinable impairment that has resulted in the functional loss required by section A or B. He suggested language for revising the listing.

Response: We have partially accepted the suggestion in that we have changed the title of the listing to ''Major dysfunction of a joint(s) (due to any cause).'' We disagree with the suggested language revisions to the listing, however. Findings such as subluxation or fixation of a joint can be due to a wide variety of causes, and some cases are amenable to treatment. Therefore, we believe that the findings on appropriate medically acceptable imaging, which aid both in determining

the cause and in defining the chronicity of an impairment, are vital to fulfilling the requirements of this listing.

1.03 Reconstructive Surgery or Surgical Arthrodesis of a Major Weight-Bearing Joint

Comment: One commenter stated that return of effective ambulation within 12 months is subjective and may cause difficulties from an adjudicative standpoint. Another commenter suggested that the new listing is too restrictive because it replaces the return to full weight bearing with the more restrictive ''inability to ambulate effectively.''

Response: These concerns stem from the same issues raised by other commenters under 1.00B. We believe we have already explained, in both the NPRM and in final 1.00B, that the need for the new functional criteria and for revising this listing is to place more emphasis on the functional impact of impairments on a person's ability to work. We agree with the second commenter that many individuals might be prevented from working under the current criteria. But with advances in surgical techniques and post-surgical treatment, some individuals who are not considered fully weight bearing on a lower extremity have sufficient ability to ambulate to be able to work. Individuals who cannot return to past relevant work because return to full weight-bearing status has not occurred will be evaluated at the appropriate steps in the sequential evaluation process.

1.04 Disorders of the Spine

Comment: At least two commenters specifically indicated that this listing would be helpful and an improvement over previous listings. Three others asked for clarification of some of the terminology in this listing. One commenter pointed out that proposed listing 1.04A requires evidence of a ''motor deficit (atrophy or muscle weakness)'' while proposed listing 1.04C requires evidence of ''weakness'' alone. The commenter asked whether we intend that motor deficit, which would include either weakness or atrophy, be a requirement for proposed listing 1.04C. A second commenter asked what would be positive for straight-leg raising and how the need for frequent changes in position or posture would be documented. The third commenter suggested that the meaning of ''frequent'' in proposed listing 1.04B needs to be more clearly defined.

Response: We made some changes in final listing 1.04A to make clear that we are referring to neuro-anatomic distribution of pain. The terms ''motor loss'' and ''motor deficit'' were used interchangeably in the NPRM. For consistency in the final rules, we refer to ''motor loss'' in listing 1.04A. We further clarified that atrophy as evidence of motor loss must be associated with muscle weakness. However, we purposely did not require atrophy as a requisite for meeting listing 1.04C. As we stated in the explanation of the revisions in the NPRM, we list both spinal arachnoiditis and lumbar spinal stenosis with pseudoclaudication separately from nerve root compression because they present different signs and symptoms. While atrophy can often be an outcome of nerve root compression, this usually will not be the case with spinal stenosis. In addition, in order to meet final listing 1.04C, an individual must be unable to ambulate effectively, as defined in 1.00B1 in the NPRM (final 1.00B2b,) which is not a requirement to meet final listing 1.04A. Such inability to ambulate would be indicative of ''motor loss'' associated with extreme spinal stenosis.

We presume that the second questioner is asking what would be positive for purposes of our program. We have provided the answer to this question in our response to comments at 1.00E. The need for frequent changes in position or posture would be documented from observations by treating or examining physicians, to be supplemented by appropriate lay testimony, as needed. We do not see this as a new requirement, as we have historically sought to obtain such evidence in support of any condition that causes pain or discomfort. However, we agree with the third commenter that we need to more clearly define ''frequent'' as used in proposed listing 1.04B. In final listing 1.04 we have clarified that the changes in position or posture must be more than once every 2 hours. We believe that a longitudinal record of the effects of arachnoiditis on an individual will provide sufficient data for adjudicators to determine whether the listing is met.

1.05 Amputation (Due to Any Cause)

Comment: One commenter indicated that listing 1.05C is redundant, because both listings 1.05B and C involve amputation of a leg at or above the tarsal region with ineffective ambulation as defined in 1.00B1 in the NPRM (final 1.00B2b.)

Response: We do not agree that the listings are redundant because they are based on different circumstances stemming from different impairment mechanics. Under final listing 1.05B, an individual would be disabled if he or she has stump complications which result in the medical inability to use a prosthetic device to ambulate effectively. If there are no stump complications, modern surgery and advances in prosthetic devices should enable an individual to ambulate effectively. Final listing 1.05C would apply to someone who has had an amputation of the leg at or above the tarsal region but can only walk with a hand-held assistive device, and given that the other hand is absent, such an individual would have effectively lost the use of both upper extremities.

Comment: Two commenters suggested that listing 1.05, in general, is punitive in nature. One stated that the proposed listing presumes that individuals will have benefited from the latest in surgical techniques and prosthetic devices. This commenter stated that individuals who have not, including those who had their surgery prior to the advances in surgical and engineering techniques or those who could not afford to replace an older prosthesis with a newly perfected type, would be penalized by the new listing. The other commenter simply stated that the impairments described by the existing listings would be severe enough to be disabling and should stand. Several other commenters also disagreed with the decision to revise the existing listing for a hemipelvectomy or hip disarticulation. While one commenter agreed with this decision, the commenter and a number of others disagreed with the decision to remove the listings for amputations due to peripheral vascular disease or diabetes mellitus. In addition, one commenter suggested retaining both listings for amputations of both feet and for one hand and one foot, while another recommended retention of the listing for one hand and one foot.

Response: We already made clear our reasons for revising the listings in our explanation of revisions in the NPRM.

Overall, we believe that the level of concern expressed by the commenters results from a misunderstanding of our intent. We are not proposing that individuals who would have met the current listings will never be found disabled. Nor do we believe that these rules will disadvantage individuals who had their surgery or were fitted with a prosthesis before recent advances in surgical and engineering techniques, or individuals who could not afford a newer prosthesis. Rather, these rules reflect our judgment that surgical and engineering techniques have progressed to the point where it is no longer a relative certainty that individuals with the level of impairment described in the

current listings can automatically be deemed disabled.

Some individuals who have not benefited from recent surgical and engineering techniques can still be found to have an impairment of listing-level severity if they have insufficient lower extremity functioning to permit independent ambulation without the use of a hand-held assistive device(s) that limits the functioning of both upper extremities. As with some of our other listings, other individuals may well be found disabled at later steps in the sequential evaluation process and, we believe, at relatively little cost in time or resources to adjudicators.

The inability to afford the cost of a replacement prosthesis was an issue in the application of current listing 1.10C in Gamble v. Chater, 68 F.3d 319 (9th Cir. 1995). We issued a Social Security Acquiescence Ruling (AR) 97–2(9) (62 FR 1791) to explain our policies and how we apply the holding of the United States Court of Appeals for the Ninth Circuit in this case. In these final rules we replaced current listing 1.10C with final listing 1.05B and expanded the guidance in final 1.00J. Final listing 1.05B requires that an individual with an amputation of a lower extremity or extremities at or above the tarsal region be medically unable to use a prosthetic device to ambulate effectively as defined in 1.00B2b. In final 1.00J3 we explain that it is unnecessary to evaluate the individual's ability to walk without the prosthesis in place. We added this explanation because we recognize that individuals with the type of lower extremity amputation described in final listing 1.05B, will have an inability to ambulate effectively, as defined in 1.00B2b, when they are not using a prosthesis. This would be true whether they do not use a prosthesis because they cannot afford one, because a prosthesis has not been prescribed for them, or for other reasons. For that reason, it would be unnecessary to evaluate the individual's ability to walk without the prosthesis in place. However, we do require an evaluation of the individual's medical ability to use a prosthetic device to ambulate effectively. As the final rules sufficiently clarify the issue in Gamble, we are rescinding AR 97–2(9) under the authority of §§ 404.985(e)(4) and 416.1485(e)(4) of our regulations concurrently with these final rules.

As we already noted, medical advances in disability evaluation and treatment and program experience require that we periodically review and update the medical criteria in the listings. This is an ongoing process which we will continue. However, as indicated above, after reviewing the comments and the literature, we agree with those commenters who felt that a hemipelvectomy or hip disarticulation is still in itself sufficient to establish the existence of an impairment of listing-level severity. Therefore, final listing 1.05D has been revised to reflect the same criteria as current listing 1.10A.

Comment: One commenter noted that on page 67583 of the NPRM we state that individuals who are unable to ambulate effectively due to stump complications resulting from diabetes or other disease, may have their impairments evaluated under listing 1.05B. The commenter suggested we add a statement to this effect to the introduction to the listings.

Response: In final listing 1.05B, ''stump complications,'' means any stump complications regardless of the cause. However, to clarify that an individual with an amputation(s) due to any cause, including diabetes mellitus or other disease, will have his or her impairment evaluated under listing 1.05, we changed the title of the listing from ''Amputation,'' to ''Amputation (due to any cause).''

1.06 Fracture of the Femur, Tibia, Pelvis, or One or More of the Tarsal Bones

Comment: One commenter suggested that the listings should provide for individuals who may have achieved a solid union of their fractures in fewer than 12 months but who will take 12 months or longer, in total, to return to work.

Response: Individuals with solid union of their fractures occurring in fewer than 12 months, but with residual soft tissue damage or soft tissue complications (e.g., of muscle or connective tissue) requiring surgical or medical intervention for 12 months or longer related to the efforts directed toward the salvage or restoration of major function of the affected part could equal listing 1.08. An adult whose residual impairment is either not of listing-level severity or not expected to be of listing-level severity at 12 months after the fracture would still be evaluated at steps 4 and 5 of the sequential evaluation process.

Comment: Another commenter suggested that this listing is punitive and open to subjective interpretation, apparently because it is linked to the requirement for independent ambulation. The commenter suggested that this term needs a uniform definition.

Response: We already answered this concern, at least indirectly, under our responses to comments on proposed 1.00B1. We believe that the term is clearly defined by way of the examples provided as ways in which ambulation would be considered as ineffective.

1.08 Soft Tissue Injury (e.g., Burns) of an Upper or Lower Extremity, Trunk or Face and Head

Comment: Two commenters sought clarification of what we mean by ''major function'' of the face and head.

Response: In policy memoranda and manuals, we have generally considered such function to be related to sight, hearing, speech, mastication, and the initiation of the digestive process. In the final rules we have added new sections 1.00O and 101.00O to describe what we mean by major function of the face and head for purposes of listing 1.08. (1.00O in the NPRM will now be final 1.00G.)

Comment: One commenter questioned the role of pain for this listing, while hypothesizing that chronic lumbago and fibromyalgia might be considered under this listing, and seemed to want more objective criteria for evaluation of this listing.

Response: We do not see how fibromyalgia or lumbago would be evaluated under this listing because the listing involves surgical management of the affected soft tissue areas. To the degree that pain factors into this listing or any other musculoskeletal listing, we believe the statements provided in 1.00B2d of the introductory text to these listings, as well as in §§ 404.1529 and 416.929 of the regulations adequately describe how we consider pain and the factors used to determine how it affects an individual's ability to function.

4.12 Peripheral Arterial Disease

Comment: One commenter stated that this listing appears to have been assigned the wrong number and that it should remain 4.13, unless our intent is to eliminate current listing 4.12 for chronic venous insufficiency.

Response: The revised regulations on cardiovascular impairments published at 59 FR 6468 on February 10, 1994, renumbered chronic venous insufficiency as listing 4.11 and peripheral arterial disease as listing 4.12.

14.00B

Comment: One commenter remarked, ''The discussion of the use of the term 'severe' in the listings to describe medical severity is ambiguous. The statement that it does not have the same meaning as it does when we use it in connection with a finding at the second step of the sequential evaluation process does not adequately address the differences in the use of the term in the

listing and at step two of sequential evaluation.''

Response: The language in this section regarding how we use the term ''severe'' was not new but was in the existing Immune System listings. It describes how we use the term in a number of existing listings, not in any of the new listings introduced by the final revisions to the musculoskeletal listings. The overall severe loss of function would result in an impairment that would be profoundly disabling and not merely ''severe'' for program purposes as defined in §§ 404.1520, 416.920, and 416.924 of existing regulations. Therefore, we are not changing it.

However, we agree that the first use of ''severe'' in the paragraph to describe loss of function might be somewhat confusing, so we have changed the phrase to read, ''serious loss of function.'' Also, it is not function of the body's organs with which we are concerned in disability evaluation, but with function of the whole individual. Therefore, we have further revised this first sentence in two places to read that functional loss is ''because of disease affecting'' an organ(s) and not because of functional loss ''in'' the organ(s).

14.09 Inflammatory Arthritis

Comment: One commenter suggested rewriting this listing to avoid the potential difficulty of the listing inadequately specifying diagnostic criteria for the long list of disorders named in the introductory text to the listings. The commenter suggested that inflammatory arthritis be documented as described in 14.00B6 and that 14.09A would be met if the inflammatory arthritis were diagnosed in accordance with the criteria of a current widely accepted medical text or journal, and it resulted in inability to ambulate effectively or inability to perform fine and gross movements effectively as defined in proposed 14.00B6b and 1.00B1 and B2.

Response: The suggested revision would actually change the intent of 14.09A. The intent is that the inflammatory process itself is still active and has involved or affected two or more major joints. The suggested revision would raise the possibility that disability could be established solely on allegations of pain in an individual with a prior diagnosis of an inflammatory arthritis. Also, to suggest that inflammatory arthritis be ''diagnosed in accord with the criteria of a current widely accepted medical text or journal'' leaves the issue open to very broad interpretation and judgment.

Comment: Another commenter suggested that listing 14.09A should refer back to 1.00G (final 1.00I) on effects of treatment.

Response: Although we recognize that an individual with inflammatory arthritis likely will be under active therapy for the condition, we do not think that the effects need to be expressly considered herein. Whether effects are positive or negative is immaterial, given the degree of limitation needed to meet the criteria of listing 14.09A. According to these criteria, an individual's disease would be active and would result in inability to ambulate effectively or to perform fine and gross movements effectively.

14.09B Ankylosing Spondylitis

Comment: One commenter interpreted proposed listing 14.09B as not requiring x-ray evidence and believed this was a good decision.

Response: We believe this commenter misinterpreted our intent. We removed the requirement for corroboration of the existence of the impairment by specific laboratory tests, to include x-ray or other appropriate medically acceptable imaging, in both proposed and final listings 14.09A, C, and D. However, we have retained the requirement for appropriate medically acceptable imaging in listings 14.09B and 14.09E as the imaging is necessary to document the impairments evaluated under these listings.

Comment: Several commenters stated the new range of motion restrictions required to meet this listing and others in this section are too stringent, suggesting that fixation of the spine be left at 30° rather than 45°. One of these commenters also objected to the requirement that fixation be of the dorsolumbar and cervical spines, stating that fixation of either be considered severe enough to be presumed disabling.

Response: As with other listings, we recognize that an individual might be unable to perform many forms of gainful activity with the level of impairment contemplated in the current listings, but we do not agree that the impairment would preclude any gainful activity. However, we realize that the NPRM incorrectly required fixation of both the dorsolumbar and the cervical spines. We agree with the commenter that the required fixation of either the dorsolumbar or cervical spine is sufficiently severe to be considered disabling and we changed final 14.09B accordingly. Lesser degrees of involvement will be evaluated at later steps of the sequential evaluation process.

Comment: One commenter recommended an additional listing for individuals who are developing ankylosing spondylitis, but whose spines have not yet ankylosed. The reasoning was that in these cases the disability produced by ankylosing spondylitis is actually less once the spine has ankylosed. Before that time, the individual is in severe pain, and on the basis of this severe pain, disability should be established.

Response: Because pain is variable and some individuals might function fairly well while the process is occurring, while others might be more incapacitated by the pain, we cannot create a listing that would rely so exclusively on a symptom alone. We believe that the regulations on pain and other symptoms at §§ 404.1529 and 416.929 provide sufficient guidance on how to handle the types of situations described in the recommendation.

14.09D and E

Comment: One commenter called listing 14.09D too complicated and stated that it will be difficult for adjudicators to apply, while others considered it and 14.09E vague. One suggested that the many cross-references to other listings and the nonspecific criteria in D2 make these listings difficult to use. Three others called for more precise wording and definition of terms, particularly the term ''moderate.'' Another commenter asked what ''lesser deformity than in B'' and ''lesser articular findings'' called for in 14.09E mean and suggested these terms be defined. Still another commenter suggested that these same three terms as used in the childhood listing, 114.09, need clarification. The same commenter asked how duration of morning stiffness can be documented.

Response: We did not adopt all of these comments, but we did clarify the rules somewhat, as explained above in the summary of the changes. Listing 14.09D (and 114.09D) is based on, and uses the same criteria as, listings 14.02B, 14.03B, 14.04B, 14.05B and their counterparts in part B of the listings. As such, the new listing for inflammatory arthritides is consistent with our other existing listings for connective tissue disorders.

101.00B Loss of Function

Comment: One commenter noted, ''This section discusses functioning, but not sequential evaluation. We feel there should be a stronger reference to 'age appropriate activities.'' '

Response: The listings are not intended as a vehicle for describing the full sequential evaluation process.

Rather, this complex process is discussed throughout our regulations. Nevertheless, we recognize that musculoskeletal impairments impact differently on children depending on their ages, and we consider our references to ''age-appropriate activities'' to adequately detail this point. In final 101.00B2b(2), we explicitly state that, for children who are too young to walk independently, assessment of inability to ambulate effectively must be in terms of age-appropriate activities and normal developmental expectations, and we specifically define ''an extreme level of limitation'' for such children in terms of age-appropriate activities. In final 101.00B2c(2), we provide similar language concerning inability to perform fine and gross movements effectively, and we cross-refer to listing 110.07A which describes motor dysfunction in infants and young children.

Comment: One commenter found the criteria for evaluation of ineffective ambulation for children who are too young to be expected to walk independently ''a valuable addition to the listing as is the discussion of evaluation of the inability to perform fine and gross movements of the upper extremities for very young children in section B.2.'' However, another commenter suggested that listing-level disability for young children could be served by one set of criteria. The commenter suggested utilizing the criteria in listing 112.02B1a for gross and fine motor development for children 1–3 and 112.12B for motor development for infants up to age 1 year as an appropriate description of functional loss for ambulation, as well as fine and gross movement. These listings require motor development of no more than one-half of the child's chronological age. The commenter suggested that if the paragraphs are not changed, the examples given should be more specific for each age group.

Response: We made a minor clarifying revision to the language in the sections in question, although we have not made the changes suggested. The language in the NPRM and the final sections already utilizes the concepts and, to a degree, the language of listings 112.02B1a and 112.12B, as recommended, and we consider what we mean by loss of function for different aged children to be well-explained as written.

101.04 Disorders of the Spine

Comment: One commenter stated that current listing 101.05B should be retained, because the commenter did not consider proposed listing 114.09B to adequately apply to cases of scoliosis. However, another commenter agreed with the changes, stating that the new language in proposed 101.00J (final 101.00L) brings the listings up to basis would be evaluated under the criteria in date. A third commenter stated that if spina bifida and related impairments should be evaluated under this listing, we should spell it out.

Response: Concerning scoliosis, we agree with the second commenter, which is why we are removing the current listing. Not only does this bring the listings up to date, but it enables the adult and childhood listings to more closely parallel each other. In paragraph 101.00K2, we indicate that with disorders such as spinal dysrhaphism there may be the types of difficulties evaluated under listing 101.04. Difficulties caused by dysrhaphism on a neurogenic 111.00ff. Although we believe this is sufficiently clear to explain how and where any form of dysrhaphism, including spina bifida would be evaluated, we have added the parenthetical remark, ''(e.g., spina bifida)'' after the words, ''spinal dysrhaphism,'' to both 1.00K4, and 101.00K2 for further clarification.

Regulatory Procedures

Executive Order 12866

We have consulted with the Office of Management and Budget (OMB) and have determined that these final regulations meet the criteria for an economically significant regulatory action under Executive Order (E.O.) 12866. They are also a ''major'' rule under 5 U.S.C. 801 ff. The following is a discussion of the potential costs and benefits of this regulatory action. This assessment also contains an analysis of alternatives we considered and chose not to adopt.

These final rules benefit society by updating the current listings to provide criteria that reflect state-of-the-art medical science and technology. The final rules ensure that determinations of disability have a sound medical basis, that claimants receive equal treatment through the use of specific criteria, and that people who are disabled can be readily identified and awarded benefits if all other factors of entitlement or eligibility are met.

We are projecting savings in program expenditures and increases in administrative costs as a result of these actions, described in more detail below.

Program Savings

1. Title II

We estimate that these rules will result in reduced program outlays resulting in the following savings (in millions of dollars) to the title II program ($305 million total in a 5-year period beginning FY 2001).

Fiscal year:	
2001	$10
2002	35
2003	60
2004	85
2005	110
Total [1]	305

[1] 5-year total may not be equal to the sum of the annual totals due to rounding-out.

2. Title XVI

We estimate that these rules will result in reduced program outlays resulting in the following savings (in millions of dollars) to the SSI program ($55 million total in a 5-year period beginning FY 2001).

Fiscal year:	
2001	5$
2002	5
2003	10
2004	15
2005	20
Total [1]	55

[1] 5-year total may not be equal to the sum of the annual totals due to rounding-out.

3. Title XVIII

We estimate that these rules will result in reduced program outlays resulting in the following savings (in millions of dollars) to the title XVIII program ($60 million total in a 5-year period beginning FY 2001).

Fiscal year:	
2001	$0
2002	0
2003	10
2004	20
2005	30
Total [1]	60

[1] 5-year total may not be equal to the sum of the annual totals due to rounding-out.

4. Title XIX

We estimate that these rules will result in reduced program outlays resulting in the following savings (in millions of dollars) to the XIX program ($117 million total in a 5-year period beginning FY 2001).

Fiscal year:	
2001	$4
2002	13
2003	23
2004	33
2005	44
Total [1]	117

[1] 5-year total may not be equal to the sum of the annual totals due to rounding-out.

Program Costs

We do not expect any program costs to result from these regulations.

Administrative Savings

We do not expect any administrative savings to result from these regulations.

Administrative Costs

We expect there will be some administrative costs associated with these final rules. The final rules are expected to result in administrative costs of about 18WYs or about $1.5 million per year.

Policy Alternatives

We considered keeping the current listing criteria with only minor technical changes. When the musculoskeletal listings were last revised and published in the Federal Register we indicated that medical advances in disability evaluationa nd treatment and program experience would require that we periodically review and update the medical criteria in the listings. The current listings are now over 15 years old. Medical advances in disability evaluation and treatment and our program experience make clear that the current listings are not an accurate reflection of state-of-the-art medical science and technology. A simple technical change would not be sufficient to provide state-of-the-art criteria for deciding listing-level severity in musculoskeletal impairments. Therefore, we rejected this alternative.

If we kept the current listing criteria and made only minor technical changes, the program and administrative costs would be the same as under the current rules.

Regulatory Flexibility Act

We certify that these final regulations will not have a significant economic impact on a substantial number of small entities because they affect only individuals. Therefore, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

This final rules contain reporting requirements at: 1.00B; 1.00C; 1.00D; 1.00E; 1.00H; 1.00I; 1.00J; 1.00K; 1.00P; 14.09A; 101.00B; 101.00C; 101.00D; 101.00E; 101.00H; 101.00I; 101.00J; 101.00P; and 114.09A. The public reporting burden is accounted for in the Information Collection Requests for the various forms that the public uses to submit the information to SSA. Consequently, a 1-hour placeholder burden is being assigned to the specific reporting requirement(s) contained in the rule. We are seeking clearance of the burden referenced in the rules because these rules were not considered during the clearance of the forms. An Information Collection Request has been submitted to OMB. While these rules will be effective 90 days from publication, these burdens will not be effective until cleared by OMB. We are soliciting comments on the burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility and clarity; and on ways to minimize the burden on respondents, including the use of automated collection techniques or other forms of information technology. We will publish a notice in the **Federal Register** upon OMB approval of the informational collection requirement(s). Comments should be submitted to the OMB Desk Officer for SSA within 30 days of publication of this final rule at the following address:

Office of Management and Budget, Attn: Desk Officer for SSA, New Executive Office Building, Room 10230, 725 17th St., NW, Washington, DC 20530.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability Insurance; 96.006, Supplemental Security Income)

List of Subjects

20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors, and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Reporting and recordkeeping requirements, Supplemental Security Income (SSI).

Dated: October 16, 2001.

Larry G. Massanari,

Acting Commissioner of Social Security.

For the reasons set out in the preamble, subpart P of part 404 and subpart I of part 416 of chapter III of title 20 of the Code of Federal Regulations are amended as set forth below:

1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a), (b), and (d)–(h), 216(i), 221(a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)–(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189.

Appendix 1 to Subpart P of Part 404—[Amended]

2. Item 2 in the introductory text before part A of appendix 1 to subpart P of part 404 is revised to read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

* * * * *

2. Musculoskeletal System (1.00 and 101.00): February 19, 2009.

* * * * *

3. Listing 1.00, Musculoskeletal System, of part A of appendix 1 of subpart P of part 404 is revised to read as follows:

1.00 MUSCULOSKELETAL SYSTEM

A. *Disorders of the musculoskeletal system* may result from hereditary, congenital, or acquired pathologic processes. Impairments may result from infectious, inflammatory, or degenerative processes, traumatic or developmental events, or neoplastic, vascular, or toxic/metabolic diseases.

B. *Loss of function.*

1. *General.* Under this section, loss of function may be due to bone or joint deformity or destruction from any cause; miscellaneous disorders of the spine with or without radiculopathy or other neurological deficits; amputation; or fractures or soft tissue injuries, including burns, requiring prolonged periods of immobility or convalescence. For inflammatory arthritides that may result in loss of function because of inflammatory peripheral joint or axial arthritis or sequelae, or because of extra-articular features, see 14.00B6. Impairments with neurological causes are to be evaluated under 11.00ff.

2. How We Define Loss of Function in These Listings

a. *General.* Regardless of the cause(s) of a musculoskeletal impairment, functional loss for purposes of these listings is defined as the inability to ambulate effectively on a sustained basis for any reason, including pain associated with the underlying musculoskeletal impairment, or the inability to perform fine and gross movements effectively on a sustained basis for any reason, including pain associated with the underlying musculoskeletal impairment. The inability to ambulate effectively or the inability to perform fine and gross movements effectively must have lasted, or be expected to last, for at least 12 months. For the purposes of these criteria, consideration of the ability to perform these activities must be from a physical standpoint alone. When there is an inability to perform these activities due to a mental impairment, the criteria in 12.00ff are to be used. We will determine whether an individual can ambulate effectively or can perform fine and gross movements effectively based on the medical and other evidence in the case record, generally without developing additional evidence about the individual's ability to perform the specific activities listed as examples in 1.00B2b(2) and 1.00B2c.

b. What We Mean by Inability to Ambulate Effectively

(1) *Definition.* Inability to ambulate effectively means an extreme limitation of

the ability to walk; i.e., an impairment(s) that interferes very seriously with the individual's ability to independently initiate, sustain, or complete activities. Ineffective ambulation is defined generally as having insufficient lower extremity functioning (see 1.00J) to permit independent ambulation without the use of a hand-held assistive device(s) that limits the functioning of both upper extremities. (Listing 1.05C is an exception to this general definition because the individual has the use of only one upper extremity due to amputation of a hand.)

(2) *To ambulate effectively,* individuals must be capable of sustaining a reasonable walking pace over a sufficient distance to be able to carry out activities of daily living. They must have the ability to travel without companion assistance to and from a place of employment or school. Therefore, examples of ineffective ambulation include, but are not limited to, the inability to walk without the use of a walker, two crutches or two canes, the inability to walk a block at a reasonable pace on rough or uneven surfaces, the inability to use standard public transportation, the inability to carry out routine ambulatory activities, such as shopping and banking, and the inability to climb a few steps at a reasonable pace with the use of a single hand rail. The ability to walk independently about one's home without the use of assistive devices does not, in and of itself, constitute effective ambulation.

c. *What we mean by inability to perform fine and gross movements effectively.* Inability to perform fine and gross movements effectively means an extreme loss of function of both upper extremities; i.e., an impairment(s) that interferes very seriously with the individual's ability to independently initiate, sustain, or complete activities. To use their upper extremities effectively, individuals must be capable of sustaining such functions as reaching, pushing, pulling, grasping, and fingering to be able to carry out activities of daily living. Therefore, examples of inability to perform fine and gross movements effectively include, but are not limited to, the inability to prepare a simple meal and feed oneself, the inability to take care of personal hygiene, the inability to sort and handle papers or files, and the inability to place files in a file cabinet at or above waist level.

d. *Pain or other symptoms.* Pain or other symptoms may be an important factor contributing to functional loss. In order for pain or other symptoms to be found to affect an individual's ability to perform basic work activities, medical signs or laboratory findings must show the existence of a medically determinable impairment(s) that could reasonably be expected to produce the pain or other symptoms. The musculoskeletal listings that include pain or other symptoms among their criteria also include criteria for limitations in functioning as a result of the listed impairment, including limitations caused by pain. It is, therefore, important to evaluate the intensity and persistence of such pain or other symptoms carefully in order to determine their impact on the individual's functioning under these listings. See also §§ 404.1525(f) and 404.1529 of this part, and §§ 416.925(f) and 416.929 of part 416 of this chapter.

C. Diagnosis and Evaluation

1. *General.* Diagnosis and evaluation of musculoskeletal impairments should be supported, as applicable, by detailed descriptions of the joints, including ranges of motion, condition of the musculature (e.g., weakness, atrophy), sensory or reflex changes, circulatory deficits, and laboratory findings, including findings on x-ray or other appropriate medically acceptable imaging. Medically acceptable imaging includes, but is not limited to, x-ray imaging, computerized axial tomography (CAT scan) or magnetic resonance imaging (MRI), with or without contrast material, myelography, and radionuclear bone scans. ''Appropriate'' means that the technique used is the proper one to support the evaluation and diagnosis of the impairment.

2. *Purchase of certain medically acceptable imaging.* While any appropriate medically acceptable imaging is useful in establishing the diagnosis of musculoskeletal impairments, some tests, such as CAT scans and MRIs, are quite expensive, and we will not routinely purchase them. Some, such as myelograms, are invasive and may involve significant risk. We will not order such tests. However, when the results of any of these tests are part of the existing evidence in the case record we will consider them together with the other relevant evidence.

3. *Consideration of electrodiagnostic procedures.* Electrodiagnostic procedures may be useful in establishing the clinical diagnosis, but do not constitute alternative criteria to the requirements of 1.04.

D. *The physical examination* must include a detailed description of the rheumatological, orthopedic, neurological, and other findings appropriate to the specific impairment being evaluated. These physical findings must be determined on the basis of objective observation during the examination and not simply a report of the individual's allegation; e.g., ''He says his leg is weak, numb.'' Alternative testing methods should be used to verify the abnormal findings; e.g., a seated straight-leg raising test in addition to a supine straight-leg raising test. Because abnormal physical findings may be intermittent, their presence over a period of time must be established by a record of ongoing management and evaluation. Care must be taken to ascertain that the reported examination findings are consistent with the individual's daily activities.

E. Examination of the Spine

1. *General.* Examination of the spine should include a detailed description of gait, range of motion of the spine given quantitatively in degrees from the vertical position (zero degrees) or, for straight-leg raising from the sitting and supine position (zero degrees), any other appropriate tension signs, motor and sensory abnormalities, muscle spasm, when present, and deep tendon reflexes. Observations of the individual during the examination should be reported; e.g., how he or she gets on and off the examination table. Inability to walk on the heels or toes, to squat, or to arise from a squatting position, when appropriate, may be considered evidence of significant motor loss. However, a report of atrophy is not acceptable as evidence of significant motor loss without circumferential measurements of both thighs and lower legs, or both upper and lower arms, as appropriate, at a stated point above and below the knee or elbow given in inches or centimeters. Additionally, a report of atrophy should be accompanied by measurement of the strength of the muscle(s) in question generally based on a grading system of 0 to 5, with 0 being complete loss of strength and 5 being maximum strength. A specific description of atrophy of hand muscles is acceptable without measurements of atrophy but should include measurements of grip and pinch strength.

2. *When neurological abnormalities persist.* Neurological abnormalities may not completely subside after treatment or with the passage of time. Therefore, residual neurological abnormalities that persist after it has been determined clinically or by direct surgical or other observation that the ongoing or progressive condition is no longer present will not satisfy the required findings in 1.04. More serious neurological deficits (paraparesis, paraplegia) are to be evaluated under the criteria in 11.00ff.

F. *Major joints* refers to the major peripheral joints, which are the hip, knee, shoulder, elbow, wrist-hand, and ankle-foot, as opposed to other peripheral joints (e.g., the joints of the hand or forefoot) or axial joints (i.e., the joints of the spine.) The wrist and hand are considered together as one major joint, as are the ankle and foot. Since only the ankle joint, which consists of the juncture of the bones of the lower leg (tibia and fibula) with the hindfoot (tarsal bones), but not the forefoot, is crucial to weight bearing, the ankle and foot are considered separately in evaluating weight bearing.

G. *Measurements of joint motion* are based on the techniques described in the chapter on the extremities, spine, and pelvis in the current edition of the ''Guides to the Evaluation of Permanent Impairment'' published by the American Medical Association.

H. Documentation

1. *General.* Musculoskeletal impairments frequently improve with time or respond to treatment. Therefore, a longitudinal clinical record is generally important for the assessment of severity and expected duration of an impairment unless the claim can be decided favorably on the basis of the current evidence.

2. *Documentation of medically prescribed treatment and response.* Many individuals, especially those who have listing-level impairments, will have received the benefit of medically prescribed treatment. Whenever evidence of such treatment is available it must be considered.

3. *When there is no record of ongoing treatment.* 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). In such cases, evaluation will be made on the basis of the current objective

medical evidence and other available evidence, taking into consideration the individual's medical history, symptoms, and medical source opinions. Even though an individual who does not receive treatment may not be able to show an impairment that meets the criteria of one of the musculoskeletal listings, the individual may have an impairment(s) equivalent in severity to one of the listed impairments or be disabled based on consideration of his or her residual functional capacity (RFC) and age, education and work experience.

4. *Evaluation when the criteria of a musculoskeletal listing are not met.* These listings are only examples of common musculoskeletal disorders that are severe enough to prevent a person from engaging in gainful activity. Therefore, in any case in which an individual has a medically determinable impairment that is not listed, an impairment that does not meet the requirements of a listing, or a combination of impairments no one of which meets the requirements of a listing, we will consider medical equivalence. (See §§ 404.1526 and 416.926.) Individuals who have an impairment(s) with a level of severity that does not meet or equal the criteria of the musculoskeletal listings may or may not have the RFC that would enable them to engage in substantial gainful activity. Evaluation of the impairment(s) of these individuals should proceed through the final steps of the sequential evaluation process in §§ 404.1520 and 416.920 (or, as appropriate, the steps in the medical improvement review standard in §§ 404.1594 and 416.994).

I. Effects of Treatment

1. *General.* Treatments for musculoskeletal disorders may have beneficial effects or adverse side effects. Therefore, medical treatment (including surgical treatment) must be considered in terms of its effectiveness in ameliorating the signs, symptoms, and laboratory abnormalities of the disorder, and in terms of any side effects that may further limit the individual.

2. *Response to treatment.* Response to treatment and adverse consequences of treatment may vary widely. For example, a pain medication may relieve an individual's pain completely, partially, or not at all. It may also result in adverse effects, e.g., drowsiness, dizziness, or disorientation, that compromise the individual's ability to function. Therefore, each case must be considered on an individual basis, and include consideration of the effects of treatment on the individual's ability to function.

3. *Documentation.* A specific description of the drugs or treatment given (including surgery), dosage, frequency of administration, and a description of the complications or response to treatment should be obtained. The effects of treatment may be temporary or long-term. As such, the finding regarding the impact of treatment must be based on a sufficient period of treatment to permit proper consideration or judgment about future functioning.

J. Orthotic, Prosthetic, or Assistive Devices

1. *General.* Consistent with clinical practice, individuals with musculoskeletal impairments may be examined with and without the use of any orthotic, prosthetic, or assistive devices as explained in this section.

2. *Orthotic devices.* Examination should be with the orthotic device in place and should include an evaluation of the individual's maximum ability to function effectively with the orthosis. It is unnecessary to routinely evaluate the individual's ability to function without the orthosis in place. If the individual has difficulty with, or is unable to use, the orthotic device, the medical basis for the difficulty should be documented. In such cases, if the impairment involves a lower extremity or extremities, the examination should include information on the individual's ability to ambulate effectively without the device in place unless contraindicated by the medical judgment of a physician who has treated or examined the individual.

3. *Prosthetic devices.* Examination should be with the prosthetic device in place. In amputations involving a lower extremity or extremities, it is unnecessary to evaluate the individual's ability to walk without the prosthesis in place. However, the individual's medical ability to use a prosthesis to ambulate effectively, as defined in 1.00B2b, should be evaluated. The condition of the stump should be evaluated without the prosthesis in place.

4. *Hand-held assistive devices.* When an individual with an impairment involving a lower extremity or extremities uses a hand-held assistive device, such as a cane, crutch or walker, examination should be with and without the use of the assistive device unless contraindicated by the medical judgment of a physician who has treated or examined the individual. The individual's ability to ambulate with and without the device provides information as to whether, or the extent to which, the individual is able to ambulate without assistance. The medical basis for the use of any assistive device (e.g., instability, weakness) should be documented. The requirement to use a hand-held assistive device may also impact on the individual's functional capacity by virtue of the fact that one or both upper extremities are not available for such activities as lifting, carrying, pushing, and pulling.

K. *Disorders of the spine,* listed in 1.04, result in limitations because of distortion of the bony and ligamentous architecture of the spine and associated impingement on nerve roots (including the cauda equina) or spinal cord. Such impingement on nerve tissue may result from a herniated nucleus pulposus, spinal stenosis, arachnoiditis, or other miscellaneous conditions. Neurological abnormalities resulting from these disorders are to be evaluated by referral to the neurological listings in 11.00ff, as appropriate. (See also 1.00B and E.)

1. *Herniated nucleus pulposus* is a disorder frequently associated with the impingement of a nerve root. Nerve root compression results in a specific neuro-anatomic distribution of symptoms and signs depending upon the nerve root(s) compromised.

2. Spinal Arachnoiditis

a. *General.* Spinal arachnoiditis is a condition characterized by adhesive thickening of the arachnoid which may cause intermittent ill-defined burning pain and sensory dysesthesia, and may cause neurogenic bladder or bowel incontinence when the cauda equina is involved.

b. *Documentation.* Although the cause of spinal arachnoiditis is not always clear, it may be associated with chronic compression or irritation of nerve roots (including the cauda equina) or the spinal cord. For example, there may be evidence of spinal stenosis, or a history of spinal trauma or meningitis. Diagnosis must be confirmed at the time of surgery by gross description, microscopic examination of biopsied tissue, or by findings on appropriate medically acceptable imaging. Arachnoiditis is sometimes used as a diagnosis when such a diagnosis is unsupported by clinical or laboratory findings. Therefore, care must be taken to ensure that the diagnosis is documented as described in 1.04B. Individuals with arachnoiditis, particularly when it involves the lumbosacral spine, are generally unable to sustain any given position or posture for more than a short period of time due to pain.

3. *Lumbar spinal stenosis* is a condition that may occur in association with degenerative processes, or as a result of a congenital anomaly or trauma, or in association with Paget's disease of the bone. *Pseudoclaudication,* which may result from lumbar spinal stenosis, is manifested as pain and weakness, and may impair ambulation. Symptoms are usually bilateral, in the low back, buttocks, or thighs, although some individuals may experience only leg pain and, in a few cases, the leg pain may be unilateral. The pain generally does not follow a particular neuro-anatomical distribution, i.e., it is distinctly different from the radicular type of pain seen with a herniated intervertebral disc, is often of a dull, aching quality, which may be described as ''discomfort'' or an ''unpleasant sensation,'' or may be of even greater severity, usually in the low back and radiating into the buttocks region bilaterally. The pain is provoked by extension of the spine, as in walking or merely standing, but is reduced by leaning forward. The distance the individual has to walk before the pain comes on may vary. Pseudoclaudication differs from peripheral vascular claudication in several ways. Pedal pulses and Doppler examinations are unaffected by pseudoclaudication. Leg pain resulting from peripheral vascular claudication involves the calves, and the leg pain in vascular claudication is ordinarily more severe than any back pain that may also be present. An individual with vascular claudication will experience pain after walking the same distance time after time, and the pain will be relieved quickly when walking stops.

4. *Other miscellaneous conditions* that may cause weakness of the lower extremities, sensory changes, areflexia, trophic ulceration, bladder or bowel incontinence, and that should be evaluated under 1.04 include, but are not limited to, osteoarthritis, degenerative disc disease, facet arthritis, and vertebral fracture. Disorders such as spinal dysrhaphism (e.g., spina bifida), diastematomyelia, and tethered cord

syndrome may also cause such abnormalities. In these cases, there may be gait difficulty and deformity of the lower extremities based on neurological abnormalities, and the neurological effects are to be evaluated under the criteria in 11.00ff.

L. *Abnormal curvatures of the spine.* Abnormal curvatures of the spine (specifically, scoliosis, kyphosis and kyphoscoliosis) can result in impaired ambulation, but may also adversely affect functioning in body systems other than the musculoskeletal system. For example, an individual's ability to breathe may be affected; there may be cardiac difficulties (e.g., impaired myocardial function); or there may be disfigurement resulting in withdrawal or isolation. When there is impaired ambulation, evaluation of equivalence may be made by reference to 14.09A. When the abnormal curvature of the spine results in symptoms related to fixation of the dorsolumbar or cervical spine, evaluation of equivalence may be made by reference to 14.09B. When there is respiratory or cardiac involvement or an associated mental disorder, evaluation may be made under 3.00ff, 4.00ff, or 12.00ff, as appropriate. Other consequences should be evaluated according to the listing for the affected body system.

M. *Under continuing surgical management,* as used in 1.07 and 1.08, refers to surgical procedures and any other associated treatments related to the efforts directed toward the salvage or restoration of functional use of the affected part. It may include such factors as post-surgical procedures, surgical complications, infections, or other medical complications, related illnesses, or related treatments that delay the individual's attainment of maximum benefit from therapy.

N. *After maximum benefit from therapy has been achieved* in situations involving fractures of an upper extremity (1.07), or soft tissue injuries (1.08), i.e., there have been no significant changes in physical findings or on appropriate medically acceptable imaging for any 6-month period after the last definitive surgical procedure or other medical intervention, evaluation must be made on the basis of the demonstrable residuals, if any. A finding that 1.07 or 1.08 is met must be based on a consideration of the symptoms, signs, and laboratory findings associated with recent or anticipated surgical procedures and the resulting recuperative periods, including any related medical complications, such as infections, illnesses, and therapies which impede or delay the efforts toward restoration of function. Generally, when there has been no surgical or medical intervention for 6 months after the last definitive surgical procedure, it can be concluded that maximum therapeutic benefit has been reached. Evaluation at this point must be made on the basis of the demonstrable residual limitations, if any, considering the individual's impairment-related symptoms, signs, and laboratory findings, any residual symptoms, signs, and laboratory findings associated with such surgeries, complications, and recuperative periods, and other relevant evidence.

O. *Major function of the face and head,* for purposes of listing 1.08, relates to impact on any or all of the activities involving vision, hearing, speech, mastication, and the initiation of the digestive process.

P. *When surgical procedures have been performed,* documentation should include a copy of the operative notes and available pathology reports.

Q. *Effects of obesity.* Obesity is a medically determinable impairment that is often associated with disturbance of the musculoskeletal system, and disturbance of this system can be a major cause of disability in individuals with obesity. The combined effects of obesity with musculoskeletal impairments can be greater than the effects of each of the impairments considered separately. Therefore, when determining whether an individual with obesity has a listing-level impairment or combination of impairments, and when assessing a claim at other steps of the sequential evaluation process, including when assessing an individual's residual functional capacity, adjudicators must consider any additional and cumulative effects of obesity.

1.01 Category of Impairments, Musculoskeletal

1.02 *Major dysfunction of a joint(s) (due to any cause):* Characterized by gross anatomical deformity (e.g., subluxation, contracture, bony or fibrous ankylosis, instability) and chronic joint pain and stiffness with signs of limitation of motion or other abnormal motion of the affected joint(s), and findings on appropriate medically acceptable imaging of joint space narrowing, bony destruction, or ankylosis of the affected joint(s). With:

A. Involvement of one major peripheral weight-bearing joint (i.e., hip, knee, or ankle), resulting in inability to ambulate effectively, as defined in 1.00B2b;

or

B. Involvement of one major peripheral joint in each upper extremity (i.e., shoulder, elbow, or wrist-hand), resulting in inability to perform fine and gross movements effectively, as defined in 1.00B2c.

1.03 *Reconstructive surgery or surgical arthrodesis of a major weight-bearing joint,* with inability to ambulate effectively, as defined in 1.00B2b, and return to effective ambulation did not occur, or is not expected to occur, within 12 months of onset.

1.04 *Disorders of the spine* (e.g., herniated nucleus pulposus, spinal arachnoiditis, spinal stenosis, osteoarthritis, degenerative disc disease, facet arthritis, vertebral fracture), resulting in compromise of a nerve root (including the cauda equina) or the spinal cord. With:

A. Evidence of nerve root compression characterized by neuro-anatomic distribution of pain, limitation of motion of the spine, motor loss (atrophy with associated muscle weakness or muscle weakness) accompanied by sensory or reflex loss and, if there is involvement of the lower back, positive straight-leg raising test (sitting and supine);

or

B. Spinal arachnoiditis, confirmed by an operative note or pathology report of tissue biopsy, or by appropriate medically acceptable imaging, manifested by severe burning or painful dysesthesia, resulting in the need for changes in position or posture more than once every 2 hours;

or

C. Lumbar spinal stenosis resulting in pseudoclaudication, established by findings on appropriate medically acceptable imaging, manifested by chronic nonradicular pain and weakness, and resulting in inability to ambulate effectively, as defined in 1.00B2b.

1.05 *Amputation (due to any cause).*

A. Both hands; or

or

B. One or both lower extremities at or above the tarsal region, with stump complications resulting in medical inability to use a prosthetic device to ambulate effectively, as defined in 1.00B2b, which have lasted or are expected to last for at least 12 months;

or

C. One hand and one lower extremity at or above the tarsal region, with inability to ambulate effectively, as defined in 1.00B2b;

OR

D. Hemipelvectomy or hip disarticulation.

1.06 *Fracture of the femur, tibia, pelvis, or one or more of the tarsal bones.* With:

A. Solid union not evident on appropriate medically acceptable imaging and not clinically solid;

and

B. Inability to ambulate effectively, as defined in 1.00B2b, and return to effective ambulation did not occur or is not expected to occur within 12 months of onset.

1.07 *Fracture of an upper extremity* with nonunion of a fracture of the shaft of the humerus, radius, or ulna, under continuing surgical management, as defined in 1.00M, directed toward restoration of functional use of the extremity, and such function was not restored or expected to be restored within 12 months of onset.

1.08 *Soft tissue injury (e.g., burns)* of an upper or lower extremity, trunk, or face and head, under continuing surgical management, as defined in 1.00M, directed toward the salvage or restoration of major function, and such major function was not restored or expected to be restored within 12 months of onset. Major function of the face and head is described in 1.000.

4. Under listing 4.00, Cadiovascular System, listing 4.12, *Peripheral arterial disease,* of part A of appendix 1 of subpart P of part 404 is revised to read as follows:

4.00 CARDIOVASCULAR SYSTEM

* * * * *

4.12 *Peripheral arterial disease.* With one of the following:

A. Intermittent claudication with failure to visualize (on arteriogram obtained independent of Social Security disability evaluation) the common femoral or deep femoral artery in one extremity;

or

B. Intermittent claudication with marked impairment of peripheral arterial circulation as determined by Doppler studies showing:

1. Resting ankle/brachial systolic blood pressure ratio of less than 0.50; or

2. Decrease in systolic blood pressure at the ankle on exercise (see 4.00E4) of 50 percent or more of pre-exercise level at the ankle, and requiring 10 minutes or more to return to pre-exercise level.

5. Under listing 9.00, Endocrine System, listing 9.08, *Diabetes mellitus* of part A of appendix 1 of subpart P of part 404 is amended by removing listing 9.08C and redesignating listing 9.08D as listing 9.08C.

6. Listing 14.00, Immune System, of part A of appendix 1 of subpart P of part 404 is amended by revising the fourth and sixth paragraphs within 14.00 B and by adding a new section 14.00B6 to read as follows:

14.00 IMMUNE SYSTEM

* * * * *

B. * * *

To permit appropriate application of a listing, the specific diagnostic features that should be documented in the clinical record for each of the disorders are summarized for systemic lupus erythematosus (SLE), systemic vasculitis, systemic sclerosis and scleroderma, polymyositis or dermatomyositis, undifferentiated connective tissue disorders, and the inflammatory arthritides.

* * * * *

These disorders may preclude performance of any gainful activity by reason of serious loss of function because of disease affecting a single organ or body system, or lesser degrees of functional loss because of disease affecting two or more organs/body systems associated with significant constitutional symptoms and signs of severe fatigue, fever, malaise, weight loss, and joint pain and stiffness. We use the term ''severe'' in these listings to describe medical severity; the term does not have the same meaning as it does when we use it in connection with a finding at the second step of the sequential evaluation processes in §§ 404.1520, 416.920, and 416.924.

* * * * *

6. *Inflammatory arthritis (14.09)* includes a vast array of disorders that differ in cause, course, and outcome. For example, inflammatory spondyloarthropathies include ankylosing spondylitis, Reiter's syndrome and other reactive arthropathies, psoriatic arthropathy, Behçet's disease, and Whipple's disease, as well as undifferentiated spondylitis. Inflammatory arthritis of peripheral joints likewise comprises many disorders, including rheumatoid arthritis, Sjögren's syndrome, psoriatic arthritis, crystal deposition disorders, and Lyme disease. Clinically, inflammation of major joints may be the dominant problem causing difficulties with ambulation or fine and gross movements, or the arthritis may involve other joints or cause less restriction of ambulation or other movements but be complicated by extra-articular features that cumulatively result in serious functional deficit. When persistent deformity without ongoing inflammation is the dominant feature of the impairment, it should be evaluated under 1.02, or, if there has been surgical reconstruction, 1.03.

a. In 14.09A, the term *major joints* refers to the major peripheral joints, which are the hip, knee, shoulder, elbow, wrist-hand, and ankle-foot, as opposed to other peripheral joints (e.g., the joints of the hand or forefoot) or axial joints (i.e., the joints of the spine.) The wrist and hand are considered together as one major joint, as are the ankle and foot. Since only the ankle joint, which consists of the juncture of the bones of the lower leg (tibia and fibula) with the hindfoot (tarsal bones), but not the forefoot, is crucial to weight bearing, the ankle and foot are considered separately in evaluating weight bearing.

b. The terms *inability to ambulate effectively and inability to perform fine and gross movements effectively* in 14.09A have the same meaning as in 1.00B2b and 1.00B2c and must have lasted, or be expected to last, for at least 12 months.

c. Inability to ambulate effectively is implicit in 14.09B. Even though individuals who demonstrate the findings of 14.09B will not ordinarily require bilateral upper limb assistance, the required ankylosis of the cervical or dorsolumbar spine will result in an extreme loss of the ability to see ahead, above, and to the side.

d. As in 14.02 through 14.06, extra-articular features of an inflammatory arthritis may satisfy the criteria for a listing in an involved extra-articular body system. Such impairments may be found to meet a criterion of 14.09C. Extra-articular impairments of lesser severity should be evaluated under 14.09D and 14.09E. Commonly occurring extra-articular impairments include keratoconjunctivitis sicca, uveitis, iridocyclitis, pleuritis, pulmonary fibrosis or nodules, restrictive lung disease, pericarditis, myocarditis, cardiac arrhythmias, aortic valve insufficiency, coronary arteritis, Raynaud's phenomena, systemic vasculitis, amyloidosis of the kidney, chronic anemia, thrombocytopenia, hypersplenism with compromised immune competence (Felty's syndrome), peripheral neuropathy, radiculopathy, spinal cord or cauda equina compression with sensory and motor loss, and heel enthesopathy with functionally limiting pain.

e. The fact that an individual is dependent on steroids, or any other drug, for the control of inflammatory arthritis is, in and of itself, insufficient to find disability. Advances in the treatment of inflammatory connective tissue disease and in the administration of steroids for its treatment have corrected some of the previously disabling consequences of continuous steroid use. Therefore, each case must be evaluated on its own merits, taking into consideration the severity of the underlying impairment and any adverse effects of treatment.

* * * * *

7. In listing 14.02A, listings 14.02A8 through 14.02A10 are redesignated as listings 14.02A9 through 14.02A11, respectively and a new listing 14.02A8 is added reading as follows:

14.02 *Systemic lupus erythematosus.* * * *

A. One of the following:

* * * * *

8. Hematologic involvement, as described under the criteria in 7.00ff; or

* * * * *

8. A new listing 14.09 is added to read as follows:

14.09 *Inflammatory arthritis.*

Documented as described in 14.00B6, with one of the following:

A. History of joint pain, swelling, and tenderness, and signs on current physical examination of joint inflammation or deformity in two or more major joints resulting in inability to ambulate effectively or inability to perform fine and gross movements effectively, as defined in 14.00B6b and 1.00B2b and B2c;

or

B. Ankylosing spondylitis or other spondyloarthropathy, with diagnosis established by findings of unilateral or bilateral sacroiliitis (e.g., erosions or fusions), shown by appropriate medically acceptable imaging, with both:

1. History of back pain, tenderness, and stiffness, and

2. Findings on physical examination of ankylosis (fixation) of the dorsolumbar or cervical spine at 45° or more of flexion measured from the vertical position (zero degrees);

or

C. An impairment as described under the criteria in 14.02A.

or

D. Inflammatory arthritis, with signs of peripheral joint inflammation on current examination, but with lesser joint involvement than in A and lesser extra-articular features than in C, and:

1. Significant, documented constitutional symptoms and signs (e.g., fatigue, fever, malaise, weight loss), and

2. Involvement of two or more organs/body systems (see 14.00B6d). At least one of the organs/body systems must be involved to at least a moderate level of severity.

or

E. Inflammatory spondylitis or other inflammatory spondyloarthropathies, with lesser deformity than in B and lesser extra-articular features than in C, with signs of unilateral or bilateral sacroiliitis on appropriate medically acceptable imaging; and with the extra-articular features described in 14.09D.

9. Listing 101.00, Musculoskeletal System, of part B of appendix 1 of subpart P of part 404 is revised to read as follows:

101.00 Musculoskeletal System

A. *Disorders of the musculoskeletal system* may result from hereditary, congenital, or acquired pathologic processes. Impairments may result from infectious, inflammatory, or degenerative processes, traumatic or developmental events, or neoplastic, vascular, or toxic/metabolic diseases.

B. Loss of Function

1. *General.* Under this section, loss of function may be due to bone or joint deformity or destruction from any cause; miscellaneous disorders of the spine with or without radiculopathy or other neurological deficits; amputation; or fractures or soft tissue injuries, including burns, requiring prolonged periods of immobility or convalescence. For inflammatory arthritides that result in loss of function because of inflammatory peripheral joint or axial arthritis or sequelae, or because of extra-articular features, see 114.00E. Impairments with neurological causes are to be evaluated under 111.00ff.

2. How We Define Loss of Function in These Listings

a. *General.* Regardless of the cause(s) of a musculoskeletal impairment, functional loss for purposes of these listings is defined as the inability to ambulate effectively on a sustained basis for any reason, including pain associated with the underlying musculoskeletal impairment, or the inability to perform fine and gross movements effectively on a sustained basis for any reason, including pain associated with the underlying musculoskeletal impairment. The inability to ambulate effectively or the inability to perform fine and gross movements effectively must have lasted, or be expected to last, for at least 12 months. For the purposes of these criteria, consideration of the ability to perform these activities must be from a physical standpoint alone. When there is an inability to perform these activities due to a mental impairment, the criteria in 112.00ff are to be used. We will determine whether a child can ambulate effectively or can perform fine and gross movements effectively based on the medical and other evidence in the case record, generally without developing additional evidence about the child's ability to perform the specific activities listed as examples in 101.00B2b(2) and (3) and 101.00B2c(2) and (3).

b. What We Mean by Inability to Ambulate Effectively

(1) *Definition.* Inability to ambulate effectively means an extreme limitation of the ability to walk; i.e., an impairment that interferes very seriously with the child's ability to independently initiate, sustain, or complete activities. Ineffective ambulation is defined generally as having insufficient lower extremity functioning (see 101.00J) to permit independent ambulation without the use of a hand-held assistive device(s) that limits the functioning of both upper extremities. (Listing 101.05C is an exception to this general definition because the child has the use of only one upper extremity due to amputation of a hand.)

(2) How We Assess inability to ambulate effectively for children too young to be expected to walk independently. For children who are too young to be expected to walk independently, consideration of function must be based on assessment of limitations in the ability to perform comparable age-appropriate activities with the lower extremities, given normal developmental expectations. For such children, an extreme level of limitation means skills or performance at no greater than one-half of age-appropriate expectations based on an overall developmental assessment rather than on one or two isolated skills.

(3) *How we assess inability to ambulate effectively for older children.* Older children, who would be expected to be able to walk when compared to other children the same age who do not have impairments, must be capable of sustaining a reasonable walking pace over a sufficient distance to be able to carry out age-appropriate activities. They must have the ability to travel age-appropriately without extraordinary assistance to and from school or a place of employment. Therefore, examples of ineffective ambulation for older children include, but are not limited to, the inability to walk without the use of a walker, two crutches or two canes, the inability to walk a block at a reasonable pace on rough or uneven surfaces, the inability to use standard public transportation, the inability to carry out age-appropriate school activities independently, and the inability to climb a few steps at a reasonable pace with the use of a single hand rail. The ability to walk independently about the child's home or a short distance at school without the use of assistive devices does not, in and of itself, constitute effective ambulation.

c. What We Mean by Inability To Perform Fine and Gross Movements Effectively

(1) *Definition.* Inability to perform fine and gross movements effectively means an extreme loss of function of both upper extremities; i.e., an impairment that interferes very seriously with the child's ability to independently initiate, sustain, or complete activities. To use their upper extremities effectively, a child must be capable of sustaining such functions as reaching, pushing, pulling, grasping, and fingering in an age-appropriate manner to be able to carry out age-appropriate activities.

(2) *How we assess inability to perform fine and gross movements in very young children.* For very young children, the consideration is limitations in the ability to perform comparable age-appropriate activities involving the upper extremities given normal developmental expectations. Determinations of extreme limitation in such children should be made by comparison with the limitations for persistent motor dysfunction for infants and young children described in 110.07A.

(3) *How we assess inability to perform fine and gross movements in older children.* For older children, examples of inability to perform fine and gross movements effectively include, but are not limited to, the inability to prepare a simple meal and feed oneself, the inability to take care of personal hygiene, or the inability to sort and handle papers or files, depending upon which activities are age-appropriate.

d. *Pain or other symptoms.* Pain or other symptoms may be an important factor contributing to functional loss. In order for pain or other symptoms to be found to affect a child's ability to function in an age-appropriate manner or to perform basic work activities, medical signs or laboratory findings must show the existence of a medically determinable impairment(s) that could reasonably be expected to produce the pain or other symptoms. The musculoskeletal listings that include pain or other symptoms among their criteria also include criteria for limitations in functioning as a result of the listed impairment, including limitations caused by pain. It is, therefore, important to evaluate the intensity and persistence of such pain or other symptoms carefully in order to determine their impact on the child's functioning under these listings. See also §§ 404.1525(f) and 404.1529 of this part, and §§ 416.925(f) and 416.929 of part 416 of this chapter.

C. Diagnosis and Evaluation

1. *General.* Diagnosis and evaluation of musculoskeletal impairments should be supported, as applicable, by detailed descriptions of the joints, including ranges of motion, condition of the musculature (e.g., weakness, atrophy), sensory or reflex changes, circulatory deficits, and laboratory findings, including findings on x-ray or other appropriate medically acceptable imaging. Medically acceptable imaging includes, but is not limited to, x-ray imaging, computerized axial tomography (CAT scan) or magnetic resonance imaging (MRI), with or without contrast material, myelography, and radionuclear bone scans. ''Appropriate'' means that the technique used is the proper one to support the evaluation and diagnosis of the impairment.

2. *Purchase of certain medically acceptable imaging.* While any appropriate medically acceptable imaging is useful in establishing the diagnosis of musculoskeletal impairments, some tests, such as CAT scans and MRIs, are quite expensive, and we will not routinely purchase them. Some, such as myelograms, are invasive and may involve significant risk. We will not order such tests. However, when the results of any of these tests are part of the existing evidence in the case record we will consider them together with the other relevant evidence.

3. *Consideration of electrodiagnostic procedures.* Electrodiagnostic procedures may be useful in establishing the clinical diagnosis, but do not constitute alternative criteria to the requirements of 101.04.

D. *The physical examination* must include a detailed description of the rheumatological, orthopedic, neurological, and other findings appropriate to the specific impairment being evaluated. These physical findings must be determined on the basis of objective observation during the examination and not simply a report of the child's allegation; e.g., ''He says his leg is weak, numb.'' Alternative testing methods should be used to verify the abnormal findings; e.g., a seated straight-leg raising test in addition to a supine straight-leg raising test. Because abnormal physical

findings may be intermittent, their presence over a period of time must be established by a record of ongoing management and evaluation. Care must be taken to ascertain that the reported examination findings are consistent with the child's age and activities.

E. Examination of the Spine

1. *General.* Examination of the spine should include a detailed description of gait, range of motion of the spine given quantitatively in degrees from the vertical position (zero degrees) or, for straight-leg raising from the sitting and supine position (zero degrees), any other appropriate tension signs, motor and sensory abnormalities, muscle spasm, when present, and deep tendon reflexes. Observations of the child during the examination should be reported; e.g., how he or she gets on and off the examination table. Inability to walk on the heels or toes, to squat, or to arise from a squatting position, when appropriate, may be considered evidence of significant motor loss. However, a report of atrophy is not acceptable as evidence of significant motor loss without circumferential measurements of both thighs and lower legs, or both upper and lower arms, as appropriate, at a stated point above and below the knee or elbow given in inches or centimeters. Additionally, a report of atrophy should be accompanied by measurement of the strength of the muscle(s) in question generally based on a grading system of 0 to 5, with 0 being complete loss of strength and 5 being maximum strength. A specific description of atrophy of hand muscles is acceptable without measurements of atrophy but should include measurements of grip and pinch strength. However, because of the unreliability of such measurement in younger children, these data are not applicable to children under 5 years of age.

2. *When neurological abnormalities persist.* Neurological abnormalities may not completely subside after treatment or with the passage of time. Therefore, residual neurological abnormalities that persist after it has been determined clinically or by direct surgical or other observation that the ongoing or progressive condition is no longer present will not satisfy the required findings in 101.04. More serious neurological deficits (paraparesis, paraplegia) are to be evaluated under the criteria in 111.00ff.

F. *Major joints* refers to the major peripheral joints, which are the hip, knee, shoulder, elbow, wrist-hand, and ankle-foot, as opposed to other peripheral joints (e.g., the joints of the hand or forefoot) or axial joints (i.e., the joints of the spine.) The wrist and hand are considered together as one major joint, as are the ankle and foot. Since only the ankle joint, which consists of the juncture of the bones of the lower leg (tibia and fibula) with the hindfoot (tarsal bones), but not the forefoot, is crucial to weight bearing, the ankle and foot are considered separately in evaluating weight bearing.

G. *Measurements of joint motion* are based on the techniques described in the chapter on the extremities, spine, and pelvis in the current edition of the ''Guides to the Evaluation of Permanent Impairment'' published by the American Medical Association.

H. Documentation.

1. *General.* Musculoskeletal impairments frequently improve with time or respond to treatment. Therefore, a longitudinal clinical record is generally important for the assessment of severity and expected duration of an impairment unless the child is a newborn or the claim can be decided favorably on the basis of the current evidence.

2. *Documentation of medically prescribed treatment and response.* Many children, especially those who have listing-level impairments, will have received the benefit of medically prescribed treatment. Whenever evidence of such treatment is available it must be considered.

3. *When there is no record of ongoing treatment.* 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). In such cases, evaluation will be made on the basis of the current objective medical evidence and other available evidence, taking into consideration the child's medical history, symptoms, and medical source opinions. Even though a child who does not receive treatment may not be able to show an impairment that meets the criteria of one of the musculoskeletal listings, the child may have an impairment(s) that is either medically or, in the case of a claim for benefits under part 416 of this chapter, functionally equivalent in severity to one of the listed impairments.

4. *Evaluation when the criteria of a musculoskeletal listing are not met.* These listings are only examples of common musculoskeletal disorders that are severe enough to find a child disabled. Therefore, in any case in which a child has a medically determinable impairment that is not listed, an impairment that does not meet the requirements of a listing, or a combination of impairments no one of which meets the requirements of a listing, we will consider whether the child's impairment(s) is medically or, in the case of a claim for benefits under part 416 of this chapter, functionally equivalent in severity to the criteria of a listing. (See §§ 404.1526, 416.926, and 416.926a.) Individuals with claims for benefits under part 404, who have an impairment(s) with a level of severity that does not meet or equal the criteria of the musculoskeletal listings may or may not have the RFC that would enable them to engage in substantial gainful activity. Evaluation of the impairment(s) of these individuals should proceed through the final steps of the sequential evaluation process in § 404.1520 (or, as appropriate, the steps in the medical improvement review standard in § 404.1594).

I. Effects of Treatment

1. *General.* Treatments for musculoskeletal disorders may have beneficial effects or adverse side effects. Therefore, medical treatment (including surgical treatment) must be considered in terms of its effectiveness in ameliorating the signs, symptoms, and laboratory abnormalities of the disorder, and in terms of any side effects that may further limit the child.

2. *Response to treatment.* Response to treatment and adverse consequences of treatment may vary widely. For example, a pain medication may relieve a child's pain completely, partially, or not at all. It may also result in adverse effects, e.g., drowsiness, dizziness, or disorientation, that compromise the child's ability to function. Therefore, each case must be considered on an individual basis, and include consideration of the effects of treatment on the child's ability to function.

3. *Documentation.* A specific description of the drugs or treatment given (including surgery), dosage, frequency of administration, and a description of the complications or response to treatment should be obtained. The effects of treatment may be temporary or long-term. As such, the finding regarding the impact of treatment must be based on a sufficient period of treatment to permit proper consideration or judgment about future functioning.

J. Orthotic, Prosthetic, or Assistive Devices

1. *General.* Consistent with clinical practice, children with musculoskeletal impairments may be examined with and without the use of any orthotic, prosthetic, or assistive devices as explained in this section.

2. *Orthotic devices.* Examination should be with the orthotic device in place and should include an evaluation of the child's maximum ability to function effectively with the orthosis. It is unnecessary to routinely evaluate the child's ability to function without the orthosis in place. If the child has difficulty with, or is unable to use, the orthotic device, the medical basis for the difficulty should be documented. In such cases, if the impairment involves a lower extremity or extremities, the examination should include information on the child's ability to ambulate effectively without the device in place unless contraindicated by the medical judgment of a physician who has treated or examined the child.

3. *Prosthetic devices.* Examination should be with the prosthetic device in place. In amputations involving a lower extremity or extremities, it is unnecessary to evaluate the child's ability to walk without the prosthesis in place. However, the child's medical ability to use a prosthesis to ambulate effectively, as defined in 101.00B2b, should be evaluated. The condition of the stump should be evaluated without the prosthesis in place.

4. *Hand-held assistive devices.* When a child with an impairment involving a lower extremity or extremities uses a hand-held assistive device, such as a cane, crutch or walker, examination should be with and without the use of the assistive device unless contraindicated by the medical judgment of a physician who has treated or examined the child. The child's ability to ambulate with and without the device provides information as to whether, or the extent to which, the child is able to ambulate without assistance. The medical basis for the use of any assistive device (e.g., instability, weakness) should be documented. The requirement to use a hand-held assistive device may also impact on the child's functional capacity by virtue of the fact that one or both upper extremities are not available for such activities as lifting, carrying, pushing, and pulling.

K. *Disorders of the spine,* listed in 101.04, result in limitations because of distortion of

the bony and ligamentous architecture of the spine and associated impingement on nerve roots (including the cauda equina) or spinal cord. Such impingement on nerve tissue may result from a herniated nucleus pulposus or other miscellaneous conditions. Neurological abnormalities resulting from these disorders are to be evaluated by referral to the neurological listings in 111.00ff, as appropriate. (See also 101.00B and E.)

1. *Herniated nucleus pulposus* is a disorder frequently associated with the impingement of a nerve root, but occurs infrequently in children. Nerve root compression results in a specific neuro-anatomic distribution of symptoms and signs depending upon the nerve root(s) compromised.

2. *Other miscellaneous conditions* that may cause weakness of the lower extremities, sensory changes, areflexia, trophic ulceration, bladder or bowel incontinence, and that should be evaluated under 101.04 include, but are not limited to, lysosomal disorders, metabolic disorders, vertebral osteomyelitis, vertebral fractures and achondroplasia. Disorders such as spinal dysrhaphism, (e.g., spina bifida) diastematomyelia, and tethered cord syndrome may also cause such abnormalities. In these cases, there may be gait difficulty and deformity of the lower extremities based on neurological abnormalities, and the neurological effects are to be evaluated under the criteria in 111.00ff.

L. *Abnormal curvatures of the spine.* Abnormal curvatures of the spine (specifically, scoliosis, kyphosis and kyphoscoliosis) can result in impaired ambulation, but may also adversely affect functioning in body systems other than the musculoskeletal system. For example, a child's ability to breathe may be affected; there may be cardiac difficulties (e.g., impaired myocardial function); or there may be disfigurement resulting in withdrawal or isolation. When there is impaired ambulation, evaluation of equivalence may be made by reference to 114.09A. When the abnormal curvature of the spine results in symptoms related to fixation of the dorsolumbar or cervical spine, evaluation of equivalence may be made by reference to 114.09B. When there is respiratory or cardiac involvement or an associated mental disorder, evaluation may be made under 103.00ff, 104.00ff, or 112.00ff, as appropriate. Other consequences should be evaluated according to the listing for the affected body system.

M. *Under continuing surgical management,* as used in 101.07 and 101.08, refers to surgical procedures and any other associated treatments related to the efforts directed toward the salvage or restoration of functional use of the affected part. It may include such factors as post-surgical procedures, surgical complications, infections, or other medical complications, related illnesses, or related treatments that delay the child's attainment of maximum benefit from therapy.

N. *After maximum benefit from therapy has been achieved* in situations involving fractures of an upper extremity (101.07), or soft tissue injuries (101.08), i.e., there have been no significant changes in physical findings or on appropriate medically acceptable imaging for any 6-month period after the last definitive surgical procedure or other medical intervention, evaluation must be made on the basis of the demonstrable residuals, if any. A finding that 101.07 or 101.08 is met must be based on a consideration of the symptoms, signs, and laboratory findings associated with recent or anticipated surgical procedures and the resulting recuperative periods, including any related medical complications, such as infections, illnesses, and therapies which impede or delay the efforts toward restoration of function. Generally, when there has been no surgical or medical intervention for 6 months after the last definitive surgical procedure, it can be concluded that maximum therapeutic benefit has been reached. Evaluation at this point must be made on the basis of the demonstrable residual limitations, if any, considering the child's impairment-related symptoms, signs, and laboratory findings, any residual symptoms, signs, and laboratory findings associated with such surgeries, complications, and recuperative periods, and other relevant evidence.

O. *Major function of the face and head,* for purposes of listing 101.08, relates to impact on any or all of the activities involving vision, hearing, speech, mastication, and the initiation of the digestive process.

P. *When surgical procedures have been performed,* documentation should include a copy of the operative notes and available pathology reports.

101.01 Category of Impairments, Musculoskeletal

101.02 *Major dysfunction of a joint(s) (due to any cause):* Characterized by gross anatomical deformity (e.g., subluxation, contracture, bony or fibrous ankylosis, instability) and chronic joint pain and stiffness with signs of limitation of motion or other abnormal motion of the affected joint(s), and findings on appropriate medically acceptable imaging of joint space narrowing, bony destruction, or ankylosis of the affected joint(s). With:

A. Involvement of one major peripheral weight-bearing joint (i.e., hip, knee, or ankle), resulting in inability to ambulate effectively, as defined in 101.00B2b;

or

B. Involvement of one major peripheral joint in each upper extremity (i.e., shoulder, elbow, or wrist-hand), resulting in inability to perform fine and gross movements effectively, as defined in 101.00B2c.

101.03 *Reconstructive surgery or surgical arthrodesis of a major weight-bearing joint,* with inability to ambulate effectively, as defined in 101.00B2b, and return to effective ambulation did not occur, or is not expected to occur, within 12 months of onset.

101.04 *Disorders of the spine* (e.g., lysosomal disorders, metabolic disorders, vertebral osteomyelitis, vertebral fracture, achondroplasia) resulting in compromise of a nerve root (including the cauda equina) or the spinal cord, with evidence of nerve root compression characterized by neuro-anatomic distribution of pain, limitation of motion of the spine, motor loss (atrophy with associated muscle weakness or muscle weakness) accompanied by sensory or reflex loss and, if there is involvement of the lower back, positive straight-leg raising test (sitting and supine).

101.05 *Amputation (due to any cause).*

A. Both hands;

or

B. One or both lower extremities at or above the tarsal region, with stump complications resulting in medical inability to use a prosthetic device to ambulate effectively, as defined in 101.00B2b, which have lasted or are expected to last for at least 12 months;

or

C. One hand and one lower extremity at or above the tarsal region, with inability to ambulate effectively, as defined in 101.00B2b;

or

D. Hemipelvectomy or hip disarticulation.

101.06 *Fracture of the femur, tibia, pelvis, or one or more of the tarsal bones.* With:

A. Solid union not evident on appropriate medically acceptable imaging, and not clinically solid;

and

B. Inability to ambulate effectively, as defined in 101.00B2b, and return to effective ambulation did not occur or is not expected to occur within 12 months of onset.

101.07 *Fracture of an upper extremity* with nonunion of a fracture of the shaft of the humerus, radius, or ulna, under continuing surgical management, as defined in 101.00M, directed toward restoration of functional use of the extremity, and such function was not restored or expected to be restored within 12 months of onset.

101.08 *Soft tissue injury (e.g., burns)* of an upper or lower extremity, trunk, or face and head, under continuing surgical management, as defined in 101.00M, directed toward the salvage or restoration of major function, and such major function was not restored or expected to be restored within 12 months of onset. Major function of the face and head is described in 101.00O.

10. Listing 114.00, Immune System, of part B of appendix 1 of subpart P of part 404 is amended by revising the first and sixth paragraphs of 114.00B, by revising 114.00C2, and by adding a new section 114.00E to read as follows:

114.00 IMMUNE SYSTEM

* * * * *

B. *Dysregulation of the immune system* may result in the development of a connective tissue disorder. Connective tissue disorders include several chronic multisystem disorders that differ in their clinical manifestation, course, and outcome. These disorders are described in part A, 14.00B; inflammatory arthritis is also described in 114.00E.

* * * * *

In children the impairment may affect growth, development, attainment of age-appropriate skills, and performance of age-appropriate activities. The limitations may be

the result of serious loss of function because of disease affecting a single organ or body system, or lesser degrees of functional loss because of disease affecting two or more organs/body systems associated with significant constitutional symptoms and signs of severe fatigue, fever, malaise, weight loss, and joint pain and stiffness. We use the term ''severe'' in these listings to describe medical severity; the term does not have the same meaning as it does when we use it in connection with a finding at the second step of the sequential evaluation processes in §§ 404.1520, 416.920, and 416.924.

C. Allergies, Growth Impairments and Kawasaki Disease

* * * * *

2. If growth is affected by the disorder or its treatment by immunosuppressive drugs, 100.00, Growth impairment, may apply. Children may have growth impairment as a result of the inflammatory arthritides because of the diseases' potential effects on the immature skeleton, open epiphyses, and young cartilage and bone. In such situations, the growth impairment should be evaluated under 100.00ff.

* * * * *

E. *Inflammatory arthritis (114.09)* includes a vast array of disorders that differ in cause, course, and outcome. For example, in children inflammatory spondyloarthropathies include juvenile ankylosing spondylitis, reactive arthropathies, psoriatic arthropathy, and Behçet's disease, as well as undifferentiated spondylitis. Inflammatory arthritis of peripheral joints likewise comprises many disorders, including juvenile rheumatoid arthritis, Sjögren's syndrome, psoriatic arthritis, crystal deposition disorders, and Lyme disease. Clinically, inflammation of major joints may be the dominant problem causing difficulties with ambulation or fine and gross movements, or the arthritis may involve other joints or cause less restriction of age-appropriate ambulation or other movements but be complicated by extra-articular features that cumulatively result in serious functional deficit. When persistent deformity without ongoing inflammation is the dominant feature of the impairment, it should be evaluated under 101.02, or, if there has been surgical reconstruction, 101.03.

1. Because the features of inflammatory connective tissue diseases in children are modified by such factors as the child's limited antigenic exposure and immune reactivity, the acute inflammatory connective tissue diseases must be differentiated from each other in order to evaluate duration factors and responses to specific treatments. Chronic conditions must be differentiated from short-term reversible disorders, and also from other connective tissue diseases.

2. In 114.09A, the term *major joints* refers to the major peripheral joints, which are the hip, knee, shoulder, elbow, wrist-hand, and ankle-foot, as opposed to other peripheral joints (e.g., the joints of the hand or forefoot) or axial joints (i.e., the joints of the spine.) The wrist and hand are considered together as one major joint, as are the ankle and foot. Since only the ankle joint, which consists of the juncture of the bones of the lower leg (tibia and fibula) with the hindfoot (tarsal bones), but not the forefoot, is crucial to weight bearing, the ankle and foot are considered separately in evaluating weight bearing.

3. The terms *inability to ambulate effectively* and *inability to perform fine and gross movements effectively* in 114.09A have the same meaning as in 101.00B2b and 101.00B2c and must have lasted, or be expected to last, for at least 12 months.

4. Inability to ambulate effectively is implicit in 114.09B. Even though children who demonstrate the findings of 114.09B will not ordinarily require bilateral upper limb assistance, the required ankylosis of the cervical or dorsolumbar spine will result in an extreme loss of the ability to see ahead, above, and to the side.

5. As in 114.02 through 114.06, extra-articular features of an inflammatory arthritis may satisfy the criteria for a listing in an involved extra-articular body system. Such impairments may be found to meet a criterion of 114.09C. Extra-articular impairments of lesser severity should be evaluated under 114.09D and 114.09E. Commonly occurring extra-articular impairments include keratoconjunctivitis sicca, uveitis, iridocyclitis, pleuritis, pulmonary fibrosis or nodules, restrictive lung disease, pericarditis, myocarditis, cardiac arrhythmias, aortic valve insufficiency, coronary arteritis, Raynaud's phenomena, systemic vasculitis, amyloidosis of the kidney, chronic anemia, thrombocytopenia, hypersplenism with compromised immune competence (Felty's syndrome), peripheral neuropathy, radiculopathy, spinal cord or cauda equina compression with sensory and motor loss, and heel enthesopathy with functionally limiting pain.

6. The fact that a child is dependent on steroids, or any other drug, for the control of inflammatory arthritis is, in and of itself, insufficient to find disability. Advances in the treatment of inflammatory connective tissue disease and in the administration of steroids for its treatment have corrected some of the previously disabling consequences of continuous steroid use. Therefore, each case must be evaluated on its own merits, taking into consideration the severity of the underlying impairment and any adverse effects of treatment.

11. A new listing 114.09 is added to read as follows:

114.09 *Inflammatory arthritis.* Documented as described in 114.00E, with one of the following:

A. History of joint pain, swelling, and tenderness, and signs on current physical examination of joint inflammation or deformity in two or more major joints resulting in inability to ambulate effectively or inability to perform fine and gross movements effectively, as defined in 114.00E3 and 101.00B2b and B2c;

or

B. Ankylosing spondylitis or other spondyloarthropathy, with diagnosis established by findings of unilateral or bilateral sacroiliitis (e.g., erosions or fusions), shown by appropriate medically acceptable imaging, with both:

1. History of back pain, tenderness, and stiffness, and

2. Findings on physical examination of ankylosis (fixation) of the dorsolumbar or cervical spine at 45° or more of flexion measured from the vertical position (zero degrees);

or

C. An impairment as described under the criteria in 114.02A.

or

D. Inflammatory arthritis, with signs of peripheral joint inflammation on current examination, but with lesser joint involvement than in A and lesser extra-articular features than in C, and:

1. Significant, documented constitutional symptoms and signs (e.g., fatigue, fever, malaise, weight loss), and

2. Involvement of two or more organs/body systems (see 114.00E5). At least one of the organs/body systems must be involved to at least a moderate level of severity.

or

E. Inflammatory spondylitis or other inflammatory spondyloarthropathies, with lesser deformity than in B and lesser extra-articular features than in C, with signs of unilateral or bilateral sacroiliitis on appropriate medically acceptable imaging; and with the extra-articular features described in 114.09D.

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

Subpart I—[Amended]

12. The authority citation for subpart I of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1611, 1614, 1619, 1631(a), (c), and (d)(1), and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1382, 1382c, 1382h, 1383(a), (c), and (d)(1), and 1383b); secs. 4(c) and 5, 6(c)–(e), 14(a) and 15, Pub. L. 98–460, 98 Stat. 1794, 1801, 1802, and 1808 (42 U.S.C. 421 note, 423 note, 1382h note).

13. Section 416.926a is amended by revising paragraphs (m)(2) and (m)(4) to read as follows:

§ 416.926a Functional equivalence for children.

* * * * *

(m) * * *

(2) Any condition that is disabling at the time of onset, requiring continuing surgical management within 12 months after onset as a life-saving measure or for salvage or restoration of function, and such major function is not restored or is not expected to be restored within 12 months after onset of this condition.

* * * * *

(4) Effective ambulation possible only with obligatory bilateral upper limb assistance.

* * * * *

14. Section 416.933 is amended by revising the second sentence to read as follows:

§ 416.933 How we make a finding of presumptive disability or presumptive blindness.

* * * In the case of readily observable impairments (e.g., total blindness), we will find that you are disabled or blind for purposes of this section without medical or other evidence. * * *

15. Section 416.934 is amended by removing paragraphs (a) and (h) and redesignating paragraphs (b) through (g) as paragraphs (a) through (f) and paragraphs (i) through (j) as paragraphs (g) through (h).

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