*Where:*

$L_{L,A}$ = value as defined in section 11.2.7 of ASHRAE 103–1993

$L_G$ = value as defined in section 11.3.11.1 of ASHRAE 103–1993 at reduced input rate,

$L_C$ = value as defined in section 11.3.11.2 of ASHRAE 103–1993 at reduced input rate,

$L_J$ = value as defined in section 11.4.8.1.1 of ASHRAE 103–1993 at maximum input rate,

$t_{ON}$ = value as defined in section 11.4.9.11 of ASHRAE 103–1993,

$Q_P$ = pilot flame fuel input rate determined in accordance with section 9.2 of ASHRAE 103–1993 in Btu/h

$Q_{IN}$ = value as defined in section 11.4.8.1.1 of ASHRAE 103–1993,

$t_{OFF}$ = value as defined in section 11.4.9.12 of ASHRAE 103–1993 at reduced input rate,

$L_{S,ON}$ = value as defined in section 11.4.10.5 of ASHRAE 103–1993 at reduced input rate,

$L_{S,OFF}$ = value as defined in section 11.4.10.6 of ASHRAE 103–1993 at reduced input rate,

$L_{I,ON}$ = value as defined in section 11.4.10.7 of ASHRAE 103–1993 at reduced input rate,

$L_{I,OFF}$ = value as defined in section 11.4.10.8 of ASHRAE 103–1993 at reduced input rate,

$C_J$ = jacket loss factor and equal to:

= 0.0 for furnaces or boilers intended to be installed indoors

= 1.7 for furnaces intended to be installed as isolated combustion systems

= 2.4 for boilers (other than finned-tube boilers) intended to be installed as isolated combustion systems

= 3.3 for furnaces intended to be installed outdoors

= 4.7 for boilers (other than finned-tube boilers) intended to be installed outdoors

= 1.0 for finned-tube boilers intended to be installed outdoors

= 0.5 for finned-tube boilers intended to be installed in ICS applications

$L_{S,SS}$ = value as defined in section 11.5.6 of ASHRAE 103–1993 at reduced input rate,

$C_S$ = value as defined in section 11.5.10.1 of ASHRAE 103–1993 at reduced input rate.

10. 3 *Part-Load Efficiency at Maximum Fuel Input Rate.* Calculate the part-load efficiency at maximum fuel input rate, $Effy_{U,H}$, for condensing furnace and boilers equipped with two-stage controls, expressed as a percent and defined as:

$$Effy_{U,H} = 100 - L_{L,A} + L_G - L_C - C_J L_J - \left[\frac{t_{ON}}{t_{ON} + \left(\frac{Q_P}{Q_{IN}}\right) t_{OFF}}\right] x \left(L_{S,ON} + L_{S,OFF} + L_{I,ON} + L_{I,OFF}\right)$$

If the option in section 9.10 of ASHRAE 103–1993 (incorporated by reference, see § 430.3) is employed:

$$Effy_{U,R} = 100 - L_{L,A} + L_G - L_C - C_J L_J - \left[\frac{t_{ON}}{t_{ON} + \left(\frac{Q_P}{Q_{IN}}\right) t_{OFF}}\right] (C_S)(L_{S,SS})$$

*Where:*

$L_{L,A}$ = value as defined in section 11.2.7 of ASHRAE 103–1993,

$L_G$ = value as defined in section 11.3.11.1 of ASHRAE 103–1993 at maximum input rate,

$L_C$ = value as defined in section 11.3.11.2 of ASHRAE 103–1993 at maximum input rate,

$L_J$ = value as defined in section 11.4.8.1.1 of ASHRAE 103–1993 at maximum input rate,

$t_{ON}$ = value as defined in section 11.4.9.11 of ASHRAE 103–1993 of ASHRAE 103–1993,

$Q_P$ = pilot flame fuel input rate determined in accordance with section 9.2 of ASHRAE 103–1993 in Btu/h,

$Q_{IN}$ = value as defined in section 11.4.8.1.1 of ASHRAE 103–1993,

$t_{OFF}$ = value as defined in section 11.4.9.12 of ASHRAE 103–1993 at maximum input rate,

$L_{S,ON}$ = value as defined in section 11.4.10.5 of ASHRAE 103–1993 at maximum input rate,

$L_{S,OFF}$ = value as defined in section 11.4.10.6 of ASHRAE 103–1993 at maximum input rate,

$L_{I,ON}$ = value as defined in section 11.4.10.7 of ASHRAE 103–1993 at maximum input rate,

$L_{I,OFF}$ = value as defined in section 11.4.10.8 of ASHRAE 103–1993 at maximum input rate,

$C_J$ = value as defined in section 10.2 of this appendix,

$L_{S,SS}$ = value as defined in section 11.5.6 of ASHRAE 103–1993 at maximum input rate,

$C_S$ = value as defined in section 11.5.10.1 of ASHRAE 103–1993 at maximum input rate.

* * * * *

[FR Doc. 2013–02168 Filed 2–1–13; 8:45 am]

**BILLING CODE 6450–01–P**

## 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:** Notice of proposed rulemaking.

**SUMMARY:** We propose to revise the criteria in the Listing of Impairments (listings) that we use to evaluate claims involving genitourinary disorders in adults and children under titles II and XVI of the Social Security Act (Act). The proposed revisions reflect our program experience, advances in methods of evaluating genitourinary disorders, and comments we received in response to an advance notice of proposed rulemaking (ANPRM).

**DATES:** To ensure that your comments are considered, we must receive them by no later than April 5, 2013.

**ADDRESSES:** You may submit comments by any one of three methods—Internet, fax, or mail. Do not submit the same comments multiple times or by more than one method. Regardless of which method you choose, please state that your comments refer to Docket No. SSA–2009–0038 so that we may associate your comments with the correct regulation.

*Caution:* You should be careful to include in your comments only information that you wish to make publicly available. We strongly urge you not to include in your comments any personal information, such as Social Security numbers or medical information.

1. *Internet:* We strongly recommend that you submit your comments via the Internet. Please visit the Federal eRulemaking portal at *http://www.regulations.gov*. Use the *Search* function to find docket number SSA–2009–0038. The system will issue you a tracking number to confirm your submission. You will not be able to view your comment immediately because we must post each comment manually. It may take up to a week for your comment to be viewable.

2. *Fax:* Fax comments to (410) 966–2830.

3. *Mail:* Address your comments to the Office of Regulations and Reports Clearance, Social Security Administration, 107 Altmeyer Building, 6401 Security Boulevard, Baltimore, Maryland 21235–6401.

Comments are available for public viewing on the Federal eRulemaking portal at *http://www.regulations.gov* or in person, during regular business hours, by arranging with the contact person identified below.

**FOR FURTHER INFORMATION CONTACT:** Cheryl A. Williams, Office of Medical Listings Improvement, 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:**

**Why are we proposing to revise this body system?**

We last published final rules making comprehensive revisions to genitourinary body system listings on July 5, 2005.[1] These listings are scheduled to expire on September 6, 2013.[2] We published an ANPRM on November 10, 2009, in which we invited interested people and organizations to send us written comments and suggestions about whether and how we should revise these listings.[3] We are now proposing to update the medical criteria in the listings to reflect our program experience and to address adjudicator questions and public comments that we have received since 2005.

**What revisions are we proposing?**

We propose to:

- Revise the name of the body system from ''Genitourinary Impairments'' to ''Genitourinary Disorders'';
- Reorganize and revise the introductory text for the adult listings (section 6.00) and the childhood listings (section 106.00);
- Reorganize, revise, and rename adult listing 6.02 and childhood listing 106.02 for impairment of renal function;
- Add a listing criterion for evaluating chronic kidney disease (CKD), with impairment of kidney function, in adults (6.05) and in children (106.05);
- Reorganize and revise adult listing 6.06 and childhood listing 106.06 for nephrotic syndrome;
- Add an adult listing (6.09) for evaluating complications of CKD requiring hospitalizations; and
- Reorganize and revise childhood listing 106.07 for congenital genitourinary disorders.

**Why are we proposing to change the name of this body system?**

We propose to change the name of this body system from ''Genitourinary Impairments'' to ''Genitourinary Disorders'' to make it consistent with our names for other body systems. We have re-named other body systems to include the word ''disorders'' as we revise them, and the name change we are proposing in this NPRM is consistent with that approach.

**What changes are we proposing to the introductory text of the genitourinary adult listings?**

The following chart provides a comparison of the current introductory text for adults and the proposed introductory text:

| Current introductory text | Proposed introductory text |
|---|---|
| 6.00A *What impairments do these listings cover?* | 6.00A *Which disorders do we evaluate under these listings?* |
| 6.00B *What do we mean by the following terms in these listings?* | Removed. |
| 6.00C *What evidence do we need?* | 6.00B *What evidence do we need?* |
| 6.00D *How do we consider the effects of treatment?* | Removed. |
| 6.00E *What other things do we consider when we evaluate your chronic renal disease under specific listings?* | 6.00C *What other factors do we consider when we evaluate your chronic kidney disease?* |
| 6.00F *What does the term ''persistent'' mean in these listings?* | Removed. |
| 6.00G *How do we evaluate impairments that do not meet one of the genitourinary listings?* | 6.00D *How do we evaluate disorders that do not meet one of the genitourinary listings?* |

As the chart illustrates, we are proposing to make minor revisions to terms in the introductory text (for example, changing the word ''impairment'' to ''disorder,'' where appropriate) and to reorganize the information in the text. We propose to replace the word ''renal'' with ''kidney'' throughout the introductory text because the medical community commonly uses the word ''kidney.'' The only exception to this proposal is that we would retain the term ''renal osteodystrophy'' because it remains a common term in the medical community.

Proposed section 6.00A corresponds to current section 6.00A and explains the disorders we evaluate under the genitourinary disorders listings.

We propose to remove current 6.00B that lists definitions because we would provide a definition, as appropriate, when we first use a term in the introductory text.

Proposed section 6.00B corresponds in part to current 6.00C and explains the evidence we need to evaluate a person's CKD. We propose to revise the text to remove redundancies and to add a description of estimated glomerular filtration rate (eGFR).

Proposed section 6.00C corresponds to part of current sections 6.00C and 6.00E. We propose to revise the text to remove redundancies and add guidance on anorexia with weight loss and on complications of CKD requiring hospitalizations.

We propose to remove current 6.00D because that section's guidance is not specific to evaluating genitourinary

[1] 70 FR 38582.

[2] In the 2005 final rules, we stated that the rules would be effective for 8 years unless we extended them or revised and issued them again.

[3] 74 FR 57970. We received three comment letters. We said in the ANPRM that we would not respond directly to the comment letters. This notice of proposed rulemaking (NPRM) does adopt some of the commenters' suggestions. You may read the comment letters at *http://www.regulations.gov* by searching under docket number SSA–2009–0038.

disorders. Only one listing, proposed 6.06, would require the presence of a particular medical finding despite treatment. We do not propose to evaluate a person's response to treatment under any other listings in this section.

We propose to remove current 6.00F because we would no longer use the term ''persistent'' in these listings. Instead, we would provide specific parameters for determining whether an impairment meets the duration requirement.

Proposed section 6.00D corresponds to current section 6.00G. We propose to make minor editorial changes to the way that we cite regulations in the current section by removing the paragraph levels of the citations to shorten them.

**What changes are we proposing to the genitourinary listings for adults?**

The following chart provides a comparison of the current listings for adults and the proposed listings:

| Current listing | Proposed listing |
|---|---|
| 6.02 *Impairment of renal function* | 6.02 Removed.<br>6.03 *Chronic kidney disease,* with chronic hemodialysis or peritoneal dialysis.<br>6.04 *Chronic kidney disease,* with kidney transplant.<br>6.05 *Chronic kidney disease,* with impairment of kidney function. |
| 6.06 *Nephrotic syndrome* | 6.06 *Nephrotic syndrome.*<br>6.09 *Complications of chronic kidney disease.* |

We propose to revise current listing 6.02 by making each of the three criteria a separate listing. We believe that this revision would improve our ability to monitor claims involving CKD. It would also improve our ability to schedule continuing disability reviews because the timing of these reviews is different for each of the three criteria. We also propose to replace the term ''impairment of renal function'' in the listing title with ''chronic kidney disease.''

Proposed listing 6.03 and 6.04 correspond to current listings 6.02A and 6.02B, respectively. We are not proposing any changes to the current criteria.

Proposed listing 6.05 corresponds to current listing 6.02C. We propose to restructure the listing to clarify the requirements in the current listing.

We propose to add a criterion to proposed listing 6.05A3 for estimated glomerular filtration rate (eGFR). The glomerular filtration rate (GFR) is the best overall measure of kidney function; however, it is difficult to measure directly. Most clinicians who treat CKD use the eGFR instead of the GFR to determine the severity of a person's CKD and to make decisions about the course of treatment. The eGFR values will likely be readily available in the medical records for people with CKD.

We would replace the criterion for ''[p]ersistent motor or sensory neuropathy'' in current 6.02C2 with ''[p]eripheral neuropathy'' in proposed 6.05B2. People with CKD develop neuropathy at a later stage of the disease than they once did because of advances in CKD treatment. We do not need to replace ''persistent'' with a criterion based on a defined period of time because when neuropathy develops at a later stage of CKD, it is invariably persistent.

We would replace the criterion for ''[p]ersistent'' in current 6.02C3 with a criterion based on a defined period of time to evaluate hypertension (proposed 6.05B3a), vascular congestion (proposed 6.05B3b), and anorexia (proposed 6.05B4).

Proposed listing 6.06 for nephrotic syndrome corresponds to current listing 6.06. We propose to restructure the listing to clarify the requirements in the current listing. We would add a criterion for the urine total-protein-to-creatinine ratio (a laboratory calculation based on total protein and creatinine in a urine sample). This ratio is an alternative to the 24-hour measurement in 6.06A2a and is widely used in the clinical community to monitor proteinuria.

We propose to add listing 6.09 to evaluate complications of CKD that require periodic hospitalization. We would require a person to have at least three hospitalizations occurring at least 30 days apart to ensure that we are evaluating separate complication events. Each hospitalization must last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization. We would require that each hospitalization last at least 48 hours because we believe this period is indicative of a severe complication of CKD. We would include the hours the person spends in the emergency department immediately before hospital admission because the person is likely to be receiving the same intensity of care as he or she will receive in the hospital. We would also require that these three hospitalizations occur within a consecutive 12-month period, consistent with our rules in other body systems.

**What changes are we proposing to the introductory text of the genitourinary listings for children?**

The following chart provides a comparison of the current introductory text for children and the proposed introductory text:

| Current introductory text | Proposed introductory text |
|---|---|
| 106.00A *What impairments do these listings cover?* | 106.00A *Which disorders do we evaluate under these listings?* |
| 106.00B *What do we mean by the following terms in these listings?* | Removed. |
| 106.00C *What evidence do we need?* | 106.00B *What evidence do we need?* |
| 106.00D *How do we consider the effects of treatment?* | Removed. |
| 106.00E *What other things do we consider when we evaluate your genitourinary impairment under specific listings?* | 106.00C *What other factors do we consider when we evaluate your genitourinary disorder?* |
| 106.00F *What does the term ''persistent'' mean in these listings?* | Removed. |
| 106.00G *How do we evaluate impairments that do not meet one of the genitourinary listings?* | 106.00D *How do we evaluate disorders that do not meet one of the genitourinary listings?* |

The same basic rules for evaluating genitourinary disorders in adults apply to children. Except for minor editorial changes to make the text specific to children, we propose to repeat much of the introductory text of proposed 6.00 in the introductory text of proposed 106.00.

**What changes are we proposing to the genitourinary listings for children?**

The following chart provides a comparison of the current listings for children and the proposed listings:

| Current listing | Proposed listing |
|---|---|
| 106.02 *Impairment of renal function* | 106.02 Removed.<br>106.03 *Chronic kidney disease,* with chronic hemodialysis or peritoneal dialysis.<br>106.04 *Chronic kidney disease,* with kidney transplant.<br>106.05 *Chronic kidney disease,* with impairment of kidney function |
| 106.06 *Nephrotic syndrome* | 106.06 *Nephrotic syndrome.* |
| 106.07 *Congenital genitourinary impairments* | 106.07 *Congenital genitourinary disorder.*<br>106.09 *Complications of chronic kidney disease.* |

The proposed childhood genitourinary listings are designated 106.03 through 106.07 and 106.09. They have the same headings as their counterparts in the proposed adult listings, except for proposed 106.07, which does not have an adult counterpart.

The criteria we propose for children are the same as, or based on, the current childhood genitourinary criteria. Many of the proposed changes to the childhood listings correspond to the changes we propose to make in the adult listing. Since we have already described these proposed changes above, we describe here only those changes that are unique to children or that require further explanation.

Proposed listing 106.05 for CKD with impairment of kidney function incorporates the criteria in current 106.02C and 106.02D. We would revise the current requirement that a finding is present ''over at least 3 months.'' We would require, instead, that the finding is present ''on at least two occasions at least 90 days apart during a consecutive 12-month period.'' This proposed revision corresponds to our proposal to replace the word ''persistent'' in the adult listings. The proposed revision is also consistent with our rules in other body systems.

In proposed 106.06 for nephrotic syndrome, we would change the required serum albumin level from ''2.0 g/dL (100 ml) or less'' to 3.0 g/dL or less. We are proposing this change so that the childhood criterion is consistent with the corresponding adult criterion.

We propose to revise current 106.07 by creating two listings: proposed 106.07 and proposed 106.09.

Proposed 106.07 for congenital genitourinary disorder corresponds to current 106.07A. We would incorporate the guidance in current 106.00E4 by adding a requirement that a child must have at least three urological surgical procedures occurring in a consecutive 12-month period, with at least 30 days between procedures. We would also add a criterion that would consider a child disabled for 1 year from the date of the last urological surgery. Our program experience has shown that children who have had these surgeries need a period of 1 year before we can evaluate any remaining limitations resulting from the impairment.

Proposed 106.09 for complications of CKD corresponds to current 106.07B and 106.07C. We would expand our consideration of complications to include other types of CKD complications that require hospitalization. Current 106.07B does not require hospitalization. We propose to add a hospitalization requirement in proposed 106.09 for consistency with the adult criteria. We believe this change would have minimal impact on children with CKD complications because most children who require parenteral antibiotics are hospitalized for this treatment. We believe that three hospitalizations in a 12-month period establish CKD complications of listing-level severity because CKD complications that require hospitalization are generally more serious and involve longer recovery periods than those treated solely in outpatient settings.

**What time period should we use for finding disability following a kidney transplant?**

We propose to retain our current policy for a finding of disability for a period of one year following a kidney transplant. Thereafter, we consider the residual impairment, including post-transplant kidney function, any rejection episodes, adverse effects of ongoing treatment, and complications in other body systems. We are specifically interested in any comments of suggestions you have about this policy, such as whether the time period we use is appropriate, whether we should use a longer time period, and, if so, what time period we should use.

**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. Sections 205(a), 702(a)(5), and 1631(d)(1).

**How long would these proposed rules be effective?**

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

**Clarity of These Proposed Rules**

Executive Order 12866, as supplemented by Executive Order 13563, requires each agency to write all rules in plain language. In addition to your substantive comments on these proposed rules, we invite your comments on how to make them easier to understand.

For example:

- Would more, but shorter, sections be better?
- Are the requirements in the rules clearly stated?
- Have we organized the material to suit your needs?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rules easier to understand?
- Do the rules contain technical language or jargon that is not clear?
- Would a different format make the rules easier to understand, e.g., grouping and order of sections, use of headings, paragraphing?

**When will we start to use these rules?**

We will not use these rules until we evaluate public comments and publish

final rules in the **Federal Register**. All final rules we issue include an effective date. We will continue to use our current rules until that date. If we publish final rules, we will include a summary of those relevant comments we received along with responses and an explanation of how we will apply the new rules.

**Regulatory Procedures**

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

We consulted with the Office of Management and Budget (OMB) and determined that this NPRM meets the criteria for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. Therefore, OMB reviewed it.

*Regulatory Flexibility Act*

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

*Paperwork Reduction Act*

This NPRM does not create any new or affect any existing collections and, therefore, does not require Office of Management and Budget approval under the Paperwork Reduction Act.

*References*

We consulted the following references when we developed these proposed rules:


Copelovitch, L., Warady, B., & Furth, S. (2011). Insights from the Chronic Kidney Disease in Children. *Clinical Journal of the American Society of Nephrology, 6*(8), 2047–2053. doi:10.2215/CJN.10751210.

Furth, S., Abraham, A. G., Jerry-Fluker, J., Schwartz, G. J. Benfield, M., Kaskel, F., et al. (2011). Metabolic Abnormalities, Cardiovascular Disease Risk Factors, and GFR Decline in Children with Chronic Kidney Disease. *Clinical Journal of the American Society of Nephrology, 6*(9), 2132–2140. doi:10.2215/CJN.07100810.

Furth, S. L., Cole, S. R., Moxey-Mims, M., Kaskel, F., Mak, R., Schwartz, G., et al. (2006). Design and Methods of the Chronic Kidney in Children (CKiD) Prospective Cohort Study. *Clinical Journal of the American Society of Nephrology, 1*(5), 1006–1015. doi:10.2215/CJN.01941205.

Gipson, D. S., Massengill, S. F., Trachtman, H., Greenbaum, L. A., Yao, L., Nagaraj, S., et al. (2009). Management of Childhood Onset Nephrotic Syndrome. *Pediatrics, 124*(2), 747–757. doi:10.1542/peds.2008–1559.

Gordillo, R., & Sptizer, A. (2009). The Nephrotic Syndrome. *Pediatrics in Review, 30*(3), 94–105. doi:10.1542/pir.30–3–94.

Gulati, S. (2011, June 21). Chronic Kidney Disease in Children. *Medscape Reference.* Retrieved from *http://emedicine.medscape.com/article/984358-overview.*

Hogg, R., Furth, S., Eknoyan, G., Levey, A. S., Lemley, K. V., Portman, R., et al. (2003). National Kidney Foundation's Kidney Disease Outcome Quality Initiative Clinical Practice Guidelines for Chronic Kidney Disease in Children and Adolescents: Evaluation, Classification, and Stratification. *Pediatrics, 111*(6), 1416–1421. doi:10.1542/peds.111.6.1416.

Kliegman, R. M., Stanton, B. F., Schor, N. F., St. Geme III, J. W., & Behrman, R. E. (2011). *Nelson Textbook of Pediatrics* (19th ed.). Philadelphia, PA: Elsevier Saunders.

Lurbe, E., Alvarez, V., & Redon. J. (2004). Predictors of Progression in Hypertensive Renal Disease in Children. *Journal of Clinical Hypertension, 64*(4), 186–191. doi:10.1111/j.1524–6175.2004.02617.x.

Miller, W.G. (2009). Estimating Equations for Glomerular Filtration Rate in Children: Laboratory Considerations. *Clinical Chemistry, 55*(3), 402–403. doi:10.1373/clinchem.2008.122218.

National Kidney Foundation (2010). *Frequently Asked Questions About GFR Estimates.* Retrieved from: *http://www.kidney.org/professionals/kls/pdf/12-10-4004_KBB_FAQs_AboutGFR–1.pdf.*

National Kidney Foundation (2006). KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease. The Guidelines are available at: *http://www.kidney.org/professionals/kdoqi/guidelines_anemia/pdf/AnemiaInCKD.pdf.*

National Kidney Foundation (2007). KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Diabetes and Chronic Kidney Disease. These Guidelines are available at: *http://www.kidney.org/professionals/kdoqi/pdf/Diabetes_AJKD_FebSuppl_07.pdf*]

National Kidney Foundation (2005). KDOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Children with Chronic Kidney Disease. The Guidelines are available at: *http://www.kidney.org/professionals/kdoqi/guidelines_pedbone/index.htm.*

National Kidney Foundation (2003). KDOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease. The Guidelines are available at: *http://www.kidney.org/professionals/KDOQI/guidelines_bone/index.htm.*

National Kidney Foundation (2002). KDOQI Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification and Stratification. These Guidelines are available at: *http://www.kidney.org/professionals/kdoqi/pdf/ckd_evaluation_classification_stratification.pdf.*

National Kidney Foundation (2009). KDOQI Clinical Practice Guidelines for Nutrition in Children with CKD: 2008 Update. *American Journal of Kidney Diseases, 53*(Supp.2), S1–S124. doi:10.1053/S0272–6386(09)00054–7. These Guidelines are available at: *http://www.kidney.org/professionals/kdoqi/guidelines_updates/pdf/CPGPedNutr2008.pdf.*

Renal Physicians Association (2010). Shared Decision-Making in the Appropriate Initiation of and Withdrawal from Dialysis. *RPA Clinical Practice Guideline* (Second ed., pp. 121–155). Rockville, MD: Renal Physicians Association.

Vassalotti, J., Stevens, L., & Levey, A. (2007) Testing for Chronic Kidney Disease: A Position Statement from the National Kidney Foundation. *American Journal of Kidney Diseases, 50*(2), 169–180. doi:10.1053/j/ajkd.2007.06.013.


We included these references in the rulemaking record for these proposed rules and will make them available for inspection by interested individuals who make arrangements with the contact person identified above.

(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: January 25, 2013.

**Michael J. Astrue,**

*Commissioner of Social Security.*

For the reasons set out in the preamble, we propose to amend 20 CFR part 404, subpart P as set forth below:

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

### Subpart P—[Amended]

■ 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 revising item 7 of the introductory text before part A of appendix 1 to read as follows:

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

* * * * *

7. Genitourinary Disorders (6.00 and 106.00): [DATE 5 YEARS FROM THE EFFECTIVE DATE OF THE FINAL RULES].

* * * * *

■ 3. Amend part A of appendix 1 to subpart P of part 404 by revising the body system name for section 6.00 in the table of contents to read as follows:

* * * * *

**Part A**

* * * * *

6.00 Genitourinary Disorders

* * * * *

■ 4. Revise section 6.00 in part A of appendix 1 to subpart P of part 404 to read as follows:

* * * * *

**Part A**

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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. 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 chronic kidney disease. 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 chronic kidney disease 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 chronic kidney disease?*

1. *Chronic hemodialysis or peritoneal dialysis.*

a. Dialysis is a treatment for chronic kidney disease 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. We will accept a report from an acceptable medical source that describes your chronic kidney disease and the need for ongoing dialysis to satisfy the requirements in 6.03.

b. If you are undergoing chronic hemodialysis or peritoneal dialysis, your chronic kidney disease 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 chronic kidney disease 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 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 chronic kidney disease 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 with weight loss.* Anorexia is a frequent sign of chronic kidney disease 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 chronic kidney disease.* The hospitalizations in 6.09 may be for different complications of chronic kidney disease. Examples of complications that may result in hospitalization include stroke, congestive heart failure, hypertensive crisis, or acute kidney failure requiring a short course of hemodialysis.

*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$^2$ 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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■ 5. Amend part B of appendix 1 to subpart P of part 404 by revising the body system name for section 106.00 in the table of contents to read as follows:

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**Part B**

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106.00 Genitourinary Disorders

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■ 6. Revise section 106.00 in part B of appendix 1 to subpart P of part 404 to read as follows:

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**Part B**

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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. 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, exotrophic 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 chronic kidney disease. 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 chronic kidney disease 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 chronic kidney disease 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. We will accept a report from an acceptable medical source that describes your chronic kidney disease and the need for ongoing dialysis to satisfy the requirements in 106.03.

b. If you are undergoing chronic hemodialysis or peritoneal dialysis, your chronic kidney disease 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 chronic kidney disease 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 chronic kidney disease.* The hospitalizations in 106.09 may be for different complications of chronic kidney disease. Examples of complications that may result in hospitalization include stroke, congestive heart failure, hypertensive crisis, or acute kidney failure requiring a short course of hemodialysis.

*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 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$^2$ or less; or

C. Estimated glomerular filtration rate (eGFR) of 30 ml/min/1.73m$^2$ or less.

106.06 *Nephrotic syndrome,* with A and B:

A. 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 albumin of 3.0 g/dL or less, or

2. Proteinuria of 40 mg/m²/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 day 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.

[FR Doc. 2013–02166 Filed 2–1–13; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 51

**[EPA–R09–OAR–2012–0904, FRL–9775–9]**

## Partial Approval and Disapproval of Air Quality Implementation Plans; Arizona; Regional Haze and Visibility Transport; Extension of Comment Period

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice; extension of comment period.

**SUMMARY:** EPA is extending the public comment period for a proposed rule published in the **Federal Register** on December 21, 2012, with a former deadline for comments of February 4, 2013. The new deadline of March 6, 2013, will provide an additional 30 days for a total of 75 days to comment on our proposal. The proposal is to approve in part and disapprove in part a revision to Arizona's State Implementation Plan (SIP) to implement the regional haze program for the first planning period through 2018. The proposal includes all portions of the State's regional haze SIP except for three electric generating stations that were addressed in a final rule published on December 5, 2012.

**DATES:** Comments on the proposed rule published on December 21, 2012 (77 FR 75704) must be received on or before March 6, 2013.

**ADDRESSES:** You may submit comments, identified by Docket ID No. EPA–R09–OAR–2012–0904, by one of the following methods:

- *Federal Rulemaking portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Email: r9azreghaze@epa.gov.*
- *Fax:* 415–947–3579 (Attention: Gregory Nudd)
- *Mail, Hand Delivery or Courier:* Gregory Nudd, EPA Region 9, Air Division (AIR–2), 75 Hawthorne Street, San Francisco, California 94105. Hand and courier deliveries are only accepted Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays. Special arrangements should be made for deliveries of boxed information.

**FOR FURTHER INFORMATION CONTACT:** Gregory Nudd, U.S. EPA, Region 9, Planning Office, Air Division, Air-2, 75 Hawthorne Street, San Francisco, CA 94105. Gregory Nudd can be reached at telephone number (415) 947–4107 and via electronic mail at *r9azreghaze@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

### A. Instructions for Submitting Comments

EPA's policy is to include all comments received in the public docket without change. We may make comments available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be CBI or other information for which disclosure is restricted by statute. Do not submit information that you consider to be CBI or that is otherwise protected through *http://www.regulations.gov* or email. The *http://www.regulations.gov* web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA, without going through *http://www.regulations.gov,* we will include your email address as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should not include special characters or any form of encryption, and be free of any defects or viruses.

### B. Docket

The proposed rule published on December 21, 2012, relies on documents, information and data that are listed in the index on *http://www.regulations.gov* under docket number EPA–R09–OAR–2012–0904. Although listed in the index, some information is not publicly available (e.g., Confidential Business Information (CBI)). Certain other material, such as copyrighted material, is publicly available only in hard copy form. Publicly available docket materials are available either electronically at *http://www.regulations.gov* or in hard copy at the Planning Office of the Air Division, AIR–2, EPA Region 9, 75 Hawthorne Street, San Francisco, CA 94105. EPA requests that you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 9–5:00 PST, excluding Federal holidays.

### C. Submitting Confidential Business Information

Do not submit CBI to EPA through *http://www.regulations.gov* or email. Clearly mark the part or all of the information that you claim as CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, you must submit a copy of the comment that does not contain the information claimed as CBI for inclusion in the public docket. We will not disclose information so marked except in accordance with procedures set forth in 40 CFR part 2.

### D. Tips for Preparing Comments

When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (e.g., subject heading, **Federal Register** date and page number).
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.