minor deficiencies in the performance of an accreditation function, including minor failure to comply with this subpart A, FDA will notify the body that it has 90 days to submit to FDA a plan of corrective action addressing the problems specified by FDA. This plan must include a summary of planned corrective actions and a schedule for their implementation.

(1) If the corrective action plan is received within the 90-day time period specified and is satisfactory to FDA, FDA will notify the body that it is on probationary approval status until further notice. This probationary status will remain in effect until such time as the body can demonstrate to the satisfaction of FDA that it has successfully implemented or is implementing the corrective action plan within the established schedule, and the corrective actions taken have substantially eliminated all identified problems. When such determination of restoration of satisfactory performance is made, FDA will restore the body to full approval status.

(2) If the body does not submit a satisfactory corrective action plan within the designated 90-day time period or does not implement an FDA-approved corrective action plan within the time interval specified in the corrective action plan (as amended, with FDA approval, if necessary) FDA will withdraw approval of the body as an accrediting body. In cases of withdrawal of approval of accrediting bodies, if FDA finds that there are satisfactory assurances that the unacceptable performance of the accrediting body has been substantially resolved, on application by the accrediting body, FDA may reinstate the approval of the accrediting body, unless there have been fraud or material false statements.

§ 900.7 Hearings.

Opportunities to challenge final adverse actions taken by FDA regarding approval of accrediting bodies, withdrawal of approval of accrediting bodies, or rejection of a proposed fee shall be communicated through notices of opportunity for informal hearings in accordance with part 16 of this chapter.

Dated: December 9, 1993.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 93–30992 Filed 12–16–93; 10:51 am]

BILLING CODE 4160–01–F

21 CFR Part 900

[Docket No. 93N–0351]

Quality Standards and Certification Requirements for Mammography Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim rule with request for comments.

SUMMARY: The Food and Drug Administration (FDA) is issuing regulations to implement the Mammography Quality Standards Act of 1992 (the MQSA), which requires the establishment of a Federal certification and inspection program for mammography facilities; regulations and standards for accrediting bodies for mammography facilities; and standards for mammography equipment, personnel, and practices, including quality assurance. This rule establishes requirements for certification of mammography facilities, including quality standards for mammography. This action is being taken to assure safe, accurate, and reliable mammography on a nationwide basis. The agency requests comments on the contents of this document.

DATES: These regulations are effective February 22, 1994. Written comments by January 20, 1994. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a certain publication in 21 CFR 900.12(d)(1)(i), effective February 22, 1994.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Charles K. Showalter, Center for Devices and Radiological Health (HFZ–200), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–3311.

SUPPLEMENTARY INFORMATION:

I. Background

Breast cancer is a leading cause of death among women and is most treatable in the early stages (Ref. 1). Research indicates that, with widespread use of high-quality mammography, breast cancer mortality could be significantly reduced through the identification of early cancerous lesions and early implementation of treatment, especially in older women. However, the quality of mammography at some facilities has been found to be inadequate, resulting in missed diagnosis of early lesions, delayed treatment, and otherwise avoidable increases in mortality (Refs. 2 and 3). Concerns about mammography quality and breast cancer prompted the establishment of various private, State, and Federal programs for assuring quality mammography. Disadvantages of such programs are that they are either voluntary, such as the Mammography Accreditation Program of the American College of Radiology (ACR), or are mandatory but do not apply to all facilities in the United States, such as State programs and programs administered by the Health Care Financing Administration (HCFA). Also, most of these programs lack important mammography quality evaluation criteria or oversight mechanisms, such as clinical image review and on-site inspections of facilities. Therefore, on a nationwide level, there are no universal mandatory standards for providing safe, accurate, and reliable mammography services.

In order to rectify this situation, the MQSA (Pub. L. 102–539) was enacted to establish uniform, national quality standards for mammography. The MQSA amends part F of Title III of the Public Health Service Act (the PHS Act) (42 U.S.C. 262 *et seq.*) by adding new section 354 (42 U.S.C. 263b) to establish a comprehensive statutory mechanism for certification and inspection of all mammography facilities under the regulatory jurisdiction of the United States. Under the MQSA, only those facilities which are in compliance with uniform Federal standards for safe, high-quality mammography services may lawfully continue operation after October 1, 1994. Operation after that date is contingent on receipt, after application, of a certificate from the Secretary of Health and Human Services (HHS) (the Secretary), and by delegation, FDA, that the facility meets the minimum mammography quality standards promulgated under section 354(f) of the PHS Act. This requirement applies to all facilities producing, processing, or interpreting mammograms, whether for screening or diagnostic purposes, except for facilities of the Department of Veterans Affairs.

The authority to implement the MQSA was delegated by HHS to FDA. FDA is issuing this interim rule to establish regulations implementing provisions of section 354(b), (c), (d), (e), and (f) of the PHS Act pertaining to certification procedures and quality standards for mammography. A more detailed legislative history and clinical rationale for this regulation is provided in the preamble for the accreditation

regulations published elsewhere in this issue of the Federal Register.

Specifically, the MQSA requires the following:

1. Accreditation of mammography facilities by private, nonprofit organizations or State agencies which have met the standards established by the Secretary for accrediting bodies and have been approved by the Secretary. The MQSA requires a direct Federal audit of the accrediting bodies through facility inspections by Federal officers. It also requires that, as a part of the overall accreditation process, clinical mammograms from each facility be evaluated for quality.

2. An annual mammography facility physics survey, consultation, and evaluation performed by a certified or State-licensed/approved medical physicist.

3. Annual inspection of mammography facilities, to be performed by Federally-certified or State-certified inspectors. The MQSA requires a Federal audit of the facility inspection program by inspections of a sample of facilities.

4. Establishment of qualification standards for interpreting physicians, mammography technologists, medical physicists, and mammography facility inspectors.

5. Specification of boards or organizations eligible to certify the adequacy of training and experience of particular mammography personnel.

6. Establishment of quality standards for mammography equipment and practices, including quality assurance and quality control programs.

7. Establishment by the Secretary of a National Mammography Quality Assurance Advisory Committee. Among other things, the advisory committee will advise the Secretary on the appropriate quality standards for the mammography facilities and the accrediting bodies.

8. Establishment of standards governing recordkeeping for patient files and requirements concerning mammography reporting and patient notification by physicians.

II. Provisions of the Rule

The MQSA requires the Secretary to set quality standards for certification of mammography facilities. The Senate report on the MQSA states that such standards must be no less stringent than those established by ACR (Ref. 4). The legislative history indicates that Congress intended that the standards established by the ACR program serve as the starting point for quality standards, although Congress also intended that, over time, the standards should undergo improvements stimulated by Federal oversight. Thus, FDA has reviewed the ACR standards and procedures in arriving at the content of this interim rule (Refs. 5 and 6). FDA has also reviewed standards and procedures developed by HCFA, a part of HHS which operates a system of certification for facilities under Medicare (December 31, 1990, 55 FR 53510). FDA's review has also included relevant State accreditation programs.

On December 14, 1993, the President signed legislation (H. Rept. 2202) granting interim rule authority to the Secretary for promulgation of standards required by the MQSA under section 354(e) pertaining to accreditation bodies and under section 354(f) pertaining to quality standards. FDA, in this interim rule, is also establishing some regulations under section 354(b), (c), and (d) because, in FDA's judgment this is necessary for a full implementation of section 354(e) and (f). The interim rule authorization was provided in recognition of the fact that the certification deadline of October 1, 1994, could not be met without streamlining the process for initial promulgation of standards. Granting of this interim rule authority, rather than extension of the deadline to develop standards, was decided on because of the perceived urgent public health need for Federal mammography standards. FDA has chosen to use this authority in order to meet the October 1, 1994, deadline for certification of facilities. While FDA believes that there is an urgent public health need for standards to be in effect, the agency also wants to provide time for facilities to meet the standards so that they can continue lawfully to operate and so that quality mammography will be available.

Under the interim rule legislation, the Secretary is authorized to issue temporary, interim rules setting forth standards for approving accrediting bodies and quality standards for mammography facilities, under sections 354(e) and (f) of the PHS Act. Under the abbreviated process, the Secretary is required to adopt existing standards to the maximum extent feasible, such as those established by HCFA, private voluntary accreditation bodies (e.g., ACR) and some States. Also, in developing the interim rules, the Secretary is not required to consult the National Mammography Quality Assurance Advisory Committee. However, following issuance of the initial standards, Congress intends that the Secretary proceed with the more extensive rulemaking procedures envisioned by the original enactment of the MQSA, including the statutorily required consultation with the Advisory Committee.

Thus, the interim rule authority permits the Secretary to expedite establishment of legally binding initial accreditation and quality standards based on standards currently in use. These initial standards will be used to accredit and certify facilities before the October 1, 1994, deadline, while the Secretary simultaneously continues to evaluate and develop the final standards under section 354(e) and (f) of the PHS Act. This second set of final regulations will supersede the initial regulations.

Because these regulations fall short of implementing the entire MQSA, FDA expects, in the future, to propose for notice and comment further implementing regulations not made necessary by section 354(e) and (f) of the PHS Act, such as regulations implementing section 354(r) concerning funding.

The certification regulations implemented by this interim rule are consistent with the congressional intent to incorporate existing standards to the maximum extent possible. Significant provisions of the certification regulations are summarized below.

A. General

Subpart B of a new part 900 has been established for regulations pertaining to certification of mammography facilities. Section 900.10 of new subpart B sets forth the applicability of certification requirements. As specified by the MQSA, covered facilities include all facilities under the regulatory jurisdiction of the United States that provide mammography services, except facilities of the Department of Veterans Affairs.

B. Requirements for Certification

Section 354(b) of the PHS Act requires that, by October 1, 1994, facilities obtain and prominently display an HHS-issued certificate or provisional certificate in order to: (1) Operate radiological equipment for mammography, (2) provide for processing of film used in mammography (at the facility or elsewhere), and (3) provide for interpretation of mammograms (at the facility or elsewhere). Section 354(c) and (d) of the PHS Act specify application, issuance and renewal requirements for certificates and provisional certificates as follows: certificates may be issued or renewed with an effective period of up to 3 years, and provisional certificates may be in effect for up to 6 months, with a one-time 90-day extension allowance for extenuating circumstances. Also, in section 354(d) of the PHS Act it is

stipulated that applicants for certificates should not be required to provide in an application to the Secretary any information which the applicant has already supplied to the body which accredited the applicant, except as required by the Secretary.

Certification requirements and procedures are set forth in new § 900.11. To implement the certification requirements before the statutory deadline, FDA envisions the likelihood of issuing certificates automatically to facilities already accredited by organizations whose existing accreditation program substantially meets the requirements of subpart A of part 900. For example, ACR would meet these criteria, since the ACR includes the statutorily mandated clinical image review as part of its accreditation process, among other requirements. Therefore, if the ACR applies to FDA for approval as an accrediting body and is so approved, ACR-accredited facilities (over 6,000 of the estimated 10,000 or more facilities in the United States) would qualify for automatic certification. In addition, if, based on their existing standards, other existing accrediting organizations are approved as accrediting bodies by FDA, facilities already accredited by such bodies under such standards would also receive automatic certification. However, in order for any facility to receive automatic certification, it will first be necessary that the body which accredited the facility successfully apply to FDA for approval as an accrediting body in accordance with subpart A of part 900.

Because facilities must be accredited in order to obtain a certificate, FDA provides procedures in new § 900.11(a) for obtaining a list of FDA-approved accrediting bodies. Facilities should note that, because of the concurrent publication of regulations for accreditation and certification, such a list will not be available until such time as FDA receives, evaluates, and rules on applications from potential accrediting bodies.

In keeping with the provision to limit duplicative submission of application information, FDA has established a certificate application system whereby a facility need only submit the statutorily mandated certificate application information to the accrediting body from which it obtained accreditation. In accordance with subpart A of part 900, accrediting bodies will then be required to notify FDA of the names and addresses of facilities they accredit within 5 days of the date of accreditation. FDA will issue certificates to facilities on the basis of such notifications from accrediting bodies, with no further action required on the part of facilities. FDA believes that this is the most efficient means of issuing certificates, eliminating the need for a special FDA application form and minimizing information collection and dissemination requirements.

A similar procedure has been established for provisional certificates. Facilities that have not obtained a certificate by October 1, 1994, but have applied for accreditation from an approved accrediting body will be eligible to receive a provisional certificate. To obtain a provisional certificate, a facility must submit the statutorily mandated application information to the accrediting body from which the facility has applied for accreditation. New facilities may also submit such information directly to FDA. If the accrediting body cannot act on a final certification application by the October 1, 1994 deadline, the accrediting body must then be required to notify FDA of having received an acceptable application, and FDA will issue a provisional certificate on the basis of such notification, with no further action required on the part of the facility. To request an additional 90-day extension to a provisional certificate, prior FDA approval is required because of differing statutory criteria. A facility should submit to the accrediting body a statement of what it is doing to obtain certification and information documenting that a significant adverse impact on the regional availability of mammography would result if such extension was not granted. That information must be forwarded by the accrediting body to FDA, which will determine whether such an extension would be justified.

FDA has designed the certificate issuance and renewal system so that future applications for renewal of certificates will be submitted, received and acted upon steadily over time, rather than all together. Although section 354(c)(1) of the PHS Act allows FDA to issue certificates with an effective period of up to 3 years, FDA believes that to set such an effective period for initial certificates would result in FDA having to process and renew over 10,000 certificates during a short time period within each renewal cycle. To avoid such a situation, FDA has established the expiration date for initial certificates to be 30 days after the expiration date of a facility's existing accreditation, with subsequent certification renewals then having an effective period of 3 years. This system will spread certification renewals over time because the thousands of facilities that are expected to be eligible for automatic certification, as discussed above, were accredited steadily over a period of years. Therefore, under the certification system established, since the expiration of facilities' accreditation is staggered over time, expiration of certificates will be similarly staggered, allowing more efficient use of FDA resources. This system offers the additional advantage for facilities, accrediting bodies, and FDA of closely coupling the accreditation and certification periods.

C. Quality Standards

Section 354(f) of the PHS Act requires the establishment by the Secretary (and by delegation, FDA) of quality standards that facilities must meet in order to become certified. Comparable standards must be adopted and imposed by accrediting bodies in accordance with subpart A of part 900. The quality standards that must be established include: (1) Standards that require establishment and maintenance of a quality assurance and quality control program, which must be overseen by a qualified medical physicist; (2) standards that require use of radiological equipment specifically designed for mammography; (3) requirements for training, licensure, certification and experience of personnel involved with mammography, including interpreting physicians, radiologic technologists, and medical physicists; (4) requirements that facilities maintain mammograms in the permanent medical records of a patient for specified time periods and prepare written reports of the results of any mammogram, as well as communicate those results to the patient in lay terms if the patient has no physician; and (5) standards relating to special techniques for mammography of patients with breast implants.

In § 900.12 of this interim rule, FDA has established standards for personnel, equipment, and practices which are substantially the same as those of the ACR; in fact, FDA has incorporated by reference the ACR's standards for quality assurance and quality control. FDA participated in the development of the ACR standards and believes that they are based on sound scientific principles and clinical judgment gained through extensive experience developing mammography quality assurance practices. The rationale for the ACR standards incorporated in this regulation is provided in a report from the National Council on Radiation Protection and Measurements, which formed the basis for the ACR standards (Ref. 7). FDA believes that the use of the

ACR standards in implementing the MQSA will substantially improve the overall level of mammography quality in the United States, while also allowing FDA to meet the statutory deadlines established by Congress, although FDA believes that improvements in the standards may be necessary over time. FDA solicits comments on what those improvements should be.

For mammography personnel, FDA has established training, certification, education and experience requirements which FDA believes are sufficiently stringent to ensure quality mammography, while allowing needed flexibility to certain organizations with highly mobile personnel, such as the military and Indian Health Service. FDA has also established alternative criteria to the requirements for licensing and certification of medical physicists, in accordance with section 354(f)(1)(E)(iii) of the PHS Act. This provision allows such alternatives in the first 5 years after the date of enactment of the MQSA in order to minimize initial problems with medical physicist shortages that could otherwise arise.

Standards for equipment, dose, quality assurance and quality control are consistent with ACR requirements, and the rationale for these requirements is provided in Ref. 7. Quality assurance and quality control (QA/QC) standards have been addressed partially with an incorporation by reference. FDA has incorporated by reference the most recent ACR QA/QC standards for equipment, rather than develop and codify separate such FDA standards, because, for now, the ACR standards are acceptable without alteration, and the incorporation by reference enables FDA to substantially reduce the volume of material published in the **Federal Register** and Code of Federal Regulations (CFR). FDA has codified its own standards for other aspects of QA/QC pertaining to phantom images, clinical images, clinical image interpretation, and medical physicist surveys.

Requirements established for reporting and recordkeeping are consistent with the requirements of the PHS Act. As discussed in the regulations for subpart A of part 900, FDA does not believe that sufficient information is presently available with regard to special requirements for mammography of patients with breast implants. FDA requests comments on the appropriate contents of such standards for consideration in development of the final rule for subpart B (and for subpart A).

D. Revocation of Facility Accreditation or Accrediting Body Approval

In accordance with section 354(e)(2) and (e)(5) of the PHS Act, FDA has established regulations in new § 900.13 pertaining to the effects on certification of: (1) Revocation of a facility's accreditation by an accrediting body, and (2) withdrawal of the approval of an accrediting body by the Secretary. In cases of revocation of a facility's accreditation, the facility's certificate will remain in effect until such time as determined by the agency. This will allow the agency to evaluate the basis for revocation and determine what further action may be required, such as an inspection, corrective action plan, or revocation of the facility's certificate. Withdrawal of approval of an accrediting body may have no bearing on the quality of mammography being performed at facilities accredited by that body. Therefore, FDA believes that such facilities should be allowed a reasonable amount of time (1 year) to become reaccredited and recertified, subject to FDA's determination that the facilities continue to perform quality mammography.

As specifically authorized by the legislation signed by the President on December 14, 1993 (H. Rept. 2202), this interim rule implementing section 354(b), (c), (d), (e), and (f) of the PHS Act is being issued without proceeding through the normal notice-and-comment rulemaking process in order to enable FDA to meet the statutory deadline of October 1, 1994, for certification of all certifiable mammography facilities. Comments on this interim rule can be submitted to FDA and will be considered in the development of the final rule. The value of these comments will be enhanced by the extent to which the comments reflect an understanding of the MQSA and support their statements with: (1) Scientific and technical data from the scientific literature and from their own experience, and/or (2) detailed rationale and justification. In addition to considering comments received on this interim rule, the FDA will consult the National Mammography Quality Assurance Advisory Committee (which has been chartered and whose members are in the process of being selected) in the development of final regulations, as required by section 354(n) of the PHS Act.

III. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. "The National Strategic Plan for the Early Detection and Control of Breast and Cervical Cancers," U.S. Department of Health and Human Services, 1993.

2. Conway, B. J., J. L. McCrohan, F. G. Rueter, and O. H. Suleiman, "Mammography in the Eighties," *Radiology*, 177:335–39, 1990.

3. "Screening Mammography—Low Cost Services Do Not Compromise Quality," U.S. GAO, GAO/HRD–90–32, January 1990.

4. "Report on the Mammography Quality Standards Act of 1992," U.S. Senate, Report 102–448, October 1, 1992.

5. American College of Radiology, "American College of Radiology Mammography Accreditation Program," July 1993.

6. American College of Radiology, "Mammography Quality Control: Radiologist's Manual, Radiologic Technologist's Manual, and Medical Physicist's Manual," February, 1992.

7. National Council on Radiation Protection and Measurements, "Mammography—User's Guide," NCRP Report No. 85, August, 1987.

IV. Paperwork Reduction Act of 1980

This interim rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35). The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Quality Standards and Certification Requirements for Mammography Facilities under Pub. L. 102–539—General Requirements.

Description: FDA is issuing an interim rule to implement the certification and quality standards provisions of the MQSA. This rule establishes requirements for certification of mammography facilities, including quality standards for mammography. This action is being taken to assure safe, accurate, and reliable mammography on a nationwide basis.

As required by section 3504(h) of the Paperwork Reduction Act of 1980, FDA has submitted a copy of this interim rule to OMB for its review of these information collection requirements. Other organizations and individuals desiring to submit comments regarding this burden estimate or any aspects of these information collection requirements, including suggestions for

reducing the burden, should direct them to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs, OMB, rm. 3208, New Executive Office Bldg., Washington, D.C. 20503, Attention: Desk Officer for FDA.

ESTIMATED ANNUAL BURDEN FOR REPORTING

CFR Section	No. of respondents	No. of responses per respondent	Total annual responses	Hours per response	Total hours
21 CFR 900.11(b)(2)	25	1	25	2	50
Total					50

ESTIMATED ANNUAL BURDEN FOR RECORDKEEPING

CFR Section	No. of recordkeepers	Annual hours per recordkeeping	Total annual burden hours
21 CFR 900.11(c)(1)	1,000	1	1,000
21 CFR 900.12(e)(1)	10,000	1	10,000
Total Annual Burden			11,050

V. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(3) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Economic Impact

Executive Order 12866 requires us to assess the costs and benefits of proposed rules. For those rules which have an annual effect on the economy of $100 million or more, or have certain adverse effects on the economy such as a reduction in productivity or competition, a benefit cost analysis must be prepared. We do not believe that these rules are economically significant under the Executive Order criteria. However, the voluntary Regulatory Flexibility Analysis (RFA) presented below covers both benefits and costs. We have complied with other requirements of the Executive Order (e.g., consistency with a statutory mandate, avoidance of interference with State, local, or tribal functions).

The Regulatory Flexibility Act requires us to prepare an RFA if a rule has a significant effect on a substantial number of small entities. For purposes of the act, FDA classifies nearly all mammography facilities as small entities. We do not have sufficient information to determine conclusively whether or not this test is met. Regardless, in the spirit of the act we have prepared the following RFA.

There are approximately 10,000 mammography facilities in the United States. These rules will impose on many of them incremental costs of meeting quality standards relating to personnel, equipment, quality assurance, and medical records.

For purposes of our analysis, we assume that approximately 8,200 facilities already have accreditation or have applied for accreditation and will not incur significant additional costs. Because our interim standards are largely based on and consonant with ACR standards, these facilities should face little additional cost. Moreover, most of these facilities have already been regulated under HCFA rules governing screening mammography under Medicare, and those rules impose similar requirements in a number of areas.

For the remaining 1,800 facilities, we have estimated costs for each substantive requirement (these estimates are available in the Threshold Analysis on file with the docket clerk). In total, we estimate that personnel standards will impose one-time costs of about $2 million, and recurring costs of about $3 million. One-time equipment costs are likely to be about $23 million. Recurring quality assurance costs are likely to total about $19 million. Recurring medical record costs are likely to be about $5 million. In total, the quality standards rule is likely to create one-time costs of about $26 million and recurring costs of about $27 million. Amortizing the one-time costs, the annual cost of the interim rule is about $33 million. Across 1,800 facilities, the average cost will be about $18,000 a year. (A copy of the detailed calculations underlying these numbers is on file with the Dockets Management Branch).

There are 23.5 million mammograms performed annually in the United States, at an average reimbursement of about $100. Total revenues are approximately $2.35 billion, or an average of $235,000 per facility. Thus, expected costs of meeting the quality standards are likely to be about 8 percent of revenues.

In addition, we expect that accreditation costs, borne overwhelmingly by facilities, will be approximately $9 million a year, less than $900 a facility. Most of this cost is due to the requirement for an annual physics survey.

Thus, for those facilities facing involuntary costs, we expect annual costs to average about $19,000 a facility to upgrade under the new regulatory system. Assuming average annual revenues of $235,000, this cost would average about 8 percent of revenues. However, it is possible that this group of facilities may perform fewer mammograms than average, and cost impacts may be proportionately higher. It is also likely that at least some facilities, those with obsolete equipment and low volume, will elect to stop performing mammography rather than upgrade, particularly in areas where there are competing facilities that meet these standards. We do not have any data on likely numbers facing unusually high costs, and welcome comments on the scope and magnitude of such problems.

There are several benefits associated with the uniform national oversight of mammography facilities provided for by this interim rule. First, as discussed in the preamble, research indicates that widespread use of high-quality mammography could significantly reduce breast cancer mortality, especially in older women; however, at some mammography facilities, the quality of service does not permit accurate, reliable detection of early carcinoma. Because the MQSA requires all facilities in the United States to be accredited and to meet quality standards

established by FDA, there should be improvement in the detection rate of early disease. This improvement may be in part due to the clinical image review aspect of the MQSA, which will provide quality monitoring at a level not previously achieved. In addition, by requiring periodic inspections of mammography facilities, the MQSA provides greater assurance of facility adherence to appropriate quality assurance practices.

Improved mammography quality could allow more patients to enjoy the benefits of early detection and thereby reduce the morbidity associated with treating later stage disease. There may also be a reduction in the number of malpractice claims filed for failure to diagnose early breast cancer.

Unfortunately, there are insufficient data available to quantify the potential benefits of the MQSA. Such quantification would require an estimate of the number of lives that could be saved, the number of patients that could be treated at earlier stages, and the number of malpractice claims that could be eliminated as a direct result of the MQSA. The MQSA has a provision for evaluating the functioning and effectiveness of breast cancer screening in the United States, including the role of the MQSA in this process, and such an evaluation will contribute scientific knowledge about these topics. This in turn could contribute quantifiable information about the benefits of the MQSA.

While we do not now have the data that would allow a precise estimate of benefits, their potential magnitude is substantial. For example, if 1 percent of the roughly 13.6 million women screened annually in fact have cancer, if as few as 1 percent of these get false negative results, if these rules could prevent one-half of those false negatives, and if one-fourth of those women's lives could be saved by early treatment, then about 170 lives annually would be saved by these rules. Using any conventional method of valuing lives saved, this would be many times higher than the costs of these regulations. In fact, saving even a handful of lives annually—and we expect far greater effects—would justify the costs of this regulatory approach.

The statute is prescriptive in establishing the new regulatory system. By design, it does not permit a substantially different regulatory approach than the one we have presented. However, it does allow for discretion on details of the individual standards. In devising these standards we sought to avoid unnecessary burden. For example, we allow training and experience, rather than a credential, as qualification for interpreting mammograms. It is possible that there are other changes in details that would either improve the effectiveness of these standards or reduce costs without compromising effectiveness. We welcome comments on any such options and will consider them carefully in revising these rules. We would particularly welcome comment on potential problems for small facilities or for rural areas and on workable solutions for these.

VII. Comments

Interested persons may, on or before January 20, 1994, submit to the Dockets Management Branch (address above) written comments regarding this interim rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 900

Electronic products, Incorporation by reference, Mammography, Medical devices, Radiation protection, Reporting and recordkeeping requirements, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 900 is amended as follows:

PART 900—MAMMOGRAPHY

1. The authority citation for 21 CFR part 900 continues to read as follows:

Authority: Secs. 519, 537, and 704(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i, 360nn, and 374(e)); sec. 354 of the Public Health Service Act (42 U.S.C. 263b).

2. New subpart B, consisting of §§ 900.10 through 900.14, is added to read as follows:

Subpart B—Quality Standards and Certification

Sec.

Subpart B—Quality Standards and Certification

§ 900.10 Applicability.

The provisions of this subpart are applicable to all facilities under the regulatory jurisdiction of the United States that provide screening and/or diagnostic mammography services, with the exception of facilities of the Department of Veterans Affairs.

§ 900.11 Requirements for certification.

(a) *General.* After October 1, 1994, a certificate issued by FDA will be required for lawful operation of all facilities. In order to obtain a certificate from FDA, facilities are required to meet the quality standards in § 900.12 and to be accredited by an accrediting body approved by FDA. On request from a facility, FDA will provide such facility with a current list of approved accrediting bodies. Any request for such list shall include the name and address of the facility and must be sent to the address provided in § 900.3(b).

(b) *Application*—(1) *Certificates.* When applying for accreditation to an approved accrediting body, a facility shall submit to such accrediting body the information required in 42 U.S.C. 263b(d)(1). If and when the facility becomes accredited, information required for certification of the facility shall be forwarded to FDA by the accrediting body, in accordance with § 900.4(g)(4).

(2) *Provisional certificates.* Facilities that have not obtained a certificate by October 1, 1994, but have applied for accreditation to an approved accrediting body by then are eligible to receive a provisional certificate. To receive a provisional certificate, a facility shall submit the information required in 42 U.S.C. 263b(c)(2) to an approved accrediting body. New facilities may also submit such information directly to FDA. If and when the accrediting body determines that such application is sufficiently complete for review purposes, this fact shall be communicated to FDA by the accrediting body in accordance with § 900.4(g)(5). To apply for a 90-day extension to a provisional certificate, a facility shall submit to the accrediting body a statement of what the facility is doing to obtain certification and evidence that a significant adverse impact on the regional availability of mammography would result if such facility did not obtain an extension. Such information shall be forwarded to FDA by the accrediting body in accordance with § 900.4(g)(5).

(c) *Issuance and renewal of certificates*—(1) *Certificates.* FDA will issue a certificate to a facility within 30 days of receipt of notification from an approved accrediting body of the accreditation of such facility. The initial certificate for a facility shall remain in effect until 30 days after the date of expiration of the facility's existing

accreditation unless certification and/or accreditation of the facility is revoked prior to such deadline. FDA will issue a renewed certificate to a previously certified facility within 30 days of receipt of notification from an approved accrediting body of renewal of the accreditation of such facility. A renewed certificate shall be effective for a period of 3 years from the date of issuance, unless certification and/or accreditation of the facility is revoked prior to such deadline.

(2) *Provisional certificates.* FDA will issue a provisional certificate to a facility within 10 days of receipt of notification from an approved accrediting body of satisfaction of the requirements of paragraph (b)(2) of this section. A provisional certificate shall be effective for 6 months from the date of issuance. FDA will issue a 90-day extension for a provisional certificate within 10 days of receipt from the accrediting body of the information required in paragraph (b)(2) of this section, provided that FDA determines that the statutory prerequisites for the extension as set forth in section 354(c)(2) of the Public Health Service Act have been met. No renewal of a provisional certificate beyond the 90-day extension can occur.

§ 900.12 Quality standards.

The following requirements establish the minimum quality standards that must be met by a facility to be eligible for certification to provide screening and/or diagnostic mammography services:

(a) *Personnel.* The following requirements apply to personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities. Lists of personnel certifying bodies approved by FDA and referenced in this section may be obtained by submitting to FDA at the address specified in § 900.3(b) a request containing the information needed and the name and address of the facility.

(1) *Interpreting physician.* Interpreting physicians shall meet the following requirements:

(i) Be licensed to practice medicine in the State or facility in which they are practicing; and

(ii) Have the following training:

(A) Be certified by one of the bodies approved by FDA to certify interpreting physicians; or

(B) Have had at least 2 months of documented full-time training in the interpretation of mammograms, including instruction in radiation physics, radiation effects, and radiation protection; and

(C) Have 40 hours of documented continuing medical education in mammography. Time spent in residency specifically devoted to mammography will be accepted, if documented in writing by the radiologist; and

(iii) Have the following initial experience:

(A) Have read and interpreted the mammograms from the examinations of at least 240 patients in the 6 months preceding application; or

(B) Read and interpret mammograms as specified in paragraph (a)(1)(iii)(A) of this section under the direct supervision of a fully qualified interpreting physician; and

(iv) Have the following continuing experience:

(A) Continue to read and interpret mammograms from the examination of an average of at least 40 patients per month over 24 months; and

(B) Continue to participate in education programs, either by teaching or completing an average of at least five continuing medical education credits in mammography per year.

(2) *Radiological technologist.* Radiological technologists shall meet the following requirements:

(i) Have a license to perform radiographic procedures in the State or facility where they are practicing; or

(ii) Have certification by one of the bodies approved by FDA to certify radiologic technologists; and

(iii) For those radiological technologists associated with facilities applying for accreditation before October 1, 1996:

(A) Have undergone training specific to mammography, either through a training curriculum or special mammography course, and accumulate at least an average of five continuing education units per year related to mammography; or

(B) Have 1 year of experience in the performance of mammography and by October 1, 1996, meet the training requirements of paragraph (a)(2)(iii)(A) of this section; and

(iv) For those radiological technologists associated with facilities applying for accreditation on and after October 1, 1996, meet the requirements of paragraph (a)(2)(i) or (a)(2)(ii) of this section and undergo specific training in mammography through documented curriculum and on-the-job training under the direct supervision of experienced mammographers; and

(v) Participate in formal continuing education programs and accumulate an average of at least five continuing education units in mammography per year.

(3) *Medical physicist.* Medical physicists shall meet the following requirements:

(i) Have a license or approval by a State to conduct evaluations of mammography equipment and procedures as required under the Public Health Service Act; or

(ii) Have certification in an accepted specialty area by one of the bodies approved by FDA to certify medical physicists; or

(iii) For those medical physicists associated with facilities applying for accreditation before October 27, 1997, meet the following criteria:

(A) Have a masters, or higher, degree in physics, radiological physics, applied physics, biophysics, health physics, medical physics, engineering, radiation science, or in public health with a bachelor's degree in the physical sciences; and

(B) Have 1 year of training in medical physics specific to diagnostic radiological physics; and

(C) Have 2 years of experience in conducting performance evaluation of mammography equipment; and

(iv) Participate in continuing education programs related to mammography, either by teaching or completing an average of at least five continuing education units per year.

(b) *Equipment*—(1) Radiographic equipment designed for conventional radiographic procedures that have been modified or equipped with special attachments for mammography shall not be used for mammography.

(2) Radiographic equipment used for mammography shall:

(i) Be certified pursuant to § 1010.2 of this chapter as meeting the applicable requirements of §§ 1020.30 and 1020.31 of this chapter in effect at the date of manufacture;

(ii) Be specifically designed for mammography;

(iii) Incorporate a breast compression device; and

(iv) Have the provision for operating with a removable grid, except for xeromammography systems.

(c) *Dose.* The average glandular dose delivered during a single cranio-caudal view of an accepted phantom simulating a 4.5 centimeter thick, compressed breast consisting of 50 percent glandular and 50 percent adipose tissue, shall not exceed 3.0 milliGray (0.3 rad) per exposure for screen-film mammography procedures and 4.0 milliGray (0.4 rad) per exposure for xeromammography procedures. The dose shall be determined at least annually under the technique factors and conditions that

are used to produce the phantom images submitted for accreditation.

(d) *Quality assurance*—(1) *Equipment.* Each facility shall establish and maintain a quality assurance program to assure the adequate performance of the radiographic equipment and other equipment and materials used in conjunction with such equipment sufficient to assure the reliability and clarity of its mammograms. The program shall also require periodic monitoring of the dose delivered by the facility's examination procedures to ensure that it does not exceed the limit specified in paragraph (c) of this section and is appropriate for the image receptor used. Such quality insurance program shall:

(i) For screen-film systems, be substantially the same as that described in the 1992 edition of "Mammography Quality Control: Radiologist's Manual, Radiologic Technologist's Manual, and Medical Physicist's Manual," prepared by the American College of Radiology, Committee on Quality Assurance in Mammography, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American College of Radiology, Mammography Accreditation Program, 1891 Preston White Dr., Reston, VA 22091–5431; and may be inspected at the Center for Devices and Radiological Health, Division of Mammography and Radiation Programs (HFZ–200), 5600 Fishers Lane, Rockville, MD 20857; or may be examined at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC; or

(ii) For systems with alternate image receptor modalities, be substantially the same as the quality assurance program recommended by the image receptor manufacturer, which, if followed, will allow a facility to maintain high image quality; and

(iii) For all image receptors, provide for the maintenance of log books documenting compliance with the applicable requirements in paragraph (d)(1) of this section and recording corrective actions taken.

(2) *Phantom images.* Each facility shall establish and maintain a program to assess the performance of the mammography system through the evaluation of radiographic images obtained with a phantom. The phantom must be of a type approved or accepted by the American College of Radiology or of an equivalent type accepted by FDA. The phantom images must score at least the minimum required by the accrediting body.

(3) *Clinical images.* Each facility shall establish and maintain a clinical image quality control program, including:

(i) Monitoring of mammograms repeated due to poor image quality; and

(ii) Maintenance of records, analysis of results, and a description of any remedial action taken on the basis of such monitoring.

(4) *Clinical image interpretation.* Each facility shall establish a system for reviewing outcome data from all mammography performed, including followup on the disposition of positive mammograms and correlation of surgical biopsy results with mammogram reports.

(5) *Surveys.* As a part of its overall quality assurance program, each facility shall have a medical physicist establish, monitor, and direct the procedures required by paragraphs (d)(1), (d)(2), and (d)(3) of this section and perform a survey of the facility to assure that it meets the quality control and equipment standards as specified in paragraph (b)(2) of this section. Such surveys shall be performed at least annually, and reports of such surveys shall be prepared and transmitted to the accrediting body in accordance with § 900.4(d)(1). Each such report shall be retained by the facility until such time as the next annual survey is satisfactorily completed.

(e) *Medical records.* (1) Each facility shall maintain mammograms and associated records in a permanent medical record of the patient as follows:

(i) For a period of not less than 5 years, or not less than 10 years, if no additional mammograms of the patient are performed at the facility, or longer if mandated by State or local law; or

(ii) Until requested by the patient to permanently transfer the records to a medical institution, or to a physician of the patient, or to the patient herself, and the records are so transferred.

(2) Each facility shall prepare a written report of the results of any mammography examination. Such report shall be completed as soon as reasonably possible and shall:

(i) Be signed by the interpreting physician; and

(ii) Be provided to the patient's physicians (if any); or

(A) If the patient's physician is not available or if the patient does not have a physician, the report shall be sent directly to the patient; and

(B) If such report is sent to the patient, it shall include a summary written in language easily understood by a lay person; and

(iii) Be maintained in the patient's record in accordance with paragraph (e)(1) of this section.

§ 900.13 Revocation of accreditation and accrediting body approval.

(a) *Accreditation.* If a facility's accreditation is revoked by an accrediting body, the facility's certificate shall remain in effect until such time as determined by the agency on a case-by-case basis after an investigation into the reasons for the revocation. If FDA determines that the revocation was justified by violations of applicable quality standards, FDA will revoke or suspend the facility's certificate and/or require the submission and implementation of a corrective action plan, whichever action will protect the public health in the least burdensome way.

(b) *Accrediting body approval.* If the approval of an accrediting body is revoked by FDA, the certificates of the facilities accredited by such body shall remain in effect for a period of 1 year after the date of such revocation subject to FDA's determination that the facility continues to perform quality mammography. By the end of a year following revocation of approval of a facility's accrediting body, the facility must obtain accreditation by another accrediting body.

§ 900.14 Hearings regarding certification decisions.

Opportunities to challenge final adverse actions taken by FDA regarding denials of certification or suspension or revocations of certification of facilities will be communicated through notices of opportunity for informal hearings in accordance with part 16 of this chapter.

Dated: December 10, 1993.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 93–30991 Filed 12–16–93; 10:51 am]

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Part VIII

Department of Health and Human Services

Social Security Administration

20 CFR Part 404
Revised Medical Criteria for Determination of Disability, Musculoskeletal System and Related Criteria; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

20 CFR Part 404

[Regulations No. 4]

RIN 0960–AB01

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

AGENCY: Social Security Administration, HHS.

ACTION: Proposed rules.

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

DATES: To be sure that your comments are considered, we must receive them no later than February 22, 1994.

ADDRESSES: Comments should be submitted in writing to the Commissioner of Social Security, Department of Health and Human Services, P.O. Box 1585, Baltimore, Maryland 21235, or delivered to the Office of Regulations, Social Security Administration, 3–B–1 Operations Building, 6401 Security Boulevard, Baltimore, Maryland 21235, between 8:00 a.m. and 4:30 p.m. on regular business days. You may direct comments by telefax to (410) 966–0869. Comments may be inspected during these same hours by making arrangements with the contact person shown below.

FOR FURTHER INFORMATION CONTACT: Irving Darrow, Esq., Legal Assistant, Office of Regulations, Social Security Administration, 6401 Security Boulevard, Baltimore, Maryland 21235, telephone (410) 966–0512.

SUPPLEMENTARY INFORMATION: 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 under age 18 claiming SSI benefits based on disability, "disability" means that an impairment(s) substantially reduces the child's ability to function independently, appropriately, and effectively in an age-appropriate manner. 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 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. Part B contains criteria for evaluating impairments of children under age 18 when the criteria in part A do not give appropriate consideration to the particular effects of the disease processes in childhood. In evaluating disability for 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.

When the musculoskeletal listings were last 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 paragraphs of the listings and provide that the current listings in part A and part B of the musculoskeletal system will no longer be effective on December 6, 1993. We are now proposing revisions to update the listings for the musculoskeletal system in 1.00 (part A) and 101.00 (part B) and to make the revised listings effective for 7 years from the date of publication of the final rules.

In developing these proposed revisions to the listings for the musculoskeletal system and related listings, we obtained the individual views of members of various professional organizations, including the American Academy of Orthopedic Surgeons, the American College of Physicians, the American Rheumatism Association, the Arthritis Foundation, the Lupus Research Institute, the American Academy of Physical Medicine and Rehabilitation, and the National Institutes of Health, and with the individual help of Federal and State representatives who have expertise in the evaluation of disability claims involving musculoskeletal impairments. Likewise, in developing the proposed revisions to the part B criteria, we obtained the individual views of experts in the fields of pediatric rheumatology and orthopedics, including a pediatric medical consultant from our Office of Disability.

These proposed rules revise the musculoskeletal listings in 1.00 and 101.00 to bring them up to date and to broaden their scope. Also, because rheumatoid arthritis is a connective tissue disorder that should be grouped with the other connective tissue disorders, we are proposing to remove the criteria for rheumatoid arthritis currently in listings 1.02 and 101.02 and to establish new listings 14.09 and 114.09 in the Immune System listings. Proposed new listings 14.09 and 114.09 would cover all the inflammatory arthritides, including rheumatoid arthritis. We are also proposing to remove listings in 4.00 and 9.00 that include musculoskeletal criteria that are no longer applicable because of medical and technical advances.

The proposed listings put less emphasis on disease labeling, or diagnosis, and emphasize the functional impact of impairments on a person's ability to work, or, in the case of a child under age 18, on the child's ability to perform age-appropriate activities, as defined in § 416.924ff. The proposed listings recognize that musculoskeletal impairments result from many causes. Some of the listings recognize that musculoskeletal impairments may have effects on other organs or body systems which cumulatively lead to severe functional deficits. In children, chronic illness may also impact upon many of the mental domains and behaviors, and significantly restrict age-appropriate activities.

The following is a detailed summary of the proposed changes in the musculoskeletal system listings (1.00ff and 101.00ff), immune system listings (14.00ff and 114.00ff) and related

changes in 4.00 and 9.00 of part A, and our reasons for proposing these changes.

Revisions to Appendix 1

We propose to revise the second paragraph of the introduction to Appendix 1 to show that the part A and part B musculoskeletal system listings will expire 7 years after publication of the final regulations in the **Federal Register**.

Revisions to Part A of Appendix 1

1.00 Musculoskeletal System

We propose to reorganize and revise 1.00, the preface to part A of the musculoskeletal listings, to bring it up to date, to reflect the proposed new listings, and to facilitate its use by our disability evaluators and members of the public.

1.00A Disorders of the Musculoskeletal System

We propose to add a new brief introductory section to describe the pathologic processes that may cause musculoskeletal impairments.

1.00B Loss of Function

We propose to renumber the section on loss of function from 1.00A to 1.00B and to expand the section to provide more information about the causes of, and ways to evaluate, loss of function resulting from musculoskeletal impairment. The opening paragraph 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 proposed revisions would also add to this paragraph the following impairments that are in the current listings: Bone or joint deformity or destruction due to any cause, miscellaneous disorders of the spine with or without radiculopathy or other neurologic deficits, amputation, and fractures or soft tissue injuries, including burns, requiring prolonged periods of immobility or convalescence. These proposed additions make the list of possible causes of functional loss due to musculoskeletal impairments correspond to the listed impairments. We also propose to expand the guidance about musculoskeletal "deformity" to clarify that the term refers to joint deformity due to any cause. A new second sentence would be added to explain that musculoskeletal impairments may also result from inflammatory peripheral joint or axial arthritis or sequelae, and to provide a cross-reference to proposed listing 14.09, which would be used to evaluate these disorders.

The proposed second paragraph is new. It is based in part on current 1.00A, but it also contains new material. It explains that, regardless of the underlying cause of a musculoskeletal impairment, the functional loss that must result from certain listed impairments is defined in terms of an "inability to ambulate effectively on a sustained basis" or an "inability to perform fine and gross movements effectively on a sustained basis" for any reason, including pain. The terms represent new criteria we are proposing for the measurement of loss of function in several of the proposed listings. Because our intent in the proposed listings is to emphasize the impact of the impairment(s) on a person's ability to perform gainful activity, these proposed criteria would clarify the degree of musculoskeletal functional limitations required to establish a listing-level impairment. We also propose to use the same criteria in part B, which, in the case of a child claiming SSI benefits based on disability, describes the child's ability to perform age-appropriate activities.

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

Proposed 1.00B1 and 1.00B2 define what we mean by "inability to ambulate effectively" and "inability to perform fine and gross movements effectively." Both sections describe "extreme" functional loss, consistent with our other listings. However, as in our other listings, the proposed criteria do not require that an individual be entirely unable to walk or to use his or her upper extremities because 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.

Proposed 1.00B1 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. Even profoundly impaired individuals can often stand for a period of time, although they may not be able to walk effectively.

In 1.00B3, we propose to clarify the statement about pain that is in the second sentence of current 1.00A. The current provision may give the erroneous impression that there must be objective medical findings that directly support the severity of a person's pain. The proposed language, which is consistent with our rules for the evaluation of symptoms, including pain, in §§ 404.1529 and 416.929 and §§ 404.1525(f) and 416.925(f), clarifies that there need only be objective medical evidence of the existence of an impairment which could reasonably be expected to cause pain or other symptoms. 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 those of the proposed musculoskeletal listings that include symptoms.

1.00C Diagnosis and Evaluation

Proposed 1.00C expands the guidance in the third sentence of current 1.00A. The first sentence of the proposed new paragraph corresponds to the current rule. We propose to expand it to say that both the evaluation and the diagnosis of musculoskeletal impairments should be supported by detailed clinical and laboratory findings. Although several of the proposed listings are geared toward evaluating function in order to determine impairment severity, diagnosis may be important for predicting duration, 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 propose to revise the reference to x-ray evidence to include other, modern imaging techniques. 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 propose to expand the criteria in 1.00C and throughout the preface and listings to include all medically acceptable imaging techniques.

We also move the seventh paragraph in current 1.00B to 1.00C and make some minor, nonsubstantive changes in the paragraph. The paragraph would be revised to state that electrodiagnostic and myelographic procedures may be useful for establishing a diagnosis but do not constitute alternative criteria to the requirements in proposed listing 1.04, the listing for disorders of the spine, which corresponds to current listing 1.05C. We are proposing this revision because neither electrodiagnostic testing nor

myelography provides information about the particular effects of an individual's impairment on his or her functioning; they only provide information about the existence of an impairment that could be the cause of such limitations. We propose to move this paragraph because it fits more logically with the discussion of evaluation techniques in 1.00C.

1.00D The Physical Examination

Proposed 1.00D draws extensively from the fourth and fifth paragraphs of current 1.00B. Those paragraphs are currently included under the heading, "Disorders of the spine," even though much of the information they contain is relevant to examinations for any musculoskeletal impairments. We, therefore, propose a new section headed, "The physical examination," to make clear that these criteria are not to be confined to disorders of the spine. We have moved parts of the fourth paragraph that are relevant only to examinations of the spine to proposed 1.00E, "Examination of the spine." In addition, we have made a number of nonsubstantive editorial changes for clarity and precision.

In the next-to-the last sentence of the proposed 1.00D, which corresponds to the third sentence of the fifth paragraph of the current rule, we propose to change the reference from "a record of ongoing treatment" to "a record of ongoing management and evaluation." We propose this change because not all individuals with disorders of the spine 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 bedrest, 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 propose to include the last sentence from the third paragraph of current 1.00B as the last sentence of proposed 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 suggests, but also for the assessment of the claimant's overall ability to function.

1.00E Examination of the Spine

As pointed out in the explanation for proposed 1.00D, we have retained the sentences from the fourth paragraph of current 1.00B that pertain only to examinations of the spine in the proposed section that describes examinations for disorders of the spine, now proposed 1.00E. We have 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.

The last sentence of the second paragraph of the proposed rule 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 11.00. The reference to "neurological abnormalities" in the current 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 have, therefore, clarified the statement and provided examples of residual neurological abnormalities that would be disabling under the neurological listings. We are also proposing to delete the second and third sentence of the second paragraph of current 1.00B because they would be redundant in the context of the proposed rules.

1.00F Duration of Impairment

We propose to add a new 1.00F to explain that musculoskeletal impairments usually improve with time or treatment. Therefore, we propose that documentation include a longitudinal clinical record covering at least 3 months of management and evaluation. We provide a similar requirement in a number of listings in other body systems (see, e.g., the listings in 4.00, for cardiovascular impairments, and 14.00, for immune system disorders, including connective tissue disorders). In proposed 1.00D, the phrase "management and evaluation" provides for the possibility that an individual will not receive treatment, but will only be followed by a medical source. We have also provided that a 3-month record is not invariably required. If it is clear from the evidence that the individual is disabled (for instance, if the individual has a permanent disabling impairment that will not improve) or continues to be disabled (in a continuing disability review), it will not be necessary to establish a 3-month record. Of course, other supplemental evidence, such as a consultative examination, may be obtained as necessary to establish a longitudinal record.

1.00G Effects of Treatment

Proposed 1.00G is a new section that 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 not experience improvement with the same treatment. However, 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.

1.00H Orthotic, Prosthetic, or Assistive Devices

We propose a new section 1.00H to discuss how orthotic, prosthetic, or assistive devices are to be considered in evaluating musculoskeletal impairments. The new section would explain that individuals with musculoskeletal impairments should be evaluated with and without any medically necessary orthotic, prosthetic, or assistive devices in place. This proposed rule is consistent with clinical practice; if there is an amputation, examination without the prosthesis provides information about the site of amputation, and the length and condition of the stump.

This section would also explain that when an individual has an impairment that affects the lower extremities and uses a hand-held assistive device, such as a cane or a walker, the evaluation must take into consideration how the individual is able to function both with and without the hand-held device. When an individual uses a hand-held device, he or she does not have both hands free, and this will obviously have some effect on the individual's ability to lift and carry, as well as to push and pull in some situations. We, therefore, need to know whether a person has some ability to walk without the hand-held device, and the extent of any such ability, in order to obtain an accurate picture of all of the person's functional capacities.

The proposed rule does not require evaluation of the individual's ability to walk without the use of other devices. When a person wears a lower limb prosthesis because of an amputation, it is obviously unnecessary to evaluate his or her ability to walk without the prosthesis. Also, an evaluation of the ability of a person who uses an orthosis to walk is not necessary for the same reason that we do not require measurements of vision without spectacles; that is, we want to know the individual's maximum functional ability. However, if an individual who wears a prosthesis or uses an orthosis also uses a hand-held device, we will evaluate his or her ability to ambulate without the hand-held device, but with the prosthesis or orthosis in place.

1.00I Disorders of the Spine

Proposed 1.00I would revise current 1.00B. We have reorganized and expanded the current rules.

The first sentence of the opening paragraph corresponds to the first sentence of current 1.00B. In the proposed revision, 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, spinal arachnoiditis, or lumbar spinal stenosis resulting in pseudoclaudication. We have also expanded the sentence to include other causes of limitations that should be evaluated under proposed 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 second sentence of the paragraph corresponds to the last sentence of the second paragraph in current 1.00B, and is a brief restatement of the principles in 1.00E. No substantive change is intended from the current rule.

Proposed 1.00I1 through 1.00I4 describe the various impairments we refer to in the opening paragraph: Herniated nucleus pulposus (proposed 1.00I1), spinal arachnoiditis (proposed 1.00I2), lumbar spinal stenosis resulting in pseudoclaudication (proposed 1.00I3), and other miscellaneous conditions (proposed 1.00I4). 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 dysraphism, diastematomyelia, and tethered cord syndrome, that are more appropriately evaluated under the neurological listings.

1.00J Abnormal Curvatures of the Spine

We are proposing a new section designated 1.00J to discuss evaluation of abnormal curvatures of the spine, including scoliosis, kyphosis, and kyphoscoliosis. We propose to focus 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 that abnormal curvatures may impair ambulation, restrict breathing, or result in an associated mental impairment. Evaluation should, therefore, be done by reference to the listing for inflammatory spondyloarthropathy, proposed listing 14.09, which describes impaired ambulation resulting from a deformed spine, or by reference to the respiratory listings or the mental disorder listings.

1.00K Continuing Medical Management

We propose to add 1.00K to explain what we mean by the term "under continuing surgical management," which is a term we use in proposed listings 1.07 and 1.08 and in current listing 1.12. The proposed provision explains that "surgical management" includes more than the surgery itself. It includes various procedures post-surgery, complications of surgery (such as infections) and other factors associated with surgery that may limit functioning and contribute to a finding of disability.

1.00L After Maximum Benefit From Therapy

Proposed 1.00L, which discusses evaluation after the achievement of maximum benefit from surgical or medical therapy in certain situations, corresponds to current 1.00C. We propose to revise and expand 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 (proposed 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 surgical management including recovery time following intervention and any complications from the intervention.

1.00M Surgical Procedures

Proposed 1.00M 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 pathology reports when surgery has been performed.

1.00N Major Joints

This proposed section corresponds to current 1.00D. Current 1.00D explains that the wrist and hand are considered together as one major joint, but it does not have a similar provision for the ankle and foot; instead, it refers only to the ankle and does not mention the foot. The proposed section would correct this inadvertent omission. We have also simplified the provisions.

1.00O Measurements of Joint Motion

Proposed 1.00O corresponds to current 1.00E. We propose to revise the current section to bring it up to date and to broaden its scope. We propose to delete the reference 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 proposed rule refers only to the "Guides to the Evaluation of Permanent Impairment", which is used throughout the country by physicians and surgeons. The proposed 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.

1.01 Category of Impairments, Musculoskeletal

In addition to moving current listing 1.02 to 14.00, we propose to delete two of the current listings. We propose to delete the criteria in current listing 1.05B, which is met with generalized osteoporosis with pain, limitation of motion, paravertebral muscle spasm, and vertebral fracture. Our experience has shown the listing to be unclear. Moreover, osteoporosis of the severity indicated in the current listing is most often encountered in women over the age of 65; inasmuch as benefits based on disability under both titles II and XVI are not paid after the age of 65, the listing does not apply to the majority of people who have an impairment of listing-level severity.

Nevertheless, the proposed listings would include individuals under age 65 who do have osteoporosis of listing-level severity. We have included "vertebral fractures" in the list of examples of conditions that are included under proposed listing 1.04, for disorders of the spine resulting in compromise of a nerve root, which would be the most common reason that vertebral fractures would be of listing-level severity. Proposed listing 1.02A would cover the situations in which there is hip involvement resulting in

impaired ability to walk, a situation that is not included in the current listing.

We also propose to delete current listing 1.08, "Osteomyelitis or septic arthritis." With advances in treatment and surgical techniques, both osteomyelitis and septic arthritis are 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 reduce residual functional capacity sufficiently to result in a finding of disability at the last step of the sequential evaluation process, including a determination whether the impairment has lasted or can be expected to last for at least 12 months. Residuals of these impairments may also result in disability; any residuals (such as a fused hip joint in a bad position or a knee joint in a bad position) may be evaluated under the appropriate listings, or later in the sequential evaluation process when we make a residual functional capacity assessment. Septic arthritis that is associated with human immunodeficiency virus (HIV) infection is listed separately in our current rules, under listing 14.08M.

1.02 Deficit of Musculoskeletal Function of a Major Joint(s)

This proposed listing would consolidate into one listing paragraph A of current listing 1.03, "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 current listings describe gross anatomical deformities. We also propose to expand the scope of the listing to include deficits of musculoskeletal function from any cause of deformity, not just arthritis. Current listing 1.03B, for reconstructive surgery or surgical arthrodesis of a major weight-bearing joint, would be retained as a separate listing 1.03, described below.

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

We propose to broaden the range of conditions that would be disabling under proposed listing 1.02 for reasons similar to the proposed broadening of current listing 1.02, explained below. Although diagnosis may be necessary to resolve duration issues, the common denominator in all of the medical conditions with similar mechanical problems is whether they cause functional restrictions that are disabling.

Because proposed listing 1.02 is based on a criterion for 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). Proposed listing 1.02A, requires gross anatomical deformity of one major weight-bearing joint and would, therefore, replace the requirement for deformity of two feet now in listing 1.09B with a less anatomically based, more functionally based criterion; moreover, the proposed criterion does not require involvement of both lower extremities or even specifically of the feet. Proposed listing 1.02B would replace the requirement for involvement of both hands with a requirement for involvement of any major joint in each upper extremity and, again, a functional 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 of listing-level severity, and to determine if they are disabled, we may have to assess their residual functional capacity.

Also, for reasons explained above under proposed 1.00N, we propose to add a reference to the "ankle-foot" in proposed listing 1.02A as another major weight-bearing joint in which arthritis can be an impairment of listing-level severity. As throughout these listings, we propose to update the criterion for x-ray evidence by replacing it with a reference to "medically acceptable imaging techniques."

We also propose to delete 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 techniques and function of the joint. Furthermore, since proposed 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

Proposed listing 1.03 corresponds to current listing 1.02B. The current listing describes individuals who have undergone reconstructive surgery or surgical arthrodesis of a major 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 proposed listing would change the criterion for failure to return to "full weight-bearing status" to the criterion for inability to ambulate effectively used in proposed listing 1.02 and other proposed listings. We are proposing this change because, 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. The proposed revision would, therefore, ensure that this proposed listing is set at the same level of functional severity as the other proposed listings.

We believe that it is more logical to list separately the criterion in current listing 1.03B, instead of in proposed listing 1.02, which is normally for arthritis, because inability to ambulate effectively could result for reasons other than arthritis. The listing is more akin to current listing 1.11 (proposed listing 1.06), which is for nonunion of a fracture.

1.04 Disorders of the Spine

This proposed 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, and facet arthritis; these 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 proposed 1.00I. We do not propose to describe 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 proposed 1.00I, we propose three separate sets of criteria under listing 1.04, for nerve root compression (proposed listing 1.04A), spinal arachnoiditis (proposed listing 1.04B), and lumbar spinal stenosis resulting in pseudoclaudication (proposed listing 1.04C). We propose to list spinal arachnoiditis and lumbar spinal stenosis with pseudoclaudication separately because they present different signs and symptoms than does nerve root compression (which has many causes, including spinal stenosis) and neither condition is adequately covered by the current rule.

Of the criteria proposed for listing 1.04, proposed listing 1.04A corresponds most closely to current listing 1.05C. We propose to replace the examples in the current rule with the examples in proposed listing 1.04 and the discussions in proposed 1.00I. We also propose to add a criterion for positive straight-leg raising in the sitting and supine positions when there is involvement of the lower back. We also propose to delete 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 propose to remove the requirement in current listing 1.05C that limitation of motion of the spine be "significant." The requirement is imprecise and, more importantly, we would consider any limitation of motion to be significant if it were accompanied by the other requirements of the proposed listing. We also would no longer require anatomic or radicular distribution of both sensory and reflex abnormalities, but would 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, we do propose to require an "anatomic distribution" of pain to make clear that the nerve root compression would have to be reasonably expected to cause the pain. This proposed requirement is consistent with our evaluation of pain and other symptoms pursuant to §§ 404.1529 and 416.929 of our rules. We also propose to clarify what we mean by "motor deficit"—that is, atrophy or muscle weakness. We explain in proposed 1.00E, discussed earlier, what we require to show atrophy.

Finally, proposed 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 have moved the requirement to proposed 1.00F, where it is a general requirement that is to be applied to all of the listings. Therefore, there is no change in this requirement from the current rules in listing 1.05C.

Proposed 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, proposed listing 1.04B describes severe burning or painful dysesthesia resulting in the need for frequent changes in position or posture, and proposed listing 1.04C describes chronic nonradicular pain and weakness resulting in an inability to ambulate effectively.

1.05 Amputation

We propose to combine current listings 1.09 and 1.10, which both deal with amputations, into a single listing 1.05 for amputations. As stated earlier, the "anatomical deformity" criterion of current listing 1.09 would be evaluated under proposed listing 1.02.

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

We propose to replace the listings that currently include a criterion for amputation of the foot (current listings 1.09B and 1.09C) with listings based on inability to ambulate effectively, and to delete 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 for developing 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 proposed revisions and deletions 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, proposed listing 1.05B would replace 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 prothesis effectively) with a requirement for inability to ambulate effectively due to stump complications regardless of the cause of the amputation, the level of the amputation, or whether there is amputation of one or both limbs. Similarly, proposed listing 1.05C would replace 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 assistance device. (We have also added an exception to the definition of "inability to ambulate effectively" in 1.00B1 to take this listing into account, inasmuch as individuals with amputation of a hand will not generally use bilateral upper limb assistance.) Because current listing 1.10B (amputation at or above the tarsal region due to peripheral vascular disease or diabetes mellitus) would be deleted, we are also proposing to delete the redundant listings in other body systems, listing 4.12C ("Amputation at or above the tarsal region due to peripheral arterial disease") and listing 9.08C ("Amputation at, or above, the tarsal region due to diabetic necrosis or peripheral arterial disease").

Proposed listing 1.05D, for hemipelvectomy or hip disarticulation with amputation of the other lower extremity at or above the tarsal region, corresponds to current listing 1.10A but adds a requirement for amputation of the other lower extremity at or above the tarsal region. With modern advances in treatment, a hemipelvectomy or hip disarticulation is no longer in itself sufficient to establish the existence of an impairment of listing-level severity; however, it is still a sufficiently severe impairment that amputation of the foot on the remaining lower extremity would establish disability.

1.06 Fracture of a Lower Extremity

Proposed listing 1.06 corresponds to current listing 1.11. We propose to revise the criterion for inability to return

to full weight-bearing status within 12 months of onset to a criterion for inability to ambulate effectively for the same (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 propose to restructure 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.

1.07 Fracture of an Upper Extremity

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

1.08 Soft Tissue Injury

Proposed listing 1.08 corresponds to current listing 1.13. We have revised the heading to make clear that the listing is appropriate for the evaluation of burns. We also propose to expand the scope of the rule to include soft tissue injuries to the trunk, face, and head. The criteria for "surgical management" are the same as in proposed 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."

14.00 Immune System

For reasons explained above, we propose to move the criteria in 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 are, therefore, proposing to establish new sections in the preface to 14.00 and a new listing 14.09 which corresponds to current listing 1.02. We are also proposing to revise and broaden our current criteria, as explained below.

14.00B6 Inflammatory Arthritis

Proposed 14.00B6 is a new section we propose to add 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.

The proposed section explains that, even though the term "inflammatory arthritis" connotes a vast array of disorders which differ in cause, course, and outcome, all the chronic forms have one thing in common: They can result in limitations in the ability to do work-related activities. The section provides examples of some of the disorders that affect the spine (inflammatory spondyloarthropathies). It also provides examples of disorders that affect the peripheral joints. Among the first group of disorders are ankylosing spondylitis, Reiter's syndrome, and Behcet's disease. The second group includes rheumatoid arthritis, Sjögren's syndrome, and psoriatic arthritis. We also provide a description of some of the factors that can cause functional deficit. In addition, we have provided a reminder that when the conditions are quiescent but have caused musculoskeletal deformity, it is still appropriate to use proposed listing 1.02, which describes gross anatomical deformity due to any cause, or proposed listing 1.03, which describes reconstructive surgery or surgical arthrodesis of a major weight-bearing joint.

In the subparagraphs of proposed 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 proposed 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 proposed 1.00. In addition, in proposed 14.00B6c, we do not provide a functional criterion for ankylosing spondylitis and other ankylosing spondyloarthropathies (proposed 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, the individual will have functional limitations that result in an impairment of listing-level severity.

In proposed 14.00B6d, we provide guidance about establishing the existence of an impairment of listing-level severity based upon extra-articular findings. We also provide examples of kinds of extra-articular findings that may be seen with the inflammatory arthritides in the various different body systems. Although many of the extra-articular findings are the same as those that may be seen in other extra-articular 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.

In addition to proposing new 14.00B6, we are also proposing to make minor, nonsubstantive revisions to two of the paragraphs of current 14.00B. In the fourth paragraph of current 14.00B, we propose to add a reference to the inflammatory arthritides to the list of disorders summarized in the section. In the first sentence of the sixth paragraph of the section, we have added joint pain and stiffness to the list of significant constitutional symptoms and signs to recognize the characteristic symptoms and signs of inflammatory arthritides.

14.09 Inflammatory Arthritis

For reasons explained above, we propose to redesignate current listing 1.02 as listing 14.09. We also propose to change its heading from "Active rheumatoid arthritis and other inflammatory arthritis" to "Inflammatory arthritis," to emphasize that we include a host of syndromes characterized by chronic joint inflammation, not just rheumatoid arthritis. The proposed change also emphasizes the functional consequences of joint inflammation as a determinant of disabling impairment rather than focusing on specific etiologic diagnoses. The proposed change would recognize 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, at bottom 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 proposed revision, therefore, provides several bases for determining whether an impairment is of listing-level severity. It advances the concept of graded severity of the 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 of the illness not involving the joints (extra-articular features) which together impair an individual's functioning to the degree described in these proposed listings. Thus, proposed 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, whereas proposed listings 14.09C, 14.09D, and 14.09E would be met with less severe joint findings than in proposed listings 14.09A and 14.09B, but with extra-articular features that

establish the existence of an impairment of listing-level severity.

Proposed listing 14.09A would replace 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. With one important exception described in the next paragraph, the proposed listing is essentially unchanged from the current rule. We are proposing to clarify and simplify the current provisions and to replace the requirement for involvement of "multiple" major joints with the more precise requirement for "two or more" major joints. Consistent with other proposed listings, we propose to replace the 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 also propose to remove the requirement for existence of the listed findings despite prescribed therapy for at least 3 months and clinical activity expected to last at least 12 months. This is because we have already provided a general requirement for these findings, applicable to all of the connective tissue disorder listings, in the third paragraph of current 14.00B. Thus, we have not eliminated the criterion but only moved it from the listing to the preface.

The exception noted above is that we propose to delete the requirements in current listing 1.02B for corroboration of the existence of the impairment by specific laboratory tests, except for medically acceptable imaging techniques. We propose this change because inflammatory arthritis with the findings described in proposed 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 restriction.

Ankylosing spondylitis, currently evaluated under listing 1.05A, would be evaluated under proposed listing 14.09B, which would list "ankylosing spondylitis and other spondyloarthropathy." Because the emphasis in these proposed listings is on function, the proposed listing would not require the extensive x-ray evidence of calcification of spinal ligaments and abnormal apophyseal articulations, and bilateral ankylosis of the sacroiliac joints now required in current listing 1.05A, but would provide for a degree of ankylosis of the cervical and dorsolumbar spines that correlates with an inability to ambulate effectively. We also propose to broaden the current criterion for a finding of bilateral sacroiliac ankylosis to include those disorders that are characterized by either unilateral or bilateral sacroilitis.

Proposed 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 proposed 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.

Proposed 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 findings than in listing 14.09C. It provides the same kind of criteria as in current 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 body systems, at least one of which must be involved to at least a moderate level of severity. To reflect the symptoms of these particular disorders, we would also include joint pain and morning stiffness of at least 2 hours' duration in addition to the list of symptoms and signs we include for the other connective tissue disorders.

Similarly, proposed listing 14.09E is a listing for inflammatory spondyloarthropathies that do not meet the deformity requirements of proposed listing 14.09B or the extra-articular requirements of proposed listing 14.09C. The severity requirements are the same as those for proposed listing 14.09D.

Revisions to Part B of Appendix 1

101.00 Musculoskeletal System

We propose to reorganize, revise, and expand 101.00, the preface to part B of the musculoskeletal listings, to be consistent with the proposed revisions in part A. We propose additional criteria in proposed 101.00 to give appropriate consideration to the particular effects of the disease processes in children. For example, in 101.00B1 and 101.00B2, we propose 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, proposed 101.00B1 would define 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 would be defined by reference to the descriptions of motor dysfunction in the current listing for multiple body dysfunction, listing 110.07A.

In other instances, we would alter in part B the criteria proposed in 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 propose to move current listing 101.02, for juvenile rheumatoid arthritis, to the immune system listings in 114.00. For this reason, we propose to delete current 101.00A, which addresses the documentation of juvenile rheumatoid arthritis. We do not propose to move it into the preface 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 propose to expand the listings to address all forms of inflammatory arthritis in children. As in the proposed adult rules, however, proposed 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 propose to delete the discussion currently in 101.00C. This section of the current rules explains that degenerative arthritis may be the end stage of many skeletal diseases and conditions. The discussion, though correct, has no special relevance to the proposed rules, which are functionally based.

101.01 Category of Impairments, Musculoskeletal

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

We propose to delete listing 101.05B, "Scoliosis," and listing 101.05C, "Kyphosis or lordosis," and to add to the preface a new section 101.00J, "Abnormal curvatures of the spine," which corresponds to proposed 1.00J in

the adult rules. We propose to delete the criteria for a spinal curve measuring 60 degrees or greater in current listing 101.05B1 and for kyphosis or lordosis measuring 90 degrees or greater in current listing 101.05C because these measurements represent arbitrary findings which do not focus on the functional impact of the abnormal curvature. We are proposing instead a provision which parallels the provision being proposed for the adult listings, and focuses evaluation on the functional impact of abnormal curvatures; i.e., impaired ambulation, ventilatory restriction, or emotional withdrawal or isolation. As in the adult rules, we propose a reference to listing 114.09B when the spinal deformity is so severe that it results in ineffective ambulation; the reference is to the respiratory listings in 103.00 when there is restricted breathing because of the deformity, and to the mental disorder listings in 112.00 when there are emotional effects.

We propose to delete current listing 101.05B2, which provides for a finding of "meets" when a child has undergone 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 so that it is no longer possible to assume that the duration requirement will be met. 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 normal activities of daily living can now be expected in less than one year following spinal fusion.

The proposed deletion of current listing 101.05B would also correct a printing error. The current listing provides 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 "VC," or vital capacity.

Finally, consistent with the proposed revisions to the listings in part A, we also propose to delete listing 101.08, "Chronic osteomyelitis." We provide our reasons for the proposed deletion in the explanation under part A for the proposed deletion of listing 1.08.

Proposed listings 101.02 through 101.08 are in most instances the same as the corresponding proposed adult rules explained above. Proposed listings 101.03 and 101.05 through 101.08 are new, and are the same as the corresponding proposed adult listings, 1.05 through 1.08. We are proposing them to maintain structural and content consistency with the adult listings. The following is an explanation of proposed listings 101.02 and 101.04, which would revise current listings 101.03 and 101.05.

101.02 Deficit of Musculoskeletal Function of a Major Joint(s) (Due to Any Cause)

This proposed listing corresponds to current listing 101.03, "Deficit of musculoskeletal function." The proposed 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 weight-bearing joint or one major joint in each upper extremity.

The functional limitations in the proposed 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 * * *") would be subsumed under the definition of "inability to ambulate effectively." Current listing 101.03C ("Inability to perform age-related personal self-care activities * * *") would be subsumed under the definition of "inability to perform fine and gross movements effectively."

101.04 Disorders of the Spine

This proposed listing corresponds to current listing 101.05. Proposed 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 would be consistent with the proposed 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, therefore, 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 are proposing to delete current listing 101.05A, for fracture of a vertebra with spinal cord involvement, because it describes a spinal cord injury and is, therefore, 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 preface to the immune system listings in part A and proposed listing 14.09, we propose to change the heading of listing 101.02 from "Juvenile rheumatoid arthritis" to "Inflammatory arthritis" to provide more comprehensive consideration of the features and functional impact of any of the inflammatory arthritides and to move all of the criteria for juvenile rheumatoid arthritis and the inflammatory arthritides into 114.00. In proposed 114.00E, we provide essentially the same provision for children that we proposed 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. Proposed 114.00E1 and 114.00E6, however, have no counterparts in proposed part A. Proposed 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 have limited antigenic exposure and immune reactivity.

For reasons we explain below, we are proposing to delete current listing 101.02B, which provides for a finding of "meets" when a child with rheumatoid arthritis is dependent on steroids. In proposed 114.00E6, we explain why steroid dependence in and of itself is insufficient to establish an impairment of listing-level severity.

We propose to revise 114.00B, which currently refers to the descriptions of the connective tissue disorders in 14.00B, to add a cross-reference to proposed 114.00E. We are also proposing technical revisions to 114.00B so that it will parallel 14.00B. The changes we are proposing conform the two sections, but do not substantively change the rules; rather, they would remove any question that might arise from our using slightly

different language in two sections that are intended to say the same thing.

We propose to add a new second sentence in 114.00C2, which describes growth impairments resulting from connective tissue disorders. The new provision would explain that many children with inflammatory arthritides have growth impairments because of the diseases' effects on the immature skeleton, open epiphyses, and young cartilage and bone.

The proposed listing criteria in 114.09 are the same as the corresponding adult listing in part A and would replace the criteria in current listing 101.02A.

We are proposing to delete current listing 101.02B, which provides for a finding of "meets" when a child with rheumatoid arthritis is dependent on steroids. 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

As previously explained, because we are proposing to delete current listing 1.10B in part A, "Amputation at or above the tarsal region due to peripheral vascular disease or diabetes mellitus," we are also proposing changes to the cardiovascular system and endocrine system listings to conform with the proposed deletion. Thus, we are also proposing to delete listing 4.12C, for peripheral arterial disease resulting in amputation at or above the tarsal region, and listing 9.08C, for diabetes mellitus with amputation at or above the tarsal region due to diabetic necrosis or peripheral arterial disease. Current listing 9.08D will become listing 9.08C under this proposal. We propose these changes because 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. Significant refinements in surgical techniques for developing soft tissue flaps to cover the stump, as well as engineering advancements, which have produced prosthetic devices which minimize and distribute stress, permit some individuals with amputation above the tarsal level to work. Those individuals who are unable to ambulate effectively due to stump complications may still have their impairments evaluated under proposed listing 1.05B.

In addition, we are proposing 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 7.00.

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, therefore, propose to add 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 would become listing 14.02A8. This would require renumbering 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.

Regulatory Procedures

Executive Order 12291

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

Paperwork Reduction Act

These proposed regulations contain reporting requirements which are subject to approval by the Office of Management and Budget (OMB). The revised listing of impairments describes the kinds of disorders the Social Security Administration (SSA) considers severe enough to meet the definition of "disabled" for benefit purposes, and lists the types of evaluations and documentation needed to support such disorders.

However, SSA already has OMB clearance to collect this information using forms such as the SSA–831 (OMB No. 0960–04–0437), SSA–832 (OMB No. 0960–04–0443) and the SSA–833 (OMB No. 0960–0442).

Regulatory Flexibility Act

We certify that these proposed regulations will not have a significant economic impact on a substantial number of small entities because they affect only disability claimants and beneficiaries under title II and title XVI of the Social Security Act. Therefore, a regulatory flexibility analysis as provided in Public Law 96–354, the Regulatory Flexibility Act, is not required.

(Catalog of Federal Domestic Assistance Program No. 93.802, Social Security Disability Insurance.)

List of Subjects in 20 CFR Part 404

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

Dated: August 20, 1993.

Lawrence H. Thompson,

Principal Deputy Commissioner of Social Security.

Approved: October 4, 1993.

Donna E. Shalala,

Secretary of Health and Human Services.

Part 404 of Chapter III of Title 20 of the Code of Federal Regulations is proposed to be amended as follows:

PART 404—[AMENDED]

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

Authority: Secs. 202, 205(a), (b), and (d) through (h), 216(i), 221(a) and (i), 222(c), 223, 225, and 1102 of the Social Security Act; 42 U.S.C. 402, 405(a), (b), and (d) through (h), 416(i), 421(a) and (i), 422(c), 423, 425, and 1302.

2. The second introductory paragraph in appendix 1 to subpart P—Listing of Impairments is revised to read as follows:

Appendix 1 to Subpart P—Listing of Impairments

* * * * *

The musculoskeletal system listings in 1.00 and 101.00 will no longer be effective on (7 YEARS AFTER THE DATE OF PUBLICATION OF FINAL REGULATIONS IN THE **Federal Register**) unless extended or revised and promulgated again.

* * * * *

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* under this section may be due to bone or joint deformity or destruction from any cause; miscellaneous disorders of the spine with or without radiculopathy or other neurologic deficits; amputation; or fractures or soft tissue injuries, including burns, requiring prolonged periods of immobility or convalescence. Inflammatory arthritides, which may result in loss of function because of inflammatory peripheral joint or axial arthritis or sequelae, or because of extra-articular manifestations, are to be evaluated under 14.09.

Regardless of the underlying cause(s), functional loss for purposes of these listings is defined as the inability to ambulate effectively on a sustained basis or the inability to perform fine and gross movements effectively on a sustained basis for any reason, including pain. 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.

1. *Inability to ambulate effectively* means an extreme limitation of the ability to walk. Ineffective ambulation is defined generally as having insufficient lower extremity functioning (see 1.00H) to permit independent ambulation without the use of a hand-held assistive device 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.)

To ambulate effectively, individuals must be capable of sustaining a reasonable walking pace over a sufficient distance to afford them the ability 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 a block 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 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.

2. *Inability to perform fine and gross movements effectively* means an extreme loss of function of both upper extremities. To use their upper extremities effectively, individuals must be capable of sustaining reasonable use of both upper extremities to perform such functions as reaching, pushing, pulling, grasping, and fingering to afford them the ability 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, or the inability to place files in a file cabinet at or above waist level. The need for intermittent assistance for the purposes of buttoning or tying does not, in and of itself, constitute ineffective functioning.

3. *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 work activities, medical signs or laboratory findings must show the existence of a medical impairment(s) that could reasonably be expected to produce the pain or other symptoms. The musculoskeletal listings that include pain or other symptom 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 this chapter.

C. *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 (i.e., weakness, atrophy), sensory or reflex changes, circulatory deficits, and laboratory findings, including findings on medically acceptable imaging techniques. Medically acceptable imaging techniques include, but are not limited to, x-ray imaging, computerized axial tomography (CAT scan) or magnetic resonance imaging (MRI), with or without contrast material, and radionuclear bone scans.

Electrodiagnostic procedures and myelographic 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 rheumatologic, 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* 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), motor and sensory abnormalities, 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 or lower arms, at a stated point above and below the knee or elbow given in inches or centimeters. A specific description of atrophy of hand muscles is acceptable without measurements of atrophy but should include measurements of grip and pinch strength.

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. Severe neurological

deficits (paraparesis, paraplegia) are to be evaluated under the criteria in 11.00.

F. *Duration of impairment.* Musculoskeletal impairments frequently improve with time or respond to treatment. Therefore, a longitudinal clinical record covering a period of at least 3 months of management and evaluation, and the expectation that the impairment will last for 12 months, are usually necessary for the assessment of severity and expected duration of impairment, unless the claim can be decided favorably on the basis of the current evidence.

G. *Effects of treatment.* 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 impair the individual.

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, which 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.

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.

H. *Orthotic, prosthetic, or assistive devices.* Musculoskeletal impairments should be examined with and without any medically necessary orthotic, prosthetic, or assistive devices in place. When an individual with an impairment involving a lower extremity or extremities uses a hand-held assistive device, the individual's ability to ambulate must be evaluated without the use of the device to determine whether, or the extent to which, the individual is able to ambulate without assistance. In this case, the requirement to use a hand-held assistive device may 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. If there has been an amputation, the condition of the stump should be evaluated. The medical basis for the use of any assistive device (e.g., instability, weakness) should be documented.

I. *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 tissues may result from a herniated nucleus pulposus, spinal stenosis, arachnoiditis, or other miscellaneous conditions. Neurological impairment resulting from these disorders may additionally be evaluated by referral to the neurological listings in 11.00.

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

2. *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.

The cause of spinal arachnoiditis often remains obscure, but it may be related to 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 medically acceptable imaging techniques. 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 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 pattern is generally nonanatomical, i.e., it is distinctly different from the radicular type of pain seen with a herniated intervertebral disc, and the pain 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 by stopping walking.

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, diastematomyelia, and tethered cord syndrome may also cause such abnormalities. In these cases, there may be obvious gait difficulty and deformity of the lower extremities on a neurogenic basis. Therefore, these impairments should be evaluated on the basis of the neurological effects under the criteria in 11.00.

J. *Abnormal curvatures of the spine.* In addition to the musculoskeletal effects of abnormal curvatures of the spine (e.g., scoliosis, kyphosis, kyphoscoliosis), which can result in impaired ambulation, these conditions may also adversely affect an individual's ability to breathe or may result in marked disfigurement with emotional withdrawal or isolation. When there is impaired ambulation, evaluation of equivalence may be made by reference to 14.09B. When there is respiratory involvement or an associated mental disorder, evaluation may be made under 3.00 or 12.00, as appropriate.

K. *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 surgical complications, infections, or other medical complications, related illnesses, or related treatments that delay the individual's attainment of maximum benefit from therapy.

L. *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 medically acceptable imaging techniques for any 6-month period after the last definitive surgical procedure, 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 a period of 6 months after the last definitive surgical procedure, i.e., maximum therapeutic benefit has been reached, then the symptoms, signs, and laboratory findings associated with such surgeries, complications, and recuperative periods are no longer the sole factors to be considered because maximal medical restoration will have been completed. Evaluation at this point must be made on the basis of the demonstrable residual impairment, if any, as demonstrated by the symptoms, signs, and laboratory findings, and other relevant evidence.

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

N. *Major joints* are the hip, knee, shoulder, elbow, wrist-hand, or ankle-foot. The wrist and hand are considered together as one major joint, as are the ankle and foot.

O. *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.

1.01 Category of Impairments, Musculoskeletal

1.02 *Deficit of musculoskeletal function of a major 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 medically acceptable imaging techniques of joint space narrowing, bony destruction, or ankylosis of the affected joint(s). With:

A. Involvement of one major weight-bearing joint (i.e., hip, knee, or ankle-foot), resulting in inability to ambulate effectively, as defined in 1.00B1;

or

B. Involvement of one major 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 1.00B2.

1.03 *Reconstructive surgery or surgical arthrodesis* of a major weight-bearing joint, with inability to ambulate effectively, as defined in 1.00B1, 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 anatomic distribution of pain, limitation of motion of the spine, motor deficit (atrophy 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 medically acceptable imaging techniques, manifested by severe burning or painful dysesthesia, resulting in the need for frequent changes in position or posture;

or

C. Lumbar spinal stenosis resulting in pseudoclaudication, established by findings on medically acceptable imaging techniques, manifested by chronic nonradicular pain and weakness, and resulting in inability to ambulate effectively, as defined in 1.00B1.

1.05 *Amputation.*

A. Both hands;

or

B. One or both lower extremities at or above the tarsal region, with inability to ambulate effectively, as defined in 1.00B1, due to stump complications which have lasted or are expected to last for at least 12 months from onset;

or

C. One hand and one lower extremity at or above the tarsal region, with inability to ambulate effectively, as defined in 1.00B1, without an obligatory hand-held assistive device;

or

D. Hemipelvectomy or hip disarticulation with amputation of the other lower extremity at or above the tarsal region.

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

A. Solid union not evident on medically acceptable imaging techniques and not clinically solid, when such determination is feasible;

and

B. Inability to ambulate effectively, as defined in 1.00B1, 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 directed toward restoration of functional use of the extremity, and such function was not restored or expected to be restored within 12 months after onset.

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

4. Listing 4.12, Cardiovascular System, of part A of appendix 1 of subpart P 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. Listing 9.08, Endocrine System, of part A of appendix 1 of subpart P is amended by removing paragraph 9.08C and redesignating paragraph 9.08D as paragraph 9.08C.

Listing 14.00, Immune System, of part A of appendix 1 of subpart P of part 404 is amended as follows:

6. In listing 14.00B, the fourth and sixth paragraphs are revised 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 severe loss of function in a single organ or body system, or lesser degrees of functional loss in two or more organs/body systems associated with significant constitutional symptoms and signs of severe fatigue, fever, malaise, and weight loss, 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.

* * * * *

7. A new paragraph 14.00B6 is added to read as follows:

6. *Inflammatory arthritis (14.09)* includes a vast array of disorders which 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. However, all the chronic forms (i.e., disorders that are expected to last clinically for at least 12 months) have the potential to result in functional loss that may preclude the performance of any gainful activity. 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 which cumulatively result in functional deficit. When deformity without ongoing inflammation is the dominant manifestation 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 hip, knee, shoulder, elbow, wrist-hand, and ankle-foot. The wrist and hand are considered together as one major joint, as are the ankle and foot.

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 1.00B1 and 1.00B2.

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 and dorsolumbar spines will result in inability to see ahead and to the side.

d. As in 14.02 through 14.06, extra-articular findings of an inflammatory arthritis may satisfy the criteria for an involved extra-articular body system, and should be evaluated under 14.09C. Extra-articular findings 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 deficit, and heel enthesopathy with functionally limiting pain.

* * * * *

8. In listing 14.02, paragraphs 14.02A8 through 14.02A10 are redesignated as paragraphs 14.02A9 through 14.02A11, respectively, and a new paragraph 14.02A8 is added to read as follows:

14.02 *Systemic lupus erythematosus.* Documented as described in 14.00B1, with:

A. One of the following:

* * * * *

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

* * * * *

9. 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 1.00B1 and B2.

or

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

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

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

or

C. With 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 findings than in C, and:

1. Significant, documented constitutional symptoms and signs (e.g., joint pain, morning stiffness of at least 2 hours' duration, fatigue, fever, malaise, weight loss), and

2. Involvement of two or more organs/body systems (see 14.00B6). 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 findings than in C, with signs of unilateral or bilateral sacroiliitis on medically acceptable imaging techniques, and the extra-articular findings described in 14.09D.

10. 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* under this section may be due to bone or joint deformity or destruction from any cause; miscellaneous disorders of the spine with or without radiculopathy or other neurologic deficits; amputation; or fractures or soft tissue injuries, including burns, requiring prolonged periods of immobility or convalescence. Inflammatory arthritides, which may result in loss of function because of inflammatory peripheral joint or axial arthritis or sequelae, or because of extra-articular manifestations, are to be evaluated under 114.09.

Regardless of the underlying cause(s), functional loss for purposes of these listings is defined as the inability to ambulate effectively on a sustained basis or the inability to perform fine and gross movements effectively on a sustained basis for any reason, including pain. 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.

1. *Inability to ambulate effectively* means an extreme limitation of the ability to walk. Ineffective ambulation is defined generally as having insufficient lower extremity functioning (see 101.00H) to permit independent ambulation without the use of a hand-held assistive device 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.)

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

Older children, who would be expected to be able to walk when compared to their peers, must be capable of sustaining a reasonable walking pace over a sufficient distance to afford them the ability to carry out age-appropriate activities of daily living. 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 a block 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 with the use of a single hand rail. The ability to walk independently about the child's home without the use of assistive devices will not, in and of itself, constitute effective ambulation.

2. *Inability to perform fine and gross movements effectively*, means an extreme loss of function of both upper extremities. To use their upper extremities effectively, individuals must be capable of sustaining reasonable use of both upper extremities to perform such functions as reaching, pushing, pulling, grasping, and fingering in an age-appropriate manner to afford them the ability to carry out age-appropriate activities of daily living.

For very young children, the consideration is the inability to perform comparable age-appropriate activities involving the upper extremities. Determinations of extreme limitations in such children should be made by comparison with the limitations for persistent motor dysfunction for infants and young children described in 110.07A.

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. The need for intermittent assistance for the purposes of buttoning or tying in a child for whom these are age-appropriate abilities does not, in and of itself, constitute ineffective functioning.

3. *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 perform work activities or to function in an age-appropriate manner, medical signs or laboratory findings must show the existence of a medical 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 impact 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* of musculoskeletal impairments should be supported, as applicable, by detailed descriptions of the joints, including ranges of motion, condition of the musculature (i.e., weakness, atrophy), sensory or reflex changes, circulatory deficits, and laboratory findings, including findings on medically acceptable imaging techniques. Medically acceptable imaging techniques include, but are not limited to, x-ray imaging, computerized axial tomography (CAT scan) or magnetic resonance imaging (MRI), with or without contrast material, and radionuclear bone scans.

Electrodiagnostic procedures and myelographic 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 rheumatologic, 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 child's daily activities.

E. *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), motor and sensory abnormalities, 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 or lower arms, at a stated point above and below the knee or elbow given in inches or centimeters. 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.

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. Severe neurological deficits (paraparesis, paraplegia) are to be evaluated under the criteria in 111.00.

F. *Duration of impairment.* Musculoskeletal impairments frequently improve with time or respond to treatment. Therefore, a longitudinal clinical record covering a period of at least 3 months of management and evaluation, and the expectation that the impairment will last for 12 months, are usually necessary for the assessment of severity and expected duration of impairment, unless the claim can be decided favorably on the basis of the current evidence.

G. *Effects of treatment.* 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 impair the individual.

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, which 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.

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.

H. *Orthotic, prosthetic, or assistive devices.* Musculoskeletal impairments should be examined with and without any medically necessary orthotic, prosthetic, or assistive devices in place. When an individual with an impairment involving a lower extremity or extremities uses a hand-held assistive device, the individual's ability to ambulate must be evaluated without the use of the device to determine whether, or the extent to which, the individual is able to ambulate without assistance. In this case, the requirement to use a hand-held assistive device may 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. If there has been an amputation, the condition of the stump should be evaluated. The medical basis for the use of any assistive device (e.g., instability, weakness) should be documented.

I. *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 tissues may result from a herniated nucleus pulposus or other miscellaneous conditions. Neurological impairment resulting from these disorders may additionally be evaluated by referral to the neurological listings in 111.00.

1. *Herniated nucleus pulposus* is a common disorder associated with the impingement of a nerve root, but occurs infrequently in children. Nerve root compression results in a specific 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, lysomal disorders, metabolic disorders, vertebral osteomyelitis, vertebral fractures and achondroplasia. Disorders such as spinal dysrhaphism, diastematomyelia, and tethered cord syndrome may also cause such abnormalities. In these cases, there may be obvious gait difficulty and deformity of the lower extremities on a neurogenic basis. Therefore, these impairments should be evaluated on the basis of the neurological effects under the criteria in 111.00.

J. *Abnormal curvatures of the spine.* In addition to the musculoskeletal effects of abnormal curvatures of the spine (e.g., scoliosis, kyphosis, kyphoscoliosis), which can result in impaired ambulation, these conditions may also adversely affect an individual's ability to breathe or may result in marked disfigurement with emotional withdrawal or isolation. When there is impaired ambulation, evaluation of equivalence may be made by reference to 114.09B. When there is respiratory involvement or an associated mental disorder, evaluation may be made under 103.00 or 112.00, as appropriate.

K. *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 surgical complications, infections, or other medical complications, related illnesses, or related treatments that delay the individual's attainment of maximum benefit from therapy.

L. *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 medically acceptable imaging techniques for any 6-month period after the last definitive surgical procedure, 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 a period of 6 months after the last definitive surgical procedure, i.e., maximum therapeutic benefit has been reached, then the symptoms, signs, and laboratory findings associated with such surgeries, complications, and recuperative periods are no longer the

sole factors to be considered because maximal medical restoration will have been completed. Evaluation at this point must be made on the basis of the demonstrable residual impairment, if any, as demonstrated by the symptoms, signs, laboratory findings, and other relevant evidence.

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

N. *Major joints* are the hip, knee, shoulder, elbow, wrist-hand, or ankle-foot. The wrist and hand are considered together as one major joint, as are the ankle and foot.

O. *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.

101.01 Category of Impairments, Musculoskeletal

101.02 *Deficit of musculoskeletal function of a major 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 medically acceptable imaging techniques of joint space narrowing, bony destruction, or ankylosis of the affected joint(s). With:

A. Involvement of one major weight-bearing joint (i.e., hip, knee, or ankle-foot), resulting in inability to ambulate effectively, as defined in 101.00B1;

or

B. Involvement of one major 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 101.00B2.

101.03 *Reconstructive surgery or surgical arthrodesis* of a major weight-bearing joint, with inability to ambulate effectively, as defined in 101.00B1, 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., lysomal 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 anatomic distribution of pain, limitation of motion of the spine, motor deficit (atrophy 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.*

A. Both hands;

or

B. One or both lower extremities at or above the tarsal region, with inability to ambulate effectively, as defined in 101.00B1, due to stump complications which have lasted or are expected to last for at least 12 months from onset;

or

C. One hand and one lower extremity at or above the tarsal region, with inability to ambulate effectively, as defined in 101.00B1, without an obligatory hand-held assistive device;

or

D. Hemipelvectomy or hip disarticulation with amputation of the other lower extremity at or above the tarsal region.

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

A. Solid union not evident on medically acceptable imaging techniques, and not clinically solid, when such determination is feasible;

and

B. Inability to ambulate effectively, as defined in 101.00B1, 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 directed toward restoration of functional use of the extremity, and such function was not restored or expected to be restored within 12 months after onset.

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

11. 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 new 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 severe loss of function in a single organ or body system, or lesser degrees of functional loss in two or more organs/body systems associated with significant constitutional symptoms and signs of severe fatigue, fever, malaise, and weight loss, 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. Many 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 100.00.

* * * * *

E. *Inflammatory arthritis (114.09)* includes a vast array of disorders which 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. However, all the chronic forms (i.e., disorders that are expected to last clinically for at least 12 months) have the potential to result in functional loss that may preclude a child from functioning independently, appropriately, and effectively in an age-appropriate manner. 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 which cumulatively result in functional deficit. When deformity without ongoing inflammation is the dominant manifestation of the impairment, it should be evaluated under 101.02, or, if there has been surgical reconstruction, 101.03.

1. Because the manifestations 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 hip, knee, shoulder, elbow, wrist-hand, and ankle-foot. The wrist and hand are considered together as one major joint, as are the ankle and foot.

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 101.00B1 and 101.00B2.

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 and dorsolumbar spines will result in inability to see ahead and to the side.

5. As in 114.02 through 114.06, extra-articular findings of an inflammatory arthritis may satisfy the criteria for an involved extra-articular body system, and should be evaluated under 114.09C. Extra-articular findings 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 deficit, 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 the adverse effects of an 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.

12. 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 101.00B1 and B2.

or

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

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

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

or

C. With 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 findings than in C, and:

1. Significant, documented constitutional symptoms and signs (e.g., joint pain, morning stiffness of at least 2 hours' duration, fatigue, fever, malaise, weight loss), and

2. Involvement of two or more organs/body systems (see 114.00E). 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 findings than in C, with signs of unilateral or bilateral sacroiliitis on medically acceptable imaging techniques, and the extra-articular findings described in 114.09D.

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