Alternative Methods of Compliance (AMOCs)

(k)(1) The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Alternative methods of compliance, approved previously in accordance with AD 2004–03–02, are approved as alternative methods of compliance with the corresponding requirements of this AD.

Related Information

(l) French airworthiness directive F–2004–147, dated August 18, 2004, also addresses the subject of this AD.

Material Incorporated by Reference

(m) You must use the service information listed in Table 1 of this AD to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approves the incorporation by reference of these documents in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To get copies of the service information, contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. To view the AD docket, go to the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, Nassif Building, Washington, DC. To review copies of the service information, go to the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

TABLE 1.—MATERIAL INCORPORATED BY REFERENCE

Airbus service bulletin	Revision level	Date
A320–27–1135	02	April 18, 2002.
A320–27–1151, including Appendix 01	Original	March 9, 2004.
A320–27–1152, including Appendix 01	Original	June 4, 2004.

Issued in Renton, Washington, on June 17, 2005.

Michael J. Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–12843 Filed 7–1–05; 8:45 am]

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SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Regulation No. 4]

RIN 0960–AF30

Revised Medical Criteria for Evaluating Genitourinary Impairments

AGENCY: Social Security Administration.

ACTION: Final rules.

SUMMARY: We are revising the criteria in the Listing of Impairments (the listings) that we use to evaluate claims involving genitourinary impairments. We apply these criteria when you claim 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 genitourinary impairments.

DATES: These rules are effective September 6, 2005.

Electronic Version

The electronic file of this document is available on the date of publication in the **Federal Register** at *http://www.gpoaccess.gov/fr/index.html*. It is also available on the Internet site for SSA (*i.e.*, Social Security Online) at *http://policy.ssa.gov/pnpublic.nsf/LawsRegs*.

FOR FURTHER INFORMATION CONTACT: Richard Bresnick, Social Insurance Specialist, Office of Regulations, Social Security Administration, 100 Altmeyer Building, 6401 Security Boulevard, Baltimore, MD 21235–6401, (410) 965–1758 or TTY (410) 966–5609. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit our Internet site, Social Security Online, at *http://www.socialsecurity.gov*.

SUPPLEMENTARY INFORMATION: We are revising and making final the rules we proposed for evaluating genitourinary impairments in the Notice of Proposed Rulemaking (NPRM) we published in the **Federal Register** on August 23, 2004 (69 FR 51777).

What Programs Do These Final Regulations Affect?

These final regulations affect disability determinations and decisions that we make under title II and title XVI of the Act. In addition, to the extent that Medicare entitlement and Medicaid eligibility are based on whether you qualify for disability benefits under title II or title XVI, these final regulations also affect the Medicare and Medicaid programs.

Who Can Get Disability Benefits?

Under title II of the Act, we provide for the payment of disability benefits if you are disabled and belong to one of the following three groups:

- Workers insured under the Act,
- Children of insured workers, and
- Widows, widowers, and surviving divorced spouses (see § 404.336) of insured workers.

Under title XVI of the Act, we provide for Supplemental Security Income (SSI) payments on the basis of disability if you are disabled and have limited income and resources.

How Do We Define Disability?

Under both the title II and title XVI programs, disability must be the result of any medically determinable physical or mental impairment or combination of impairments that is expected to result in death or which has lasted or is expected to last for a continuous period of at least 12 months. Our definitions of disability are shown in the following table:

If you claim under . . .	And you are . . .	Disability means you have a medically determinable impairment(s) as described above and that results in . . .
title II	an adult or a child	the inability to do any substantial gainful activity (SGA).
title XVI	a person age 18 or order	the inability to do any SGA.
title XVI	a person under age 18	marked and severe functional limitations.

How Do We Decide Whether You Are Disabled?

If you are seeking benefits under title II of the Act, or if you are an adult seeking benefits under title XVI of the Act, we use a five-step ''sequential evaluation process'' to decide whether you are disabled. We describe this five-step process in our regulations at §§ 404.1520 and 416.920. We follow the five steps in order and stop as soon as we can make a determination or decision. The steps are:

1. Are you working and is the work you are doing substantial gainful activity (SGA)? If you are working and the work you are doing is SGA, we will find that you are not disabled, regardless of your medical condition or your age, education, and work experience. If you are not performing SGA, we will go on to step 2.

2. Do you have a ''severe'' impairment? If you do not have an impairment or combination of impairments that significantly limits your physical or mental ability to do basic work activities, we will find that you are not disabled. If you do have a severe impairment(s), we will go on to step 3.

3. Do you have an impairment(s) that meets or medically equals the severity of an impairment in the listings? If you do, and the impairment(s) meets the duration requirement, we will find that you are disabled. If you do not, we will go on to step 4.

4. Do you have the residual functional capacity to do your past relevant work? If you do, we will find that you are not disabled. If you do not, we will go on to step 5.

5. Does your impairment(s) prevent you from doing any other work that exists in significant numbers in the national economy, considering your residual functional capacity, age, education, and work experience? If it does, and it meets the duration requirement, we will find that you are disabled. If it does not, we will find that you are not disabled.

We use a different sequential evaluation process for children who apply for payments based on disability under title XVI of the Act. We describe that sequential evaluation process in § 416.924 of our regulations. If you are already receiving benefits, we also use a different sequential evaluation process when we decide whether your disability continues. (See §§ 404.1594, 416.924, 416.994, and 416.994a of our regulations.) However, all of these processes include steps at which we consider whether your impairment meets or medically equals one of our listings.

What Are the Listings?

The listings are examples of impairments that we consider severe enough to prevent you as an adult from doing any gainful activity. If you are a child seeking SSI based on disability, the listings describe impairments that we consider severe enough to result in marked and severe functional limitations. Although the listings are contained only in appendix 1 to subpart P of part 404 of our regulations, we incorporate them by reference in the SSI program in § 416.925 of our regulations and apply them to claims under both title II and title XVI of the Act.

How Do We Use the Listings?

The listings are in two parts. There are listings for adults (part A) and for children (part B). If you are an individual age 18 or over, we apply the listings in part A when we assess your claim, and we never use the listings in part B.

If you are an individual under age 18, we first use the criteria in part B of the listings. If the listings in part B do not apply, and the specific disease process(es) has a similar effect on adults and children, we then use the criteria in part A. (See §§ 404.1525 and 416.925 of our regulations.)

If your impairment(s) does not meet any listing, we will also consider whether it medically equals any listing; that is, whether it is as medically severe. (See §§ 404.1526 and 416.926 of our regulations.)

What If You Do Not Have an Impairment(s) That Meets or Medically Equals a Listing?

We use the listings only to decide that individuals are disabled or that they are still disabled. We will not deny your claim or decide that you no longer qualify for benefits because your impairment(s) does not meet or medically equal a listing. If you are not working and you have a severe impairment(s) that does not meet or medically equal any listing, we may still find you disabled based on other rules in the ''sequential evaluation process.'' Likewise, we will not decide that your disability has ended only because your impairment(s) does not meet or medically equal a listing.

Also, when we conduct reviews to determine whether your disability continues, we will not find that your disability has ended because we have changed a listing. Our regulations explain that, when we change our listings, we continue to use our prior listings when we review your case, if you qualified for disability benefits or SSI payments based on our determination or decision that your impairment(s) met or medically equaled a listing. In these cases, we determine whether you have experienced medical improvement, and if so, whether the medical improvement is related to the ability to work. If your condition(s) has medically improved so that you no longer meet or medically equal the prior listing, we evaluate your case further to determine whether you are currently disabled. We may find that you are currently disabled, depending on the full circumstances of your case. (See §§ 404.1594(c)(3)(i) and 416.994(b)(2)(iv)(A) of our regulations.) If you are a child who is eligible for SSI payments, we follow a similar rule when we decide that you have experienced medical improvement in your condition(s). (See § 416.994a(b)(2) of our regulations.)

Why Are We Revising the Listings for the Genitourinary System?

We are revising these listings to update our medical criteria for evaluating genitourinary impairments and to provide more information about how we evaluate such impairments. We last published final rules comprehensively revising the listings for the genitourinary system in the **Federal Register** on December 6, 1985 (50 FR 50068). Because we have not comprehensively revised the listings for this body system since 1985, we believe that we need to revise and update these rules.

What Do We Mean by ''Final Rules'' and ''Prior Rules''?

Even though these rules will not go into effect until 30 days after publication of this notice, for clarity, we refer to the changes we are making here as the ''final rules'' and to the rules that will be changed by these final rules as the ''prior rules.''

When Will We Start To Use These Final Rules?

We will start to use these final rules on their effective date. We will continue to use our prior rules until the effective date of these final rules. When the final rules become effective, we will apply them to new applications filed on or after the effective date of these rules and to claims pending before us, as we describe below.

As is our usual practice when we make changes to our regulations, we will apply these final rules on or after their effective date whenever we make a determination or decision, including

in those claims in which we make a determination or decision after remand to us from a Federal court. With respect to claims in which we have made a final decision and that are pending judicial review in Federal court, we expect that the court's review of the Commissioner's final decision would be made in accordance with the rules in effect at the time of the administrative law judge's (ALJ's) decision when the ALJ's decision is the final decision of the Commissioner. If the court determines that the Commissioner's final decision is not supported by substantial evidence or contains an error of law, we would expect that the court would reverse the Commissioner's decision and remand the case for further administrative proceedings pursuant to the fourth sentence of section 205(g) of the Act, except in those few instances in which the court determines that it is appropriate to reverse the final decision and award benefits without remanding the case for further administrative proceedings. If a court reverses the Commissioner's final decision and remands the case for further administrative proceedings after the effective date of these final rules, we will apply the provisions of these final rules to the entire period at issue in the claim in our new decision issued pursuant to the court's remand.

How Long Will These Final Rules Be Effective?

These final rules will no longer be effective 8 years after the date on which they become effective, unless we extend them or revise and issue them again. This is a technical change from the 5-year effective date as we proposed in the NPRM. We made this revision from 5 to 8 years because we believe this is medically appropriate for the impairments contained in this body system. This change is also consistent with other recent final rules where we also determined that it was medically appropriate to set an expiration date 8 years from the effective date of the rules. For example, we recently set an 8-year effective date for our final rules for evaluating skin disorders (69 FR 32260, 32269 (June 9, 2004)) and for our final rules for evaluating musculoskeletal impairments (66 FR 58010, 58037 (November 19, 2001)).

What Revisions Are We Making With These Final Rules?

We are revising the listings criteria to present them in a more logical order and to make them easier to use. To do this, we are:

- Expanding the language in the introductory text (preface) in sections 6.00 and 106.00 to provide more guidance for our adjudicators, to bring it up to date, and to reflect the revised listings. We are designating all of the paragraphs in the preface with letters or numbers to make it easier to refer to them.
- Adding final sections 6.00B and 106.00B defining important terms in the listings.
- Removing listings that are obsolete to reflect the current medical practice of initiating dialysis earlier in the treatment of chronic renal failure. (We define the medical term ''renal'' in final sections 6.00B and 106.00B as ''pertaining to the kidney.'' We use the term ''renal'' in most of these listings because it is the term that physicians use.) Because of current medical practice, some of the associated complications specified in the prior listings no longer occur or reach listing-level severity. For example, we are removing prior listing 6.02C4, chronic renal disease with intractable pruritus. Although you may still have intractable pruritus, you usually will be receiving dialysis for the underlying chronic renal disease; in that case, your impairment will meet final listing 6.02A. In addition, the treatments for many of the side effects and complications of chronic renal disease have improved.
- Revising listings to reflect current medical practice and to be consistent with the terminology used in other body system listings. For example, in the childhood listings, we are changing ''Renal transplant'' (prior listing 106.02D) to ''Kidney transplantation'' (final listing 106.02B).
- Redesignating the listings in part B to correspond to listings addressing the same impairments in part A. Except for minor changes to refer to children, we are also repeating much of the language of final section 6.00 in final section 106.00. This is because the same basic rules for establishing and evaluating the existence and severity of genitourinary impairments in adults also apply to children. In the discussion of the part B listings below, we only discuss changes to the childhood listings that we have not already discussed under the changes to the adult listings in part A.
- Adding final listing 106.07 in part B to address congenital genitourinary impairments that are not addressed in final listings 106.02 or 106.06.

We are also making nonsubstantive editorial changes to update the medical terminology in the introductory text and the listings and to make the language clearer.

How Are We Changing the Introductory Text to the Listings for Evaluating Genitourinary Impairments in Adults?

Final Section 6.00 Genitourinary Impairments

We are changing the name of this body system from ''Genito–Urinary System'' to ''Genitourinary Impairments'' to more accurately show that we use these listings to evaluate whether individuals are disabled in our disability programs. We are using the same heading for section 6.00 of these final rules as for final section 106.00, even though we recognize that we list only kidney impairments in part A of the listings. We believe it is preferable to use the same heading in part A and part B of the listings, and since kidney impairments are types of genitourinary impairments, we believe this heading is appropriate.

We are expanding and reorganizing the introductory text to these listings to:

- Provide additional guidance,
- Reflect the final listings, and
- Improve clarity and readability.

Throughout the final rules, we have also made a number of minor editorial changes from the language we proposed in the NPRM; for example, to use consistent terminology throughout the final rules, to simplify language, and to correct punctuation. Because these changes were only for clarity and did not change the substance of the rules we proposed in the NPRM, we do not summarize them below.

The following is an explanation of the major features of the final rules.

Final Section 6.00A—What Impairments Do These Listings Cover?

In this new section, we explain that we use these listings to evaluate genitourinary impairments resulting from chronic renal disease. In final section 6.00A2, we provide a list of examples of chronic renal disease that can lead to renal dysfunction. This provision replaces the parenthetical statement we included in prior listing 6.02. In final section 6.00A3, we explain that we use the criteria in listing 6.06 to evaluate nephrotic syndrome due to glomerular disease.

In a technical change from the NPRM, we revised the list of examples of chronic renal disease in final section 6.00A2. The revision corrects medically inaccurate statements from the NPRM but does not change the provision substantively.

Final Section 6.00B—What Do We Mean by the Following Terms in These Listings?

In final section 6.00B, we define what we mean by important terms in these listings. In final section 6.00B5, we revised the list of examples of symptoms and signs of persistent fluid overload syndrome in response to a commenter who pointed out inconsistencies between the examples in the preamble to the NPRM and the proposed rules. In several other definitions, we made minor changes for medical accuracy and consistency of terms within the final listing:

- In final section 6.00B9, we reorganized the text, changed the description from ''massive'' proteinuria to ''heavy'' proteinuria, and removed the reference to lipiduria because it is not a defining characteristic of nephrotic syndrome.
- In final section 6.00B10, we removed the reference to ''swelling'' from the list of effects of neuropathy because it is not generally a feature of neuropathy.
- In final section 6.00B14, we removed the example of osteomyelitis, which we do not mention in these listings, and replaced it with the example of osteoporosis, which we do. We also removed the reference to ''other diseases'' because we are providing only examples in this section.

We are revising the heading of proposed section 6.00B—''What do we mean by the following terms?''—by adding ''in these listings'' in the heading of final section 6.00B. We are doing this to clarify why the list of terms in final section 6.00B is different from the list of terms in final section 106.00B in the childhood listings. We do not use all of the same terms in part B as we do in part A, so the list is different. We are also revising the heading of final section 106.00B so that it is the same as the heading of final section 6.00B.

Final Section 6.00C—What Evidence Do We Need?

In final sections 6.00C1 and C2, we expand and clarify the documentation requirements discussed in prior section 6.00A. In final section 6.00C1, we briefly explain the kinds of evidence we need to evaluate claims of renal impairment.

In final section 6.00C2, we explain that we generally need a longitudinal clinical record covering a period of at least 3 months of observations and treatment, unless we can make a fully favorable determination or decision without it. We also explain that the record should include laboratory findings, such as serum creatinine or serum albumin values, obtained on more than one examination over at least a 3-month period.

Final section 6.00C3 corresponds to prior section 6.00C. We explain that we should have laboratory findings that show your renal function before you started dialysis.

Final sections 6.00C4 and 6.00C5 correspond to prior section 6.00B, which discussed nephrotic syndrome. We are clarifying the language and specifying appropriate laboratory evidence. In the last sentence of final section 6.00C5, we explain the evidence we can use when we do not have a pathology report.

Final Section 6.00D—How Do We Consider the Effects of Treatment?

In this new section, we explain how we consider your treatment, including your response to treatment, its efficacy, and any adverse consequences.

Final Section 6.00E—What Other Things Do We Consider When We Evaluate Your Chronic Renal Disease Under Specific Listings?

This section includes guidance about how we consider issues under specific listings. In the final rules, we are moving the text from proposed section 6.00G—''How do we evaluate specific genitourinary listings?''—into this section. The subparagraphs of final section 6.00E now follow the order of the listings. We believe that this is a more logical organization than the one we originally proposed. Except as noted below, there is no significant change in the text of these rules from the NPRM.

Final section 6.00E1, ''Chronic hemodialysis or peritoneal dialysis,'' corresponds to proposed section 6.00G1. It provides information for using final listing 6.02A.

Final section 6.00E2, ''Kidney transplantation,'' corresponds to proposed section 6.00E1. It provides information for using final listing 6.02B. In it, we explain that if you have had a kidney transplant, we will consider you disabled for 12 months following the surgery because there is a greater likelihood of organ rejection and infection during the first year. We explain further that after that year we will determine whether you are still disabled based on any residual impairment(s) you have.

In a technical change from the NPRM, we deleted the proposed provision in the second sentence of the paragraph that said that we would base our continuing disability evaluation on ''the residual impairment as shown by symptoms, signs, and laboratory findings.'' We determined that the proposed provision was unnecessary and that it could have been misinterpreted. When we determine whether you are still disabled, we consider whether there has been medical improvement in your impairment(s) based on symptoms, signs, and laboratory findings; however, at other steps of the process we use to determine whether your disability continues, we consider all other relevant evidence as well. (See §§ 404.1579, 404.1594, and 416.994 of our regulations.) We also simplified the fourth sentence of the paragraph. Neither of these changes is a substantive change in the meaning of the rules we proposed.

We also revised the list of complications at the end of the fourth sentence of the paragraph for technical medical reasons and to clarify our intent. Proposed section 6.00E1b indicated that we would consider the ''use of'' immunosuppressants; however, all people who have kidney transplants must use immunosuppressants. We are clarifying in final section 6.00E2b what we meant: that when we consider whether your disability continues 1 year after your transplant we will consider any side effects from your immunosuppressant treatment. We also combined proposed sections 6.00E1b and 6.00E1d, because corticosteroids are used for immunosuppression in individuals with kidney transplants. Therefore, in final section 6.00E2b, we now indicate that we consider the side effects of your immunosuppressants, including corticosteroids. These revisions in the final rules do not change the substance of the rules as we proposed them.

Final section 6.00E3, ''Renal osteodystrophy,'' corresponds to proposed section 6.00G2. It provides information for using final listing 6.02C1. In the final rule, we removed the list of examples from final section 6.00E3 that we proposed in section 6.00G2 of the NPRM because final listing 6.02C1 also includes examples and the lists were inconsistent. In final section 6.00E3, we now refer to the list of examples in final listing 6.02C1.

Final section 6.00E4, ''Persistent motor or sensory neuropathy,'' corresponds to proposed section 6.00G3. It provides information for using final listing 6.02C2. In it, we explain what the longitudinal clinical record of persistent neuropathy must show.

Final section 6.00E5, ''Nephrotic syndrome,'' corresponds to proposed section 6.00E2. It explains what the evidence must show for your impairment to meet the requirements of

final listing 6.06A or B. In a technical change from the NPRM, we are restoring the examples of complications of nephrotic syndrome that we evaluate under other listings. In the NPRM, we proposed to remove the last sentence of prior section 6.00B, which indicated that we consider complications of nephrotic syndrome, such as severe orthostatic hypotension, recurrent infections or venous thromboses, under appropriate listings. In reviewing this proposal, we determined that this guidance could still be helpful, so we decided to include it in our section devoted to nephrotic syndrome, final section 6.00E5. In these final rules, we made minor editorial changes in the sentence for context and clarity. We also deleted the word ''severe'' from the phrase ''severe hypotension'' because we believe it is unnecessary in the sentence, which only describes some of the complications that may be associated with nephrotic syndrome, not necessarily how severe your complications must be to show disability.

The changes we made to combine proposed sections 6.00E and 6.00G in the final rules necessitated redesignation of proposed section 6.00H as final section 6.00G and changes to cross-references throughout the final rules in the preamble and listings. None of these was a substantive change to the provisions of the affected rules.

Final Section 6.00F—What Does the Term ''Persistent'' Mean in These Listings?

In final section 6.00F, we explain that the term ''persistent'' in these listings means that the longitudinal clinical record shows that, with few exceptions, the required finding(s) has been at, or is expected to be at, the level specified in the listing for a continuous period of at least 12 months. We use this term in final listings 6.02C.

Final Section 6.00G—How Do We Evaluate Impairments That Do Not Meet One of the Genitourinary Listings?

Final section 6.00G (proposed section 6.00H) is new to this body system. In it, we state our basic adjudicative principle that, if your severe impairment(s) does not meet or medically equal the requirements of a listing, we will continue the sequential evaluation process to determine whether or not you are disabled.

How Are We Changing the Criteria in the Listings for Evaluating Genitourinary Impairments in Adults?

6.01 Category of Impairments, Genitourinary Impairments

Final Listing 6.02—Impairment of Renal Function

We are removing the parenthetical examples that were in the first sentence of prior listing 6.02 because we address them in final section 6.00A2, making their inclusion in the listing redundant. In a technical change from the NPRM, we are also revising the first sentence in final listing 6.02 regarding the duration of your chronic renal disease from ''expected to last 12 months'' to ''that has lasted or can be expected to last for a continuous period of at least 12 months'' to be consistent with our definition of duration in §§ 404.1509 and 416.909.

Final listing 6.02A, ''Chronic hemodialysis or peritoneal dialysis,'' corresponds to prior listing 6.02A, except that we are removing the statement ''necessitated by irreversible renal failure'' because it is redundant.

Final listing 6.02B, ''Kidney transplantation,'' corresponds to prior listing 6.02B, ''Kidney transplant.'' We are changing the heading to use terminology that is consistent with other body system listings, such as in listing 4.09, ''Cardiac transplantation.''

Final listing 6.02C, for persistent elevation of serum creatinine or reduction of creatinine clearance, corresponds to prior listing 6.02C. In final listing 6.02C1, for renal osteodystrophy, we are replacing the word ''marked'' with the word ''significant'' in the phrase describing osteoporosis. We use the term ''marked'' in various other listings (for example, the mental disorders listings in section 12.00) and other regulations (for example, the functional equivalence regulation for evaluating disability in children, § 416.926a) to describe a particular measure of functional limitations, and it does not describe what we intend in this final listing. The change we are making in this final rule will remove any potential confusion about our intent. However, we are not changing the degree of osteoporosis required to meet this listing.

In the NPRM, we also proposed to remove the word ''severe'' from the phrase that described bone pain in the prior listing. In final listing 6.02C1, we are restoring the word in response to a comment, as discussed below. See the public comments section of this preamble for an explanation of why we decided to keep the word in this listing.

We are removing prior listings 6.02C2, for a clinical episode of pericarditis, and 6.02C4, for intractable pruritus, because current treatment for most individuals with chronic renal disease includes the initiation of dialysis earlier in the course of treatment. Previously, dialysis would be delayed, and individuals would be maintained on a low protein diet. Prior listings 6.02C2 and 6.02C4 were useful for establishing disability in these individuals. However, now it is known that the long-term prognosis improves for individuals when dialysis is initiated earlier in the course of treatment, so most patients begin dialysis earlier. Therefore, if you have pericarditis or intractable pruritus, you usually will be receiving dialysis; in that case, your impairment will meet final listing 6.02A.

Because we are removing prior listing 6.02C2, we are redesignating prior listing 6.02C3, for persistent motor or sensory neuropathy, as final listing 6.02C2.

We are reorganizing prior listing 6.02C5, for persistent fluid overload syndrome, and redesignating it as final listing 6.02C3. In addition, we provide that there must be persistent signs of vascular congestion despite prescribed therapy. In a technical change from the proposed rules, we are removing the requirement we proposed that you must demonstrate that you have symptoms in addition to the signs we required to meet this listing. If you have the signs we require in this listing, you will be unable to do any gainful activity and it is unnecessary for you to show that you also have symptoms. We are also adding a cross-reference to final section 6.00B5, where we list some examples of symptoms and signs of fluid overload syndrome.

In the NPRM, we proposed to remove prior listing 6.02C6, for persistent elevation of serum creatinine or reduction of creatinine clearance with anorexia that meets the values in table III or IV of listing 5.08. In response to public comments described below, we decided to retain the listing in the final rules. The listing is redesignated as final listing 6.02C4.

We are removing prior listing 6.02C7, for persistent hematocrits of 30 percent or less, because hematocrits at this level do not necessarily correlate with an inability to do any gainful activity.

We may still find you disabled if you have chronic renal disease and persistently low hematocrit levels. As we discuss in final section 6.00G, we must consider whether your impairment(s) satisfies the criteria of any appropriate listing. If your impairment(s) does not meet a listing,

we will determine whether it medically equals a listing. If your impairment(s) does not meet or medically equal a listing, we will proceed to the fourth and, if necessary, the fifth steps of the sequential evaluation process as described in §§ 404.1520 and 416.920. We will consider the facts of your individual case, including your symptoms, such as fatigue and weakness, which may limit your functioning.

Final Listing 6.06—Nephrotic Syndrome

We are removing the word ''significant'' from the description of anasarca in prior listing 6.06. Anasarca is, by definition, significant.

How Are We Changing the Preface to the Listings for Evaluating Genitourinary Impairments in Children?

Final Section 106.00 Genitourinary Impairments

As in final section 6.00 in the adult rules, we are changing the name of this body system to ''Genitourinary Impairments.''

We are adding a new section 106.00E4a (proposed section 106.00H) to explain how we evaluate episodic genitourinary impairments in children under final listings 106.07A, B, and C. We are also adding a new section 106.00E4c (proposed section 106.00I) to explain what we mean by ''systemic infection,'' a criterion we use in final listing 106.07B.

We are also repeating much of the preface of final section 6.00 in the preface to final section 106.00, except for minor changes that are specific to the childhood listings. We are doing this because the same basic rules for establishing and evaluating the existence and severity of genitourinary impairments in adults also apply to children.

Because we have already described these provisions under the explanation of final section 6.00, the following discussion describes only those provisions that are unique to the childhood rules or that require further explanation specific to the evaluation of children's claims. When the provisions in section 106.00 are the same as the provisions in section 6.00 and we are revising provisions in section 6.00 from the provisions we proposed in the NPRM, we are making the same changes in final section 106.00 as we are making in final section 6.00.

Final Section 106.00A—What Impairments Do These Listings Cover?

In this section, we provide general guidance on evaluating chronic renal disease or renal dysfunction and congenital genitourinary impairments in children. In final section 106.00A4, we explain that we use the criteria in final listing 106.07 to evaluate congenital genitourinary impairments and give examples of such impairments. In the final rule, we are adding another example of a congenital genitourinary impairment, extrophic urinary bladder.

Final Section 106.00E—What Other Things Do We Consider When We Evaluate Your Genitourinary Impairment Under Specific Listings?

In this section, we are significantly reorganizing the rules we proposed in sections 106.00E, G, H, and I of the NPRM. We are combining proposed sections 106.00E and 106.00G for the same reasons we combined proposed sections 6.00E and 6.00G in part A. However, we are using a different heading for this section because in final section 106.00E4, it includes information about how we evaluate congenital genitourinary impairments under listing 106.07. Therefore, unlike the corresponding section in the adult rules, it is not only about chronic renal disease.

We are also moving the provisions of proposed sections 106.00H and I to final section 106.00E4 together with relevant provisions from proposed section 106.00G. In the NPRM, we proposed three separate sections that included guidance about how we use listing 106.07:

- In proposed section 106.00G2, we provided four subparagraphs that described features of listing 106.07. Proposed section 106.00G2a simply described what proposed listing 106.07 contained. Proposed section 106.00G2b, explained that diagnostic cystoscopy did not satisfy the requirement for repeated surgical procedures, a requirement in listing 106.07A. Proposed sections 106.00G2c and G2d provided guidance about the criteria for electrolyte disturbance and hospitalizations in listing 106.07C.
- Proposed section 106.00H—''How do we evaluate episodic genitourinary impairments?''—provided guidance that was relevant only to the provisions of listing 106.07. Only listings 106.07A, B, and C include criteria for episodic events.
- Likewise, proposed section 106.00I—''What do we mean by systemic infection?''—provided guidance that was relevant only to listing 106.07B.

We are combining all of these rules in final section 106.00E4 because they all address the same listing section and we believe that it will be clearer to keep this guidance together. However, we are removing proposed section 106.00G2a in these final rules because it merely repeated what listing 106.07 requires and was unnecessary. We are also organizing the sections of 106.00E4 so they address listings 106.07A, B, and C in order, starting with general information about the overall listing section.

We did not make any substantive changes in the provisions in final section 106.00E4, but only removed headings, reorganized the sections into a clearer and more logical presentation, and made editorial changes as described below. The final rule is as follows.

Final section 106.00E4a corresponds to proposed section 106.00H. In it, we explain that each of the listings in 106.07 (that is, listings 106.07A, B, and C) includes a criterion for at least three events within a consecutive 12-month period with intervening periods of improvement. These events include urologic surgical procedures, hospitalizations, and treatment with parenteral antibiotics. The occurrence of these events within the specified time period supports the severity and chronicity of the underlying impairment(s). We also indicate that there must be at least 1 month between the events to ensure that we are evaluating separate episodes. As an editorial clarification from the NPRM, we are adding ''(that is, 30 days)'' after ''at least 1 month'' to indicate we do not necessarily mean a calendar month.

In final section 106.00E4a, we are making minor editorial changes from the language in proposed section 106.00H. For example, in section 106.00H of the proposed rules we indicated that ''some listings'' are met when the longitudinal clinical record shows that at least three events have occurred within a period of 12 consecutive months. However, as we have already noted, the only listings in which we included such criteria were listings 106.07A, B, and C. Therefore, we clarified the final rule to refer specifically to final listing 106.07. We believe that these editorial changes will make final section 106.00E4a easier to understand and use.

Final section 106.00E4b corresponds to proposed section 106.00G2b. It explains that diagnostic cystoscopy does not satisfy the requirement for repeated urologic surgical procedures in listing 106.07A. In the final rule, we added a reference to final listing 106.07A and the word ''urologic'' before the word ''surgical'' to match the language of the listing.

Final section 106.00E4c corresponds to proposed section 106.00I, ''What do

we mean by systemic infection?''. In this section, we explain that the criterion for systemic infection in listing 106.07B means an infection requiring an initial course of parenterally administered antibiotics occurring at least once every 4 months or at least 3 times a year. This chronicity supports the severity required for this listing. In the final rule, we removed a sentence that included a cross-reference because we no longer need it. All of the provisions that explain listing 106.07 are now together in final section 106.00E4. We also made a minor editorial change for context.

Final section 106.00E4d corresponds to proposed sections 106.00G2c and G2d. As we have already noted, these were the proposed provisions that explained terms in listing 106.07C. In an editorial change from the NPRM, we changed our reference to ''hospital admissions'' to ''hospitalizations'' to use language that is closer to the provision in final listing 106.07C.

The changes we made to combine proposed sections 106.00E, 106.00G, 106.00H, and 106.00I in the final rules necessitated redesignation of proposed section 106.00J as final section 106.00G and changes to cross-references throughout the final rules in the preamble and listings. None of these was a substantive change to the provisions of the affected rules.

Final Section 106.00G—How Do We Evaluate Impairments That Do Not Meet One of the Genitourinary Listings?

In final section 106.00G (proposed section 106.00J), we repeat the provisions of final section 6.00G, but also include the definition of disability for children who claim SSI payments in final section 106.00G2.

How Are We Changing the Criteria in the Listings for Evaluating Genitourinary Impairments in Children?

106.01 Category of Impairments, Genitourinary Impairments

We are adding a new listing 106.07, ''Congenital genitourinary impairments,'' specifically for children. There is no parallel listing in the adult genitourinary listings because we expect that these impairments will have been treated or resolved before adulthood. We are also redesignating the childhood listings to be consistent with the adult listings.

Final Listing 106.02—Impairment of Renal Function

In final listing 106.02, we are changing the heading of the prior listing to make it consistent with the final adult listing.

We are also reordering the sequence of impairments included under listing 106.02 to more closely follow the order in final listing 6.02:

- Final listing 106.02A, ''Chronic hemodialysis or peritoneal dialysis,'' replaces prior listing 106.02C.
- Final listing 106.02B, ''Kidney transplantation,'' replaces prior listing 106.02D.
- Final listing 106.02C, ''Persistent elevation of serum creatinine,'' replaces prior listing 106.02A.
- Final listing 106.02D, ''Reduction of creatinine clearance,'' replaces prior listing 106.02B.

Final Listing 106.06—Nephrotic Syndrome

In final listing 106.06, ''Nephrotic syndrome,'' we specify that anasarca must persist despite at least 3 months of prescribed therapy. ''Anasarca'' is a more accurate term than ''edema'' for this listing.

In final listing 106.06B, we are revising the terminology in prior listing 106.06B for measuring proteinuria to reflect current medical practice. This revision does not make the criterion more stringent. Rather, it is a more appropriate method of measuring proteinuria in children and is equivalent to the measurements used in prior listing 106.06B.

Final Listing 106.07—Congenital Genitourinary Impairments

In this new listing, we provide criteria that include consideration of repeated urologic surgical procedures, episodic systemic infections requiring parenteral antibiotics, and episodes of electrolyte disturbance requiring repeated hospitalizations. In final listing 106.07C, we made an editorial change to replace the parenthetical reference to hospitalizations ''for 24 hours or more'' with a cross-reference to final section 106.00E4d, which already explains that hospitalizations in listing 106.07C must be inpatient hospitalizations for 24 hours or more. The change eliminates an unnecessary redundancy.

Public Comments

In the NPRM we published on August 23, 2004 (69 FR 51777), we provided the public with a 60-day period in which to comment. The period ended on October 22, 2004.

We received comments from four public commenters. We carefully considered all of the comments. Because some of the comments were long, we have condensed, summarized, and paraphrased them. We have tried, however, to summarize the commenters' views accurately and to respond to all of the significant issues raised by the commenters that were within the scope of these rules.

One commenter submitted a markup of the notice pointing out stylistic and technical editorial issues in the preamble and the proposed rules. Although we do not summarize and respond to those comments below, we have made appropriate corrections in these final rules.

Other commenters noted provisions with which they agreed and did not make suggestions for changes in those provisions. We did not summarize or respond to those comments either.

The following are the significant public comments that do require a response.

Proposed Listing 6.02A, Chronic Hemodialysis or Peritoneal Dialysis

Comment: One commenter disagreed with our proposal to delete the parenthetical statement ''necessitated by irreversible renal failure'' from prior listing 6.02A. The commenter did not agree that all individuals who require chronic hemodialysis for at least 12 months would necessarily have irreversible renal failure. For example, a particular claimant could have several acute renal failures for a variety of different reasons in the course of a year. The commenter said that an individual with such episodic crises for 12 months would have an impairment that medically equals the listing but recommended that we specify that only individuals who have dialysis ''necessitated by [an] end-stage renal disease process'' would have an impairment that meets listing 6.02.

Response: We did not adopt the comment. Listing 6.02A requires that the individual have ''chronic'' renal disease with ''chronic'' hemodialysis or peritoneal dialysis. Therefore, we believe that the reference to irreversible failure was redundant and that the listing clearly does not include individuals who have a series of acute events that require dialysis.

Proposed Listing 6.02B, Kidney Transplantation

Comment: One commenter recommended that we add a cross-reference to proposed section 6.00E1 (final section 6.00E2) at the end of listing 6.02B. The commenter said that this would emphasize to our adjudicators the critical need to carefully look at the residuals of the treatment required by the transplant.

Response: We adopted the comment. In the proposed rules, we already included a cross-reference to proposed section 6.00E1 (final section 6.00E2) at

the beginning of proposed listing 6.02. In these final rules, we have moved the cross-reference to the end of the listing. For consistency, we made the same change in final listing 106.02B.

Listing 6.02C, Persistent Elevation of Serum Creatinine or Reduction of Creatinine Clearance

Comment: One commenter disagreed with our proposal to eliminate the requirement for ''severe'' bone pain for individuals with renal osteodystrophy under listing 6.02C1 and to require only that there be pain of an unspecified degree. The commenter believed that the change would require adjudicators to have to choose more frequently between whether an impairment meets or medically equals a listing and to weigh the issue of the credibility of an individual's symptoms more than the medical documentation itself. The commenter said that there was no specific demand for this modification because unspecified pain is never a basis for an allowance under our rules, but that severe pain that is ''fully documented by medical and lay evidence can be.''

Response: Although we did not agree with the commenter's rationale, we did adopt the comment. Many people with osteodystrophy do not have severe bone pain, and in reconsidering our proposed rule we realized that by deleting the word ''severe'' we might include some individuals under the listing who should not be presumed to be disabled. In final listing 6.02C1, we use the word ''severe'' to describe medical severity; it does not have the same meaning as it does when we use it in connection with a finding at the second step of the sequential evaluation process.

We do not agree with the commenter that the proposed listing would have required adjudicators to choose more frequently between whether an impairment meets or medically equals this listing or to make more difficult findings about an individual's credibility. To the contrary, we believe that these issues would have arisen less often under the proposed listing because it required only the finding of pain and not ''severe'' pain as in the prior listing. However, like the prior listing, we are restoring the word ''severe'' in the final listing for the reason stated in the previous paragraph.

Finally, although it is true that under the Act and our regulations an individual cannot be found disabled solely on the basis of a symptom, such as pain, the commenter may have misunderstood other aspects of our policies on the evaluation of symptoms. For example, in §§ 404.1525(f) and 416.925(f) of our regulations we explain that some listed impairments include symptoms usually associated with those impairments among their criteria. We then explain that:

> [g]enerally, when a symptom is one of the criteria in a [listing], it is only necessary that the symptom be present in combination with the other criteria. It is not necessary, unless the listing specifically states otherwise, to provide information about the intensity, persistence or limiting effects of the symptom as long as all other findings required by the specific listing are present.

Likewise, we do not have a requirement that an individual's pain be ''fully documented'' by the medical and lay evidence in order to establish that the individual is disabled. (See §§ 404.1529 and 416.929 of our regulations.)

Comment: Two commenters disagreed with our proposal to remove listing 6.02C6 because it was a reference listing. Both commenters pointed out that listing 6.02C6 did not simply describe the same impairment described in listing 5.08, because listing 5.08 requires weight loss ''due to any persisting gastrointestinal disorder.'' Rather, prior listing 6.02C6 described persistent anorexia associated with chronic renal disease, and the reference to the current weight values in two tables in listing 5.08 was only a severity criterion. Both commenters were concerned that some individuals would be inappropriately denied if we deleted the listing.

Response: We adopted the comments. The restored listing is listing 6.02C4 in these final rules.

Because of this change from the NPRM, we also deleted the example we proposed to include in section 6.00H1 explaining that weight loss associated with chronic renal disease should be evaluated under listing 5.08 in final section 6.00G1. We did not replace it with another example because we do not believe an example is necessary in this section.

Listing 106.07, Congenital Genitourinary Impairments

Comment: One commenter recommended that we add a new listing 106.07D to the proposed listing for children with ''[a]ny anatomical congenital malformation of a genito-urinary organ(s) which markedly limits adaptive functional capabilities of the child.'' The commenter said that this would complete all medical possibilities.

Response: We did not adopt the comment. The commenter essentially described a situation that would be covered by our rules for evaluating functional equivalence in § 416.926a of our regulations. That standard requires either an ''extreme'' limitation in one of the functional domains we list in § 416.926a(b)(1) or ''marked'' limitations in two of those domains.

Interstitial Cystitis

Comment: One commenter noted that in 2002 we issued a Social Security Ruling (SSR) explaining how to evaluate cases of individuals with interstitial cystitis. (SSR 02–2p, ''Titles II and XVI: Evaluation of Interstitial Cystitis,'' 67 FR 67436 (November 5, 2002)). The commenter recommended that we address this impairment ''in some fashion'' in the listing.

Response: We did not adopt the comment. As we indicate in SSR 02–2p, the causes of interstitial cystitis are unknown, and there are no definitive tests for the disorder; the diagnosis is made after excluding other possibilities for an individual's symptoms. Therefore, although we do recognize interstitial cystitis as a medically determinable impairment that can be very serious and result in disability under our rules, we are unable to include it in our genitourinary body system listings at this time. We also believe that SSR 02–2p provides more detailed and useful criteria than we would have been able to include in the preface to the listings.

Regulatory Procedures

Executive Order 12866

We have consulted with the Office of Management and Budget (OMB) and determined that these final rules meet the requirements for a significant regulatory action under Executive Order 12866, as amended by Executive Order 13258. Thus, they were subject to OMB review.

Regulatory Flexibility Act

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

Paperwork Reduction Act

The Paperwork Reduction Act (PRA) of 1995 says that no persons are required to respond to a collection of information unless it displays a valid Office of Management and Budget (OMB) control number. In accordance with the PRA, SSA is providing notice that OMB has approved the information collection requirements contained in sections 6.00C, 6.00E, 106.00C and 106.00E of these final rules. The OMB

Control Number for these collections is 0960–0642, expiring March 31, 2008.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability Insurance; 96.002, Social Security-Retirement Insurance; 96.004, Social Security-Survivors Insurance; and 96.006, Supplemental Security Income)

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: March 28, 2005.

Jo Anne B. Barnhart,

Commissioner of Social Security.

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

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

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

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

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

■ 2. Appendix 1 to subpart P of part 404 is amended as follows:

■ a. Item 7 of the introductory text before part A of appendix 1 is amended by revising the body system name and expiration date.

■ b. The Table of Contents for part A of appendix 1 is amended by revising the body system name for section 6.00.

■ c. Section 6.00 of part A of appendix 1 is revised.

■ d. The Table of Contents for part B of appendix 1 is amended by revising the body system name for section 106.00.

■ e. Section 106.00 of part B of appendix 1 is revised.

The revised text is set forth as follows:

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

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7. Genitourinary Impairments (6.00 and 106.00): September 6, 2013.

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Part A

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6.00 Genitourinary Impairments

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6.00 Genitourinary Impairments

A. What impairments do these listings cover?

1. We use these listings to evaluate genitourinary impairments resulting from chronic renal disease.

2. We use the criteria in 6.02 to evaluate renal dysfunction due to any chronic renal disease, such as chronic glomerulonephritis, hypertensive renal vascular disease, diabetic nephropathy, chronic obstructive uropathy, and hereditary nephropathies.

3. We use the criteria in 6.06 to evaluate nephrotic syndrome due to glomerular disease.

B. What do we mean by the following terms in these listings?

1. *Anasarca* is generalized massive edema (swelling).

2. *Creatinine* is a normal product of muscle metabolism.

3. *Creatinine clearance test* is a test for renal function based on the rate at which creatinine is excreted by the kidney.

4. *Diastolic hypertension* is elevated diastolic blood pressure.

5. *Fluid overload syndrome* associated with renal disease occurs when there is excessive sodium and water retention in the body that cannot be adequately removed by the diseased kidneys. Symptoms and signs of vascular congestion may include fatigue, shortness of breath, hypertension, congestive heart failure, accumulation of fluid in the abdomen (ascites) or chest (pleural effusions), and peripheral edema.

6. *Glomerular disease* can be classified into two broad categories, nephrotic and nephritic. Nephrotic conditions are associated with increased urinary protein excretion and nephritic conditions are associated with inflammation of the internal structures of the kidneys.

7. *Hemodialysis,* or *dialysis,* is the removal of toxic metabolic byproducts from the blood by diffusion in an artificial kidney machine.

8. *Motor neuropathy* is neuropathy or polyneuropathy involving only the motor nerves.

9. *Nephrotic syndrome* is a general name for a group of diseases involving defective kidney glomeruli, characterized by heavy proteinuria, hypoalbuminemia, hyperlipidemia, and varying degrees of edema.

10. *Neuropathy* is a problem in peripheral nerve function (that is, in any part of the nervous system except the brain and spinal cord) that causes pain, numbness, tingling, and muscle weakness in various parts of the body.

11. *Osteitis fibrosa* is fibrous degeneration with weakening and deformity of bones.

12. *Osteomalacia* is a softening of the bones.

13. *Osteoporosis* is a thinning of the bones with reduction in bone mass resulting from the depletion of calcium and bone protein.

14. *Pathologic fractures* are fractures resulting from weakening of the bone structure by pathologic processes, such as osteomalacia and osteoporosis.

15. *Peritoneal dialysis* is a method of hemodialysis in which the dialyzing solution is introduced into and removed from the peritoneal cavity either continuously or intermittently.

16. *Proteinuria* is excess protein in the urine.

17. *Renal* means pertaining to the kidney.

18. *Renal osteodystrophy* refers to a variety of bone disorders usually caused by chronic kidney failure.

19. *Sensory neuropathy* is neuropathy or polyneuropathy that involves only the sensory nerves.

20. *Serum albumin* is a major plasma protein that is responsible for much of the plasma colloidal osmotic pressure and serves as a transport protein.

21. *Serum creatinine* is the amount of creatinine in the blood and is measured to evaluate kidney function.

C. What evidence do we need?

1. We need a longitudinal record of your medical history that includes records of treatment, response to treatment, hospitalizations, and laboratory evidence of renal disease that indicates its progressive nature. The laboratory or clinical evidence will indicate deterioration of renal function, such as elevation of serum creatinine.

2. We generally need a longitudinal clinical record covering a period of at least 3 months of observations and treatment, unless we can make a fully favorable determination or decision without it. The record should include laboratory findings, such as serum creatinine or serum albumin values, obtained on more than one examination over the 3-month period.

3. When you are undergoing dialysis, we should have laboratory findings showing your renal function before you started dialysis.

4. The medical evidence establishing the clinical diagnosis of nephrotic syndrome must include a description of the extent of edema, including pretibial, periorbital, or presacral edema. The medical evidence should describe any ascites, pleural effusion, or pericardial effusion. Levels of serum albumin and proteinuria must be included.

5. If a renal biopsy has been performed, the evidence should include a copy of the report of the microscopic examination of the specimen. However, if we do not have a copy of the microscopic examination in the evidence, we can accept a statement from an acceptable medical source that a biopsy was performed, with a description of the results.

D. How do we consider the effects of treatment?

We consider factors such as the:
1. Type of therapy.
2. Response to therapy.
3. Side effects of therapy.
4. Effects of any post-therapeutic residuals.
5. Expected duration of treatment.

E. What other things do we consider when we evaluate your chronic renal disease under specific listings?

1. *Chronic hemodialysis or peritoneal dialysis* (6.02A). A report from an acceptable medical source describing the chronic renal disease and the need for ongoing dialysis is sufficient to satisfy the requirements in 6.02A.

2. *Kidney transplantation* (6.02B). If you have undergone kidney transplantation, we will consider you to be disabled for 12 months following the surgery because, during the first year, there is a greater likelihood of rejection of the organ and recurrent infection. After the first year posttransplantation, we will base our continuing disability evaluation on your residual impairment(s). We will include absence of symptoms, signs, and laboratory findings indicative of kidney dysfunction in our consideration of whether medical improvement (as defined in §§ 404.1579(b)(1) and (c)(1), 404.1594(b)(1) and (c)(1), 416.994(b)(1)(i) and (b)(2)(i), or 416.994a, as appropriate) has occurred. We will consider the:
a. Occurrence of rejection episodes.
b. Side effects of immunosuppressants, including corticosteroids.
c. Frequency of any renal infections.
d. Presence of systemic complications such as other infections, neuropathy, or deterioration of other organ systems.

3. *Renal osteodystrophy* (6.02C1). This condition is bone deterioration resulting from chronic renal disease. The resultant bone disease includes the impairments described in 6.02C1.

4. *Persistent motor or sensory neuropathy* (6.02C2). The longitudinal clinical record must show that the neuropathy is a ''severe'' impairment as defined in §§ 404.1520(c) and 416.920(c) that has lasted or can be expected to last for a continuous period of at least 12 months.

5. *Nephrotic syndrome* (6.06). The longitudinal clinical record should include a description of prescribed therapy, response to therapy, and any side effects of therapy. In order for your nephrotic syndrome to meet 6.06A or B, the medical evidence must document that you have the appropriate laboratory findings required by these listings and that your anasarca has persisted for at least 3 months despite prescribed therapy. However, we will not delay adjudication if we can make a fully favorable determination or decision based on the evidence in your case record. We may also evaluate complications of your nephrotic syndrome, such as orthostatic hypotension, recurrent infections, or venous thromboses, under the appropriate listing for the resultant impairment.

F. What does the term ''persistent'' mean in these listings?

Persistent means that the longitudinal clinical record shows that, with few exceptions, the required finding(s) has been at, or is expected to be at, the level specified in the listing for a continuous period of at least 12 months.

G. How do we evaluate impairments that do not meet one of the genitourinary listings?

1. These listings are only examples of common genitourinary impairments that we consider severe enough to prevent you from doing any gainful activity. If your severe impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that satisfies the criteria of a listing in another body system.

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. (See §§ 404.1526 and 416.926.) If you have a severe impairment(s) that does not meet or medically equal the criteria of a listing, you may or may not have the residual functional capacity to engage in substantial gainful activity. Therefore, we proceed to the fourth and, if necessary, the fifth steps of the sequential evaluation process in §§ 404.1520 and 416.920. When we decide whether you continue to be disabled, we use the rules in §§ 404.1579(b)(1) and (c)(1), 404.1594(b)(1) and (c)(1), 416.994(b)(1)(i) and (b)(2)(i), or 416.994a, as appropriate.

6.01 Category of Impairments, Genitourinary Impairments

6.02 *Impairment of renal function*, due to any chronic renal disease that has lasted or can be expected to last for a continuous period of at least 12 months. With:

A. *Chronic hemodialysis or peritoneal dialysis* (see 6.00E1).

or

B. *Kidney transplantation.* Consider under a disability for 12 months following surgery; thereafter, evaluate the residual impairment (see 6.00E2).

or

C. *Persistent elevation of serum creatinine* to 4 mg per deciliter (dL) (100 ml) or greater or *reduction of creatinine clearance* to 20 ml per minute or less, over at least 3 months, with one of the following:

1. Renal osteodystrophy (see 6.00E3) manifested by severe bone pain and appropriate medically acceptable imaging demonstrating abnormalities such as osteitis fibrosa, significant osteoporosis, osteomalacia, or pathologic fractures; or

2. Persistent motor or sensory neuropathy (see 6.00E4); or

3. Persistent fluid overload syndrome with:

a. Diastolic hypertension greater than or equal to diastolic blood pressure of 110 mm Hg; or

b. Persistent signs of vascular congestion despite prescribed therapy (see 6.00B5); or

4. Persistent anorexia with recent weight loss and current weight meeting the values in 5.08, table III or IV.

6.06 *Nephrotic syndrome,* with anasarca, persisting for at least 3 months despite prescribed therapy (see 6.00E5). With:

A. Serum albumin of 3.0 g per dL (100 ml) or less and proteinuria of 3.5 g or greater per 24 hours.

or

B. Proteinuria of 10.0 g or greater per 24 hours.

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Part B

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106.00 Genitourinary Impairments

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106.00 Genitourinary Impairments

A. What impairments do these listings cover?

1. We use these listings to evaluate genitourinary impairments resulting from chronic renal disease and congenital genitourinary disorders.

2. We use the criteria in 106.02 to evaluate renal dysfunction due to any

chronic renal disease, such as chronic glomerulonephritis, hypertensive renal vascular disease, diabetic nephropathy, chronic obstructive uropathy, and hereditary nephropathies.

3. We use the criteria in 106.06 to evaluate nephrotic syndrome due to glomerular disease.

4. We use the criteria in 106.07 to evaluate congenital genitourinary impairments such as ectopic ureter, extrophic urinary bladder, urethral valves, and neurogenic bladder.

B. What do we mean by the following terms in these listings?

1. *Anasarca* is generalized massive edema (swelling).

2. *Creatinine* is a normal product of muscle metabolism.

3. *Creatinine clearance test* is a test for renal function based on the rate at which creatinine is excreted by the kidney.

4. *Glomerular disease* can be classified into two broad categories, nephrotic and nephritic. Nephrotic conditions are associated with increased urinary protein excretion and nephritic conditions are associated with inflammation of the internal structures of the kidneys.

5. *Hemodialysis,* or *dialysis,* is the removal of toxic metabolic byproducts from the blood by diffusion in an artificial kidney machine.

6. *Nephrotic syndrome* is a general name for a group of diseases involving defective kidney glomeruli, characterized by heavy proteinuria, hypoalbuminemia, hyperlipidemia, and varying degrees of edema.

7. *Neuropathy* is a problem in peripheral nerve function (that is, in any part of the nervous system except the brain and spinal cord) that causes pain, numbness, tingling, and muscle weakness in various parts of the body.

8. *Parenteral antibiotics* refer to the administration of antibiotics by intravenous, intramuscular, or subcutaneous injection.

9. *Peritoneal dialysis* is a method of hemodialysis in which the dialyzing solution is introduced into and removed from the peritoneal cavity either continuously or intermittently.

10. *Proteinuria* is excess protein in the urine.

11. *Renal* means pertaining to the kidney.

12. *Serum albumin* is a major plasma protein that is responsible for much of the plasma colloidal osmotic pressure and serves as a transport protein.

13. *Serum creatinine* is the amount of creatinine in the blood and is measured to evaluate kidney function.

C. What evidence do we need?

1. We need a longitudinal record of your medical history that includes records of treatment, response to treatment, hospitalizations, and laboratory evidence of renal disease that indicates its progressive nature or of congenital genitourinary impairments that documents their recurrent or episodic nature. The laboratory or clinical evidence will indicate deterioration of renal function, such as elevation of serum creatinine, or changes in genitourinary function, such as episodes of electrolyte disturbance.

2. We generally need a longitudinal clinical record covering a period of at least 3 months of observations and treatment, unless we can make a fully favorable determination or decision without it. The record should include laboratory findings, such as serum creatinine or serum albumin values, obtained on more than one examination over the 3-month period.

3. When you are undergoing dialysis, we should have laboratory findings showing your renal function before you started dialysis.

4. The medical evidence establishing the clinical diagnosis of nephrotic syndrome must include a description of the extent of edema, including pretibial, periorbital, or presacral edema. The medical evidence should describe any ascites, pleural effusion, or pericardial effusion. Levels of serum albumin and proteinuria must be included.

5. If a renal biopsy has been performed, the evidence should include a copy of the report of the microscopic examination of the specimen. However, if we do not have a copy of the microscopic examination in the evidence, we can accept a statement from an acceptable medical source that a biopsy was performed, with a description of the results.

6. The medical evidence documenting congenital genitourinary impairments should include treating physician records, operative reports, and hospital records. It should describe the frequency of your episodes, prescribed treatment, laboratory findings, and any surgical procedures performed.

D. How do we consider the effects of treatment?

We consider factors such as the:

1. Type of therapy.

2. Response to therapy.

3. Side effects of therapy.

4. Effects of any post-therapeutic residuals.

5. Expected duration of treatment.

E. What other things do we consider when we evaluate your genitourinary impairment under specific listings?

1. *Chronic hemodialysis or peritoneal dialysis* (106.02A). A report from an acceptable medical source describing the chronic renal disease and the need for ongoing dialysis is sufficient to satisfy the requirements in 106.02A.

2. *Kidney transplantation* (106.02B). If you have undergone kidney transplantation, we will consider you to be disabled for 12 months following the surgery because, during the first year, there is a greater likelihood of rejection of the organ and recurrent infection. After the first year posttransplantation, we will base our continuing disability evaluation on your residual impairment(s). We will include absence of symptoms, signs, and laboratory findings indicative of kidney dysfunction in our consideration of whether medical improvement (as defined in §§ 404.1594(b)(1) and (c)(1) and 416.994a, as appropriate) has occurred. We will consider the:

a. Occurrence of rejection episodes.

b. Side effects of immunosuppressants, including corticosteroids.

c. Frequency of any renal infections.

d. Presence of systemic complications such as other infections, neuropathy, or deterioration of other organ systems.

3. *Nephrotic syndrome* (106.06). The longitudinal clinical record should include a description of prescribed therapy, response to therapy, and any side effects of therapy. In order for your nephrotic syndrome to meet 106.06A or B, the medical evidence must document that you have the appropriate laboratory findings required by these listings and that your anasarca has persisted for at least 3 months despite prescribed therapy. However, we will not delay adjudication if we can make a fully favorable determination or decision based on the evidence in your case record. We may also evaluate complications of your nephrotic syndrome, such as orthostatic hypotension, recurrent infections, or venous thromboses, under the appropriate listing for the resultant impairment.

4. *Congenital genitourinary impairments* (106.07).

a. Each of the listings in 106.07 requires a longitudinal clinical record showing that at least three events have occurred within a consecutive 12-month period with intervening periods of improvement. *Events* include urologic surgical procedures, hospitalizations, and treatment with parenteral antibiotics. To meet the requirements of

these listings, there must be at least 1 month (that is, 30 days) between the events in order to ensure that we are evaluating separate episodes.

b. Diagnostic cystoscopy does not satisfy the requirement for repeated urologic surgical procedures in 106.07A.

c. In 106.07B, *systemic infection* means an infection requiring an initial course of parenterally administered antibiotics occurring at least once every 4 months or at least 3 times a year.

d. In 106.07C, appropriate laboratory and clinical evidence document electrolyte disturbance. Hospitalizations are inpatient hospitalizations for 24 hours or more.

F. What does the term ''persistent'' mean in these listings?

Persistent means that the longitudinal clinical record shows that, with few exceptions, the required finding(s) has been at, or is expected to be at, the level specified in the listing for a continuous period of at least 12 months.

G. How do we evaluate impairments that do not meet one of the genitourinary listings?

1. These listings are only examples of common genitourinary impairments that we consider severe enough to prevent you from doing any gainful activity or that result in marked and severe functional limitations. If your severe impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that satisfies the criteria of a listing in another body system.

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing, or, in the case of a claim for SSI payments, functionally equals the listings. (See §§ 404.1526, 416.926, and 416.926a.) When we decide whether a child receiving SSI payments continues to be disabled, we use the rules in § 416.994a.

106.01 Category of Impairments, Genitourinary Impairments

106.02 *Impairment of renal function,* due to any chronic renal disease that has lasted or can be expected to last for a continuous period of at least 12 months. With:

A. *Chronic hemodialysis or peritoneal dialysis* (see 106.00E1).

or

B. *Kidney transplantation.* Consider under a disability for 12 months following surgery; thereafter, evaluate the residual impairment (see 106.00E2).

or

C. *Persistent elevation of serum creatinine* to 3 mg per deciliter (dL) (100 ml) or greater, over at least 3 months.

or

D. *Reduction of creatinine clearance* to 30 ml per minute (43 liters/24 hours) per 1.73 m2 of body surface area over at least 3 months.

106.06 *Nephrotic syndrome,* with anasarca, persisting for at least 3 months despite prescribed therapy. (See 106.00E3.) With:

A. Serum albumin of 2.0 g/dL (100 ml) or less.

or

B. Proteinuria of 40 mg/m2/hr or greater.

106.07 *Congenital genitourinary impairments* (see 106.00E4) resulting in one of the following:

A. Repeated urologic surgical procedures, occurring at least 3 times in a consecutive 12-month period.

or

B. Documented episodes of systemic infection requiring an initial course of parenteral antibiotics, occurring at least 3 times in a consecutive 12-month period (see 106.00E4).

or

C. Hospitalization (see 106.00E4d) for episodes of electrolyte disturbance, occurring at least 3 times in a consecutive 12-month period.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD08–05–042]

Drawbridge Operation Regulations; Back Bay of Biloxi, Biloxi, Harrison County, MS

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eighth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Popps Ferry Road Bascule Span Bridge across the Back Bay of Biloxi, mile 8.0, at Biloxi, Harrison County, Mississippi. This deviation allows the north bascule span of the bridge to remain closed to navigation for twelve hours on July 26, 2005 with an alternate date of August 2, 2005 in case of inclement weather. This temporary deviation is necessary for the replacement of the hydraulic hoses of the drawbridge operating system.

DATES: This deviation is effective from 7:30 a.m. on Tuesday, July 26, 2005 through 7:30 p.m. on Tuesday, August 2, 2005.

ADDRESSES: Materials referred to in this document are available for inspection or copying at the office of the Eighth Coast Guard District, Bridge Administration Branch, Hale Boggs Federal Building, room 1313, 500 Poydras Street, New Orleans, Louisiana 70130–3310 between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (504) 589–2965. The Bridge Administration Branch of the Eighth Coast Guard District maintains the public docket for this temporary deviation.

FOR FURTHER INFORMATION CONTACT: Phil Johnson, Bridge Administration Branch, telephone (504) 589–2965.

SUPPLEMENTARY INFORMATION: The City of Biloxi has requested a temporary deviation in order to replace 24 hydraulic hoses of the north bascule span of the Popps Ferry Road Bridge across the Back Bay of Biloxi, mile 8.0 at Biloxi, Harrison County, Mississippi. This temporary deviation will allow the north bascule span of the bridge to remain in the closed-to-navigation position from 7:30 a.m. to 7:30 p.m. on Tuesday, July 26, 2005 with an alternate date of Tuesday, August 2, 2005 in case of inclement weather. For vessels that do not require the full channel width to safely pass through the bridge, the south bascule span will continue to open on signal, except that it need not open from 7:30 a.m. to 9 a.m. and from 4:30 p.m. to 6 p.m. as provided for in 33 CFR 117.675(c).

The bridge has a vertical clearance of 25 feet above mean high water, elevation 0.8 feet Mean Sea Level and 26.6 feet above mean low water, elevation −0.8 feet Mean Sea Level in the closed-to-navigation position. It has a horizontal clearance of 180 feet between bascule span tips while in the open-to-navigation position, normal to the channel axis. When the south bascule span is in the open-to-navigation position and the north span remains in the closed-to-navigation position, 90 feet of horizontal clearance will be available between the north bascule span tip and the south fender facing. Navigation at the site of the bridge consists mainly of tows with barges and some recreational vessels including sailing vessels. Many of the vessels that currently require an opening of the draw will be able to pass through the bridge with only the south bascule span open. Due to prior