

We do not have information at this point on the quantity of bananas that the Philippines expects to ship to the State of Hawaii or to the U.S. territories, or the quantity and origin of bananas already imported into these destinations. However, Hawaii as well as the U.S. territories, already import bananas from other places since the volume of banana consumption is greater than their production. In general, the quantity of U.S. imports from the Philippines is expected to be relatively insignificant, equivalent to about 0.05 percent of U.S. imports from other countries. What percent would go to Hawaii depends on the demand from the consumers in the State of Hawaii and in the other U.S. territories. Consumers in Hawaii and the U.S. territories would benefit from the additional source of fresh bananas, which are of similar quality as the domestic ones.

#### Executive Order 12988

This final rule allows bananas to be imported into Guam, Hawaii, and the Northern Mariana Islands from the Philippines. State and local laws and regulations regarding bananas imported under this rule will be preempted while the fruit is in foreign commerce. Fresh fruits are generally imported for immediate distribution and sale to the consuming public, and remain in foreign commerce until sold to the ultimate consumer. The question of when foreign commerce ceases in other cases must be addressed on a case-by-case basis. No retroactive effect will be given to this rule, and this rule will not require administrative proceedings before parties may file suit in court challenging this rule.

#### National Environmental Policy Act

An environmental assessment (EA) and finding of no significant impact were prepared in 2012 for a final rule for importation of bananas from the Philippines into the continental United States. The EA provided a basis for the conclusion that the importation of bananas from the Philippines into the continental United States, under the conditions specified in that rule, would not have a significant impact on the quality of the human environment. APHIS reviewed the proposal to import bananas from the Philippines into Guam, Hawaii, and the Northern Mariana Islands under the conditions specified in this rule, and determined that this will not have a significant impact on the quality of the human environment. APHIS prepared an amended finding of no significant impact, and the Administrator of the

Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

The 2012 EA and amended finding of no significant impact were prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*); (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508); (3) USDA regulations implementing NEPA (7 CFR part 1b); and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The EA and amended finding of no significant impact may be viewed on the Regulations.gov Web site (see footnote 1). Copies of the EA and amended finding of no significant impact are also available for public inspection at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect copies are requested to call ahead on (202) 799-7039 to facilitate entry into the reading room. In addition, copies may be obtained by writing to the individual listed under **FOR FURTHER INFORMATION CONTACT**.

#### Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this final rule, which were filed under 0579-0415, have been submitted for approval to the Office of Management and Budget (OMB). When OMB notifies us of its decision, if approval is denied, we will publish a document in the **Federal Register** providing notice of what action we plan to take.

#### E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2727.

#### List of Subjects in 7 CFR Part 319

Coffee, Cotton, Fruits, Imports, Logs, Nursery stock, Plant diseases and pests, Quarantine, Reporting and

recordkeeping requirements, Rice, Vegetables.

Accordingly, we are amending 7 CFR part 319 as follows:

#### PART 319—FOREIGN QUARANTINE NOTICES

■ 1. The authority citation for part 319 continues to read as follows:

**Authority:** 7 U.S.C. 450, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

■ 2. Section 319.56–58 is amended as follows:

- a. The introductory text is revised;
- b. In paragraph (c), the date “February 9, 2015” is removed and the date “November 10, 2016” is added in its place;
- c. In paragraph (h)(2), in the second sentence, the words “introductory text of this section” are removed and the words “operational workplan required by paragraph (a)(1) of this section” are added in their place; and
- d. In the OMB citation at the end of the section, the words “number 0579–0394” are removed and the words “numbers 0579–0394 and 0579–0415” are added in their place.

The revision reads as follows:

#### § 319.56–58 Bananas from the Philippines.

Bananas (*Musa* spp., which include *M. acuminata* cultivars and *M. acuminata* x *M. balbisiana* hybrids) may be imported into the continental United States, Guam, Hawaii, and the Northern Mariana Islands from the Philippines only under the conditions described in this section.

\* \* \* \* \*

Done in Washington, DC, this 6th day of October 2014.

**Kevin Shea,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 2014–24246 Filed 10–9–14; 8:45 am]

**BILLING CODE 3410-34-P**

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#### SOCIAL SECURITY ADMINISTRATION

#### 20 CFR Part 404

[Docket No. SSA–2009–0038]

RIN 0960–AH03

#### Revised Medical Criteria for Evaluating Genitourinary Disorders

**AGENCY:** Social Security Administration.

**ACTION:** Final rules.

**SUMMARY:** These final rules revise the criteria in the Listing of Impairments (listings) that we use to evaluate cases

involving genitourinary disorders in adults and children under titles II and XVI of the Social Security Act (Act). The revisions reflect our program experience and address adjudicator questions we have received since we last comprehensively revised this body system in 2005.

**DATES:** These rules are effective December 9, 2014.

**FOR FURTHER INFORMATION CONTACT:** Cheryl A. Williams, Office of Medical Policy, Social Security Administration, 6401 Security Boulevard, Baltimore, Maryland 21235-6401, (410) 965-1020. 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:**

**Background**

We are making final the rules for evaluating genitourinary disorders that we proposed in a notice of proposed rulemaking (NPRM) we published in the *Federal Register* on February 4, 2013 at 78 FR 7695. The preamble to the NPRM provides the background for these revisions. You can view the preamble to the NPRM by visiting <http://www.regulations.gov> and searching for document “SSA-2009-0038-0005.” We are making a number of changes in response to public comments to the NPRM, which we explain below.

**Why are we revising the listings for evaluating genitourinary disorders?**

We are revising the listings for evaluating genitourinary disorders to update the medical criteria, clarify how we evaluate genitourinary disorders, and address adjudicator questions.

**Public Comments**

In the NPRM, we provided the public with a 60-day comment period, which ended on April 5, 2013. We received six comments. The comments came from members of the public, disability adjudicators, and a national association representing disability examiners in the State agencies that make disability determinations for us.

We carefully considered all of the comments. We have tried to summarize the commenters' views accurately and respond to all of the significant issues raised by the commenters that were within the scope of these rules. Some 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.

*Comment:* One commenter asked if we would require the estimated glomerular filtration rate (eGFR) to be adjusted for race and sex. The commenter also suggested that we establish an eGFR calculator to calculate the eGFR for the criterion in proposed 6.05A.

*Response:* We did not adopt this comment. The eGFR is a calculated value based on the measured serum creatinine. The formulas used by laboratories to calculate eGFR all include adjustments for age, race, and sex. We will use the eGFR value as calculated by the laboratory and will not independently calculate eGFR. Thus, we will not develop a calculator for eGFR.

*Comment:* Another commenter noted that the weight loss criterion in proposed listing 6.05B4 (body mass index (BMI) of 18.0 or less) is not consistent with the weight loss criterion in listing 5.08 (BMI of less than 17.5) and suggested that we change the criterion for consistency.

*Response:* We did not adopt this comment. We believe it is appropriate to use a different BMI criterion for listing 6.05B4 than we use in listing 5.08. The criterion in listing 6.05B4 considers the severity of a person's underlying chronic kidney disease (CKD) and its effect on his or her nutrition and metabolic status. People with CKD are unable to maintain adequate weight due to decreased dietary protein intake and decreased dietary energy intake, which are hallmarks of kidney failure. People with CKD may have an increased prevalence of protein energy malnutrition. Furthermore, listing 5.08 requires a lower BMI because the listing considers only weight loss due to any digestive disorder. Listing 5.08 does not consider the severity of the individual's underlying digestive disorder.

In listing 5.08, we require BMI of less than 17.5 calculated on at least two evaluations, at least 60 days apart, within a consecutive 6-month period. In final listing 6.05B4, we require the same number of BMI evaluations within a consecutive 12-month period. We are using the consecutive 12-month period to be consistent with the 12-month duration requirement.<sup>1</sup> The 12-month period is also consistent with the period we use when we evaluate hospitalizations due complications of a genitourinary disorder in 6.09 and 106.09.

*Comment:* One commenter expressed concern about proposed listing 6.09, regarding how to explain “CKD complications requiring hospitalizations versus hospitalizations due to a group of

co-morbid conditions, including CKD.” The same commenter also suggested that we add guidance in the introductory text to address acute worsening of CKD during hospitalizations for co-occurring conditions.

*Response:* We agree with the comment and provided clarification regarding CKD complications in final listings 6.00C8 and 106.00C5.

*Comment:* A commenter suggested revisions to proposed listing 106.07 requesting a 24-month period with 3 surgeries for childhood genitourinary disorders instead of 3 surgeries within 12-month period.

*Response:* We are not adopting this comment because using a 12-month period for evaluating an impairment is an intrinsic part of our basic definition of disability.<sup>2</sup> We consider the combinations of impairments and limitations in functioning at step 3 of the sequential evaluation process, using our medical equivalence and functional equivalence rules.<sup>3</sup> We recognize that some children who have multiple surgeries for genitourinary impairments may have limitations in functioning that last longer. In such cases, we evaluate those limitations under our medical equivalence and functional equivalence rules.

*Comment:* One commenter stated that there are undefined and poorly defined terms in the genitourinary listings. The commenter said these terms included “frequent,” “intractable,” “interferes,” “anasarca,” “anorexia,” and “severe bone pain.”

*Response:* We partially adopted this comment. We provide brief definitions for several medical terms when we first use the terms in the introductory text of these final listings. We define anasarca in 6.00C6 and 106.00C3; anorexia in 6.00C7; and “severe bone pain” and “intractable” in 6.00C3. We have not provided definitions for the terms “frequent” and “interferes.” We use these two terms in our definition of “severe bone pain” and use them in their common English usage.

*Comment:* A commenter stated that there are no listings for combinations of impairments. The commenter stated that the NPRM includes only single genitourinary disorders and leaves out many important combinations of disorders. Examples that the commenter provided included severe CKD not requiring dialysis and coronary artery disease; peripheral neuropathy and

<sup>2</sup> See 42 U.S.C. 423(d)(1)(a) and (d)(2)(a), and 1382c(a)(3)(A) and 20 CFR 404.1505, 404.1509, 416.905, 416.906, and 416.909.

<sup>3</sup> See 20 CFR 416.926 and 416.926a(a).

<sup>1</sup> 20 CFR 404.1509 and 416.909.

generalized edema; and fluid overload and coronary artery disease. The commenter also noted “a complete lack of listings that consider obesity.”

*Response:* We did not adopt this comment. We recognize that genitourinary disorders may co-occur with impairments in other body systems. In some cases, the impairment in another body system results from a genitourinary disorder; for example, peripheral neuropathy resulting from CKD. In other cases, the impairment in another body system is not related to the genitourinary disorder; for example, peripheral neuropathy resulting from diabetes mellitus.

We intend the listings to address genitourinary disorders and the complications of those disorders. When the co-occurring condition or complication is due to a genitourinary disorder, we evaluate it under final listing 6.09. However, when the co-occurring impairments are unrelated, we believe it is more appropriate to evaluate the combination under our medical equivalence rule at step 3 of the sequential evaluation process, or at steps 4 and 5 of the sequential evaluation process.<sup>4</sup> At these steps, adjudicators can account for specific combinations of impairments, complications of those impairments, and limitations of functioning on an individual case basis. We address this in the introductory text of final listing 6.00C8.

*Comment:* A commenter noted that we provide no quantitative data to show the validity of any of our genitourinary proposed listings and noted that many people engage in substantial gainful activity (SGA) even though they meet the requirements of a listing. The commenter believes that this challenges the validity of using the listings to determine whether a person is disabled.

*Response:* We disagree with this comment. Our NPRM included an extensive list of medical and other references that we relied on in proposing these rules. We also invited the public to comment on these references and the data contained within them.

The listings help to ensure that determinations or decisions of disability have a sound medical basis, that claimants receive equal treatment throughout the country, and that we can readily identify the majority of persons who are disabled. The level of severity described in the listings is such that an individual, whom is not engaging in SGA and has an impairment that meets or medically equals all of the criteria of

the listing, is generally considered unable to work because of the medical impairment alone at step three of the sequential evaluation process. Thus, when such a person’s impairment or combination of impairments meets or medically equals the level of severity described in the listing for the required duration, disability will be found on the basis of the medical facts alone in the absence of evidence to the contrary, for example, the actual performance of SGA.

*Comment:* A commenter stated that the proposed criteria discriminate against the poor because they include medical tests that people cannot afford and that we will not purchase, such as kidney or bone biopsies, imaging studies, and 24-hour urine protein tests. The same commenter also stated that requirements, such as 90 consecutive days of prescribed therapy, urologic surgical procedures, and hospitalization, discriminate against people who cannot afford treatment, and suggested that we delete the requirements “[u]nless the Administration is willing to make a commitment to purchase these.”

*Response:* We did not adopt the commenter’s suggestion. People with the very serious genitourinary impairments described in these listings generally receive the kinds of diagnostic tests and treatments described in these final rules because of urgent medical need. However, we do not penalize people who do not have the kinds of medical evidence that we describe in these listings. Under our rules, we may purchase medical examinations or tests to obtain the evidence that we need, but we will not purchase diagnostic tests that involve significant risk to the person, such as kidney or bone biopsies.<sup>5</sup> Furthermore, we provide several alternatives for people with genitourinary impairments to establish that their impairment is of listing-level severity at step three of the sequential evaluation process. If the impairment is not of listing-level severity, we may find the person disabled at subsequent steps of the sequential evaluation process when considering the person’s residual functional capacity, age, education, and work experience.

*Comment:* Two commenters pointed out stylistic and technical editorial issues in the preamble and the proposed rules.

*Response:* We have made appropriate corrections in these final rules.

### Other Changes

In addition to the changes we made in response to public comments, we revised 6.00C1 and 106.00C1 to clarify the documentation requirement for hemodialysis or peritoneal dialysis.

### What is our authority to make rules and set procedures for determining whether a person is disabled under the statutory definition?

The Act authorizes us to make rules and regulations and to establish necessary and appropriate procedures to implement them.<sup>6</sup>

### How long will these final rules be effective?

These final rules will remain in effect for 5 years after the date they become effective, unless we extend them, or revise and issue them again.

### Regulatory Procedures

#### Executive Order 12866, as Supplemented by Executive Order 13563

We consulted with the Office of Management and Budget (OMB) and determined that these final rules meet the criteria for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563 and was reviewed by OMB.

### Regulatory Flexibility Act

We certify that these final rules will not have a significant economic impact on a substantial number of small entities because they affect individuals only. Therefore, the Regulatory Flexibility Act, as amended, does not require us to prepare a regulatory flexibility analysis.

### Paperwork Reduction Act

These final rules do not create any new or affect any existing collections and, therefore, do not require OMB approval under the Paperwork Reduction Act.

(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

<sup>4</sup> See 20 CFR 404.1526 and 416.926.

<sup>5</sup> See 20 CFR 404.1519m and 416.919m.

<sup>6</sup> 42 U.S.C. 405(a), 902(a)(5), and 1383(d)(1).

insurance, Reporting and recordkeeping requirements, Social Security.

Carolyn W. Colvin,

Acting Commissioner of Social Security.

For the reasons set out in the preamble, we are amending 20 CFR part 404, subpart P as set forth below:

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

**Subpart P—Determining Disability and Blindness**

■ 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), (i), and (j), 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), (i), and (j), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189; sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

- 2. Amend appendix 1 to subpart P of part 404 by:
  - a. Revising item 7 of the introductory text before part A;
  - b. In part A:
    - i. Revising the body system name for section 6.00 in the table of contents; and
    - ii. Revising section 6.00;
  - c. In part B:
    - i. Revising the body system name for section 106.00 in the table of contents; and
    - ii. Revising section 106.00.

The revisions read as follows:

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

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7. Genitourinary Disorders (6.00 and 106.00): December 9, 2019.

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*Part A*

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6.00 Genitourinary Disorders.

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**6.00 GENITOURINARY DISORDERS**

*A. Which disorders do we evaluate under these listings?*

We evaluate genitourinary disorders resulting in chronic kidney disease (CKD). Examples of such disorders include chronic glomerulonephritis, hypertensive nephropathy, diabetic nephropathy, chronic obstructive uropathy, and hereditary nephropathies. We also evaluate nephrotic syndrome due to glomerular dysfunction under these listings.

*B. What evidence do we need?*

1. We need evidence that documents the signs, symptoms, and laboratory findings of your CKD. This evidence should include reports of clinical examinations, treatment records, and documentation of your response

to treatment. Laboratory findings, such as serum creatinine or serum albumin levels, may document your kidney function. We generally need evidence covering a period of at least 90 days unless we can make a fully favorable determination or decision without it.

2. *Estimated glomerular filtration rate (eGFR).* The eGFR is an estimate of the filtering capacity of the kidneys that takes into account serum creatinine concentration and other variables, such as your age, gender, and body size. If your medical evidence includes eGFR findings, we will consider them when we evaluate your CKD under 6.05.

3. *Kidney or bone biopsy.* If you have had a kidney or bone biopsy, we need a copy of the pathology report. When we cannot get a copy of the pathology report, we will accept a statement from an acceptable medical source verifying that a biopsy was performed and describing the results.

*C. What other factors do we consider when we evaluate your genitourinary disorder?*

1. *Chronic hemodialysis or peritoneal dialysis.*

a. Dialysis is a treatment for CKD that uses artificial means to remove toxic metabolic byproducts from the blood. Hemodialysis uses an artificial kidney machine to clean waste products from the blood; peritoneal dialysis uses a dialyzing solution that is introduced into and removed from the abdomen (peritoneal cavity) either continuously or intermittently. Under 6.03, your ongoing dialysis must have lasted or be expected to last for a continuous period of at least 12 months. To satisfy the requirements in 6.03, we will accept a report from an acceptable medical source that describes your CKD and your current dialysis, and indicates that your dialysis will be ongoing.

b. If you are undergoing chronic hemodialysis or peritoneal dialysis, your CKD may meet our definition of disability before you started dialysis. We will determine the onset of your disability based on the facts in your case record.

2. *Kidney transplant.*

a. If you receive a kidney transplant, we will consider you to be disabled under 6.04 for 1 year from the date of transplant. After that, we will evaluate your residual impairment(s) by considering your post-transplant function, any rejection episodes you have had, complications in other body systems, and any adverse effects related to ongoing treatment.

b. If you received a kidney transplant, your CKD may meet our definition of disability before you received the transplant. We will determine the onset of your disability based on the facts in your case record.

3. *Renal osteodystrophy.* This condition is the bone degeneration resulting from chronic kidney disease—mineral and bone disorder (CKD—MBD). CKD—MBD occurs when the kidneys are unable to maintain the necessary levels of minerals, hormones, and vitamins required for bone structure and function. Under 6.05B1, “severe bone pain” means frequent or intractable (resistant to treatment) bone pain that interferes with physical activity or mental functioning.

4. *Peripheral neuropathy.* This disorder results when the kidneys do not adequately filter toxic substances from the blood. These toxins can adversely affect nerve tissue. The resulting neuropathy may affect peripheral motor or sensory nerves, or both, causing pain, numbness, tingling, and muscle weakness in various parts of the body. Under 6.05B2, the peripheral neuropathy must be a severe impairment. (See §§ 404.1520(c), 404.1521, 416.920(c), and 416.921 of this chapter.) It must also have lasted or be expected to last for a continuous period of at least 12 months.

5. *Fluid overload syndrome.* This condition occurs when excess sodium and water retention in the body due to CKD results in vascular congestion. Under 6.05B3, we need a description of a physical examination that documents signs and symptoms of vascular congestion, such as congestive heart failure, pleural effusion (excess fluid in the chest), ascites (excess fluid in the abdomen), hypertension, fatigue, shortness of breath, or peripheral edema.

6. *Anasarca* (generalized massive edema or swelling). Under 6.05B3 and 6.06B, we need a description of the extent of edema, including pretibial (in front of the tibia), periorbital (around the eyes), or presacral (in front of the sacrum) edema. We also need a description of any ascites, pleural effusion, or pericardial effusion.

7. *Anorexia (diminished appetite) with weight loss.* Anorexia is a frequent sign of CKD and can result in weight loss. We will use body mass index (BMI) to determine the severity of your weight loss under 6.05B4. (BMI is the ratio of your measured weight to the square of your measured height.) The formula for calculating BMI is in section 5.00G.

8. *Complications of CKD.* The hospitalizations in 6.09 may be for different complications of CKD. Examples of complications from CKD that may result in hospitalization include stroke, congestive heart failure, hypertensive crisis, or acute kidney failure requiring a short course of hemodialysis. If the CKD complication occurs during a hospitalization that was initially for a co-occurring condition, we will evaluate it under our rules for determining medical equivalence. (See §§ 404.1526 and 416.926 of this chapter.) We will evaluate co-occurring conditions, including those that result in hospitalizations, under the listings for the affected body system or under our rules for medical equivalence.

*D. How do we evaluate disorders that do not meet one of the genitourinary listings?*

1. The listed disorders are only examples of common genitourinary disorders that we consider severe enough to prevent you from doing any gainful activity. If your 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 of this

chapter.) Genitourinary disorders may be associated with disorders in other body systems, and we consider the combined effects of multiple impairments when we determine whether they medically equal a listing. If your impairment(s) 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. We proceed to the fourth and, if necessary, the fifth steps of the sequential evaluation process in §§ 404.1520 and 416.920 of this chapter. We use the rules in §§ 404.1594 and 416.994 of this chapter, as appropriate, when we decide whether you continue to be disabled.

#### 6.01 Category of Impairments, Genitourinary Disorders

6.03 *Chronic kidney disease*, with chronic hemodialysis or peritoneal dialysis (see 6.00C1).

6.04 *Chronic kidney disease*, with kidney transplant. Consider under a disability for 1 year following the transplant; thereafter, evaluate the residual impairment (see 6.00C2).

6.05 *Chronic kidney disease*, with impairment of kidney function, with A and B:

A. Reduced glomerular filtration evidenced by one of the following laboratory findings documented on at least two occasions at least 90 days apart during a consecutive 12-month period:

1. Serum creatinine of 4 mg/dL or greater; or
2. Creatinine clearance of 20 ml/min. or less; or
3. Estimated glomerular filtration rate (eGFR) of 20 ml/min/1.73m<sup>2</sup> or less.

AND

B. One of the following:

1. Renal osteodystrophy (see 6.00C3) with severe bone pain and imaging studies documenting bone abnormalities, such as osteitis fibrosa, osteomalacia, or pathologic fractures; or

2. Peripheral neuropathy (see 6.00C4); or

3. Fluid overload syndrome (see 6.00C5) documented by one of the following:

a. Diastolic hypertension greater than or equal to diastolic blood pressure of 110 mm Hg despite at least 90 consecutive days of prescribed therapy, documented by at least two measurements of diastolic blood pressure at least 90 days apart during a consecutive 12-month period; or

b. Signs of vascular congestion or anasarca (see 6.00C6) despite at least 90 consecutive days of prescribed therapy, documented on at least two occasions at least 90 days apart during a consecutive 12-month period; or

4. Anorexia with weight loss (see 6.00C7) determined by body mass index (BMI) of 18.0 or less, calculated on at least two occasions at least 90 days apart during a consecutive 12-month period.

6.06 *Nephrotic syndrome*, with A and B:

A. Laboratory findings as described in 1 or 2, documented on at least two occasions at least 90 days apart during a consecutive 12-month period:

1. Proteinuria of 10.0 g or greater per 24 hours; or
2. Serum albumin of 3.0 g/dL or less, and

a. Proteinuria of 3.5 g or greater per 24 hours; or

b. Urine total-protein-to-creatinine ratio of 3.5 or greater.

AND

B. Anasarca (see 6.00C6) persisting for at least 90 days despite prescribed treatment.

6.09 *Complications of chronic kidney disease* (see 6.00C8) requiring at least three hospitalizations within a consecutive 12-month period and occurring at least 30 days apart. Each hospitalization must last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization.

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#### Part B

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106.00 Genitourinary Disorders.  
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#### 106.00 GENITOURINARY DISORDERS

*A. Which disorders do we evaluate under these listings?*

We evaluate genitourinary disorders resulting in chronic kidney disease (CKD). Examples of such disorders include chronic glomerulonephritis, hypertensive nephropathy, diabetic nephropathy, chronic obstructive uropathy, and hereditary nephropathies. We also evaluate nephrotic syndrome due to glomerular dysfunction, and congenital genitourinary disorders, such as ectopic ureter, exstrophic urinary bladder, urethral valves, and Eagle-Barrett syndrome (prune belly syndrome), under these listings.

#### *B. What evidence do we need?*

1. We need evidence that documents the signs, symptoms, and laboratory findings of your CKD. This evidence should include reports of clinical examinations, treatment records, and documentation of your response to treatment. Laboratory findings, such as serum creatinine or serum albumin levels, may document your kidney function. We generally need evidence covering a period of at least 90 days unless we can make a fully favorable determination or decision without it.

2. *Estimated glomerular filtration rate (eGFR)*. The eGFR is an estimate of the filtering capacity of the kidneys that takes into account serum creatinine concentration and other variables, such as your age, gender, and body size. If your medical evidence includes eGFR findings, we will consider them when we evaluate your CKD under 106.05.

3. *Kidney or bone biopsy*. If you have had a kidney or bone biopsy, we need a copy of the pathology report. When we cannot get a copy of the pathology report, we will accept a statement from an acceptable medical source verifying that a biopsy was performed and describing the results.

C. What other factors do we consider when we evaluate your genitourinary disorder?

1. *Chronic hemodialysis or peritoneal dialysis*.

a. Dialysis is a treatment for CKD that uses artificial means to remove toxic metabolic byproducts from the blood. Hemodialysis

uses an artificial kidney machine to clean waste products from the blood; peritoneal dialysis uses a dialyzing solution that is introduced into and removed from the abdomen (peritoneal cavity) either continuously or intermittently. Under 106.03, your ongoing dialysis must have lasted or be expected to last for a continuous period of at least 12 months. To satisfy the requirement in 106.03, we will accept a report from an acceptable medical source that describes your CKD and your current dialysis, and indicates that your dialysis will be ongoing.

b. If you are undergoing chronic hemodialysis or peritoneal dialysis, your CKD may meet our definition of disability before you started dialysis. We will determine the onset of your disability based on the facts in your case record.

#### 2. *Kidney transplant*.

a. If you receive a kidney transplant, we will consider you to be disabled under 106.04 for 1 year from the date of transplant. After that, we will evaluate your residual impairment(s) by considering your post-transplant function, any rejection episodes you have had, complications in other body systems, and any adverse effects related to ongoing treatment.

b. If you received a kidney transplant, your CKD may meet our definition of disability before you received the transplant. We will determine the onset of your disability based on the facts in your case record.

3. *Anasarca* (generalized massive edema or swelling). Under 106.06B, we need a description of the extent of edema, including pretibial (in front of the tibia), periorbital (around the eyes), or presacral (in front of the sacrum) edema. We also need a description of any ascites, pleural effusion, or pericardial effusion.

4. *Congenital genitourinary disorder*. Procedures such as diagnostic cystoscopy or circumcision do not satisfy the requirement for urologic surgical procedures in 106.07.

5. *Complications of CKD*. The hospitalizations in 106.09 may be for different complications of CKD. Examples of complications from CKD that may result in hospitalization include stroke, congestive heart failure, hypertensive crisis, or acute kidney failure requiring a short course of hemodialysis. If the CKD complication occurs during a hospitalization that was initially for a co-occurring condition, we will evaluate it under our rules for determining medical equivalence. (See § 416.926 of this chapter.) We will evaluate co-occurring conditions, including those that result in hospitalizations, under the listings for the affected body system or under our rules for medical equivalence.

*D. How do we evaluate disorders that do not meet one of the genitourinary listings?*

1. The listed disorders are only examples of common genitourinary disorders that we consider severe enough to result in marked and severe functional limitations. If your 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 § 416.926 of this chapter.) Genitourinary disorders may be associated with disorders in other body systems, and we consider the combined effects of multiple impairments when we determine whether they medically equal a listing. If your impairment(s) does not medically equal a listing, we will also consider whether it functionally equals the listings. (See § 416.926a of this chapter.) We use the rules in § 416.994a of this chapter when we decide whether you continue to be disabled.

106.01 Category of Impairments, Genitourinary Disorders

106.03 *Chronic kidney disease*, with chronic hemodialysis or peritoneal dialysis (see 106.00C1).

106.04 *Chronic kidney disease*, with kidney transplant. Consider under a disability for 1 year following the transplant; thereafter, evaluate the residual impairment (see 106.00C2).

106.05 *Chronic kidney disease*, with impairment of kidney function, with one of the following documented on at least two occasions at least 90 days apart during a consecutive 12-month period:

A. Serum creatinine of 3 mg/dL or greater;  
OR

B. Creatinine clearance of 30 ml/min/1.73m<sup>2</sup> or less;

OR

C. Estimated glomerular filtration rate (eGFR) of 30 ml/min/1.73m<sup>2</sup> or less.

106.06 *Nephrotic syndrome*, with A and B:

A. Laboratory findings as described in 1 or 2, documented on at least two occasions at least 90 days apart during a consecutive 12-month period:

1. Serum albumin of 3.0 g/dL or less, or
2. Proteinuria of 40 mg/m<sup>2</sup>/hr or greater;

AND

B. Anasarca (see 106.00C3) persisting for at least 90 days despite prescribed treatment.

106.07 *Congenital genitourinary disorder* (see 106.00C4) requiring urologic surgical procedures at least three times in a consecutive 12-month period, with at least 30 days between procedures. Consider under a disability for 1 year following the date of the last surgery; thereafter, evaluate the residual impairment.

106.09 *Complications of chronic kidney disease* (see 106.00C5) requiring at least three hospitalizations within a consecutive 12-month period and occurring at least 30 days apart. Each hospitalization must last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization.

\* \* \* \* \*

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## DEPARTMENT OF STATE

### 22 CFR Parts 120, 121, 123, 126, and 130

[Public Notice 8898]

RIN 1400-AD64

#### Amendment to the International Traffic in Arms Regulations: Corrections, Clarifications, and Movement of Definitions

**AGENCY:** Department of State.

**ACTION:** Final rule.

**SUMMARY:** In an effort to streamline, simplify and clarify the recent revisions to the International Traffic in Arms Regulations (ITAR) made pursuant to the President's Export Control Reform (ECR) initiative, the Department of State is amending the ITAR as part of the Department of State's retrospective plan under Executive Order 13563 completed on August 17, 2011.

**DATES:** This rule is effective October 10, 2014.

**FOR FURTHER INFORMATION CONTACT:** Mr. C. Edward Peartree, Director, Office of Defense Trade Controls Policy, Department of State, telephone (202) 663-2792; email [DDTCResponseTeam@state.gov](mailto:DDTCResponseTeam@state.gov). ATTN: Regulatory Change, Omnibus Clarifications. The Department of State's full retrospective plan can be accessed at <http://www.state.gov/documents/organization/181028.pdf>.

#### SUPPLEMENTARY INFORMATION:

##### Changes in this Rule

The following changes are made to the ITAR with this final rule: (1) Definitions previously provided in §§ 121.3, 121.4, 121.14, and 121.15 are removed from these sections and incorporated into U.S. Munitions List Categories VIII, VII, XX, and VI, respectively; (2) USML Category II is amended to clarify that grenade launchers are controlled in paragraph (a) as a result of the revisions previously made to USML Category IV pursuant to Export Control Reform; (3) USML Category IX is amended to enumerate military training not directly related to a defense article, which is a controlled activity pursuant to ITAR § 120.9(a)(3). This change is required in order to provide exporters a USML category to cite for military training when not related to a defense article; (4) The note to paragraph (b) in the specially designed definition is revised to clarify that catch-all controls are only those that generically control parts, components, accessories, and attachments for a specified article and do not identify a specific specially

designed part, component, accessory, or attachment. This revision is intended to help ensure that exporters properly apply ITAR § 120.41 when classifying their article and clarify that when a specific article is described on the USML, it is enumerated and is not part of a catch-all; (5) The definitions previously provided in ITAR § 121.8 are removed to new ITAR § 120.45; (6) The policy with regard to when forgings, castings, and machined bodies are controlled as defense articles is removed from ITAR § 121.10 and placed in ITAR § 120.6; (7) The threshold for lithium-ion batteries controlled in Category VIII(h)(13) is increased from greater than 28 volts of direct current (VDC) nominal to greater than 38 VDC nominal, so as not to control on the USML such batteries in normal commercial aviation use; (8) A control for specially designed parts, components, accessories, and attachments is added to the helmets controlled in Category VIII(h)(15); (9) The phrase "electric-generating" is added to the control describing fuel cells in Category VIII(h)(23) to clarify that fuel bladders and fuel tanks are not within this control; (10) The word "enumerated" is replaced with the word "described" in the paragraphs of the USML for technical data and defense services directly related to the defense articles in that Category to clarify that the controls on technical data and defense services apply even if the defense article is described in a catch-all; (11) Conforming changes are made to citations throughout these sections; and (12) Minor reference corrections are made to Supplement No. 1 to Part 126, including moving the footnote to the entire Supplement from the end to the opening to better clarify if an item is excluded from eligibility in any row, it is excluded from that exemption, even if also described in another row that contains a description that may also include that item.

#### Regulatory Analysis and Notices

##### *Administrative Procedure Act*

The Department of State is of the opinion that controlling the import and export of defense articles and services is a foreign affairs function of the United States Government and that rules implementing this function are exempt from 5 U.S.C. 553 and 554.

##### *Regulatory Flexibility Act*

Since the Department is of the opinion that this rule is exempt from the provisions of 5 U.S.C. 553, there is no requirement for an analysis under the Regulatory Flexibility Act.