information in accordance with section 6(b)(7) and § 1101.52 of this part.

(c) Final agency action; Commission decision. A decision of the General Counsel or the Secretariat or their designees shall be a final agency decision and shall not be appealable as of right to the Commission. However, the General Counsel or the Secretariat may in his or her discretion refer an issue to the Commission for decision.

Dated: February 14, 2014.

**Todd A. Stevenson,**

*Secretariat, Consumer Product Safety Commission.*

[FR Doc. 2014–03600 Filed 2–25–14; 8:45 am]

**BILLING CODE 6355–01–P**

## SOCIAL SECURITY ADMINISTRATION

### 20 CFR Part 404

**[Docket No. SSA–2007–0082]**

**RIN 0960–AG71**

## Revised Medical Criteria for Evaluating Human Immunodeficiency Virus (HIV) Infection and for Evaluating Functional Limitations in Immune System 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 human immunodeficiency virus (HIV) infection in adults and children under titles II and XVI of the Social Security Act (Act). We also propose to revise the introductory text of the listings that we use to evaluate functional limitations resulting from immune system disorders. The proposed revisions reflect our program experience, advances in medical knowledge, recommendations from a commissioned report and comments from medical experts and the public.

**DATES:** To ensure that your comments are considered, we must receive them by no later than April 28, 2014.

**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–2007–0082 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–2007–0082. 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 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 the listings for evaluating HIV infection?

We have not comprehensively revised the HIV infection listings, 14.08 for adults and 114.08 for children, since we first published final rules for them on July 2, 1993.[1] Although we published final rules for immune system disorders on March 18, 2008 that included changes to listings 14.08 and 114.08, the criteria in the current HIV infection listings are not substantively different from the criteria in the final rules we published in 1993.[2]

### What revisions are we proposing?

We propose to:

- Revise and expand the introductory text for evaluating HIV infection for both adults (section 14.00) and children (section 114.00);
- Revise the introductory text for evaluating functional limitations resulting from immune system disorders for adults (section 14.00);
- Remove current HIV infection listings 14.08A–J for adults;
- Add HIV infection listings 14.11A–H for adults;
- Redesignate and revise current HIV infection listing 14.08K for adults as proposed listing 14.11I;
- Remove current HIV infection listings 114.08A–K for children; and
- Add HIV infection listings 114.11A–H for children.

### How did we develop these proposed rules?

In addition to our adjudicative experience and our review of the advances in medical knowledge, treatment, and methods of evaluating HIV infection, we asked experts and the public to provide us with information that helped us develop the proposals.

We published an Advanced Notice of Proposed Rulemaking (ANPRM) in the **Federal Register** on March 18, 2008.[3] We informed the public that we were considering whether and how to update and revise the rules we use to evaluate HIV infection. We also invited interested persons and organizations to send us comments and suggestions about whether we should add, change, or remove any of the criteria in listings 14.08 and 114.08, and if so, what revisions did the commenters think we should make. We received comments from medical experts, advocates, and our adjudicators.[4]

In addition, we hosted a policy conference called ''HIV Infection in the Disability Programs'' in New York, N.Y., on September 10, 2008.[5] At this conference, we received comments and suggestions about how to update and revise our rules from professionals who work with patients with HIV infection, including physicians, medical experts, and advocates, as well as a person with HIV infection, and a mother of a child with HIV infection.

In 2009, we commissioned a report from the Institute of Medicine (IOM) of *The National Academies* on the criteria that we use to evaluate disability in persons with HIV infection. The IOM published the report, *HIV and Disability: Updating the Social Security*

[1] 58 FR 36008.

[2] 73 FR 14570.

[3] 73 FR 14409.

[4] We received seven comment letters. You may read the comment letters at *http://www.regulations.gov* under the same docket number as this notice.

[5] You can read a transcript of the policy conference at *http://www.ssa.gov/disability/SSA_HIV_Policy_Conf_Transcript.pdf*.

*Listings,* in 2010.[6] The report recommended ways to improve the utility of the HIV infection listings by improving the sensitivity and specificity of listing criteria to identify people with HIV infection who meet our definition of disability. The IOM committee reviewed the most current medical literature to determine the:

- Latest standards of care for HIV infection;
- Latest technology for the understanding of disease processes; and
- Latest science demonstrating the impact of HIV infection on patients' health and functional capacity.

Although we are not summarizing or formally responding to the comments that we received on the ANPRM or at our September 2008 policy conference, some of the changes we propose here reflect those comments.

**Would our proposal to revise the listing for evaluating HIV infection affect people who are already receiving benefits based on HIV infection?**

If these rules become final, we will not terminate any person's disability benefits solely because we have revised the listing for evaluating HIV infection, nor will we review prior allowances based on the HIV infection listing under the new rules. Unless we are otherwise required to do so (for example, by statute), we do not readjudicate previously decided cases when we revise our listings. We must periodically conduct continuing disability reviews to determine whether beneficiaries are still disabled.[7] When we do, we will not find that a person's disability has ended based on a change in a listing. In most cases, we must show that the person's impairment(s) has medically improved and that any medical improvement is ''related to the ability to work.'' [8] Even where the impairment(s) has medically improved, our regulations provide that the improvement is not ''related to the ability to work'' if it continues to meet or medically equal the ''same listing section used to make our most recent favorable decision.'' This is true even if we have deleted the listing section we used to make the most recent favorable decision.[9] When we find that medical improvement is not related to the ability to work (or, in the case of a person under age 18, the impairment still meets or medically equals the prior listing), we will find that disability continues, unless an exception to medical improvement applies.

**What changes are we proposing to the introductory text of the immune system disorders listings for adults?**

We have made one editorial change to shorten the heading in proposed 14.00F by using the commonly known abbreviation for human immunodeficiency virus, HIV.

The following is a detailed explanation of the proposed changes to the introductory text.

**Proposed Section 14.00A—What disorders do we evaluate under the immune system disorders listings?**

We propose to revise current section 14.00A4 to explain that people with HIV infection have an increased susceptibility to ''common infections'' as well as to the conditions that we describe in our HIV infection listings. We also propose to revise this section to reflect our proposal to redesignate current listing 14.08 as proposed listing 14.11.

**Proposed Section 14.00F—How do we document and evaluate HIV infection?**

We propose to update and expand the information on HIV infection that is in current section 14.00F. We also propose to remove information that is obsolete or no longer useful to our adjudicators.

We propose to revise the sentence in the introductory language of current section 14.00F to reflect the redesignation of current listing 14.08 as proposed listing 14.11.

We propose to revise current section 14.00F1 by requiring positive findings on one or more definitive laboratory tests to document HIV infection in proposed section 14.00F1a. We would no longer accept nondefinitive tests as documentation of HIV infection as the guidance in current section 14.00F1b provides. We base the guidance in the current section on the prevailing state of medical knowledge and clinical practice at the time that we published final rules in 1993. The change that we are proposing in section 14.00F1a is consistent with the current prevailing state of medical knowledge and clinical practice that requires positive findings on a definitive laboratory test(s) to diagnose HIV infection.[10]

We propose to update the information on definitive laboratory tests in current section 14.00F1a that we use to document HIV infection as follows:

- Replace the ELISA screening test in current section 14.00F1a(i) with the more inclusive and commonly used term of enzyme immunoassay (EIA) in proposed section 14.00F1a(i);
- Combine positive ''viral load'' tests in current section 14.00F1a(ii) and HIV DNA detection by polymerase chain reaction (PCR) in current section 14.00F1a(iii) under the more commonly used term of HIV nucleic acid (DNA or RNA) detection test in proposed section 14.00F1a(ii);
- Replace the descriptive language of an HIV antigen test in current section 14.00F1a(iv) with the specific term of HIV p24 antigen test in proposed section 14.00F1a(iii);
- Replace the terminology in current section 14.00F1a(v) with simpler terminology in proposed section 14.00F1a(iv) regarding HIV in viral culture; and
- Redesignate current section 14.00F1a(vi) for ''[o]ther tests that are highly specific for detection of HIV and that are consistent with the prevailing state of medical knowledge'' as proposed section 14.00F1a(v).

We propose to remove the guidance on other acceptable documentation of HIV infection in current section 14.00F1b since we would no longer accept nondefinitive laboratory tests or methods to document HIV infection. We propose to move the guidance in current section 14.00F1—that we will make every reasonable effort to obtain the results of laboratory testing—to proposed section 14.00F1b. We also explain in this section that we would not purchase laboratory testing to establish whether you have HIV infection.

We propose to add guidance in section 14.00F1c to explain what documentation we require to document a diagnosis of HIV infection when we do not have a copy of a definitive laboratory test(s).

We propose to remove the information on CD4 tests in current section 14.00F2 because it contains general information that our adjudicators do not need, is inconsistent with our proposed requirement to document HIV infection by definitive laboratory test(s), and does not reflect the CD4 count or CD4 percentage criteria in proposed listings 14.11F and 14.11G. We explain how we would use CD4 measurements in the proposed

[6] You can read the report at *http://www.nap.edu/catalog.php?record_id=12941#toc.* You can also access the report at *http://www.ssa.gov/disabilityresearch/research.htm#HIV.*

[7] §§ 404.1589 and 416.989.

[8] §§ 404.1594 and 416.994.

[9] §§ 404.1594(c)(3)(i) and 416.994(b)(2)(iv)(A). Our regulations contain a similar provision for continuing disability reviews for children eligible for SSI based on disability. See, § 416.994a(b)(2).

[10] Centers for Disease Control and Prevention. Revised surveillance case definitions for HIV infection among adults, adolescents, and children aged <18 months and for HIV infection and AIDS among children aged 18 months to <13 years — United States, 2008. *Morbidity and Mortality Weekly Report* 2008; 57(RR–10):1–8. (available at *http://www.cdc.gov/mmwr/PDF/rr/rr5710.pdf).*

listings in proposed sections 14.00F4 and 14.00F5.

We propose to redesignate and revise current section 14.00F3 as proposed section 14.00F2. For the same reason articulated in proposed section 14.00F1a for the documentation of HIV infection, we would require positive findings on definitive laboratory tests to document a manifestation of HIV infection in proposed section 14.00F2a. This change is consistent with the current prevailing state of medical knowledge and clinical practice that requires positive findings on a definitive laboratory test(s) to diagnose a manifestation of HIV infection.[11]

We propose to move the guidance in current section 14.00F3a, that we will make every reasonable effort to obtain the results of laboratory testing, to proposed section 14.00F2b. We also explain in this section that we would not purchase laboratory testing to establish whether you have a manifestation of HIV infection.

We propose to move and revise the guidance in current section 14.00F3a on how to document a manifestation of HIV infection when we do not have a copy of a definitive laboratory test(s) to proposed section 14.00F2c.

We also propose to remove the guidance on other acceptable documentation of manifestations of HIV infection in current section 14.00F3b since we would no longer accept nondefinitive laboratory tests to document manifestations of HIV infection. We also propose to remove for the same reason the guidance for other acceptable documentation in current section 14.00F3b(i) for *Pneumocystis* pneumonia, current section 14.00F3b(ii) for *Cytomegalovirus,* current section 14.00F3b(iii) for toxoplasmosis of the brain, and current section 14.00F3b(iv) for candidiasis of the esophagus.

We propose to add information in proposed section 14.00F3 about disorders connected with HIV infection that reflects proposed new listings 14.11A for multicentric Castleman disease, 14.11B for primary central nervous system lymphoma, 14.11C for primary effusion lymphoma, 14.11D for progressive multifocal leukoencephalopathy, and 14.11E for pulmonary Kaposi sarcoma.

We provide information on multicentric Castleman disease (MCD) in proposed section 14.00F3a. We explain what distinguishes MCD from localized (or unicentric) Castleman disease. We also explain what we would require to establish the diagnosis of MCD.

We provide information on primary central nervous system lymphoma (PCNSL) in proposed section 14.00F3b. We explain where it originates and what we would require to establish the diagnosis of PCNSL.

We provide information on primary effusion lymphoma (PEL) in proposed section 14.00F3c. We explain what we would require to establish the diagnosis of PEL.

We provide information on progressive multifocal leukoencephalopathy (PML) in proposed section 14.00F3d. We identify clinical findings associated with PML. We also explain what we would require to establish the diagnosis of PML.

We provide information on pulmonary Kaposi sarcoma (PKS) in proposed section 14.00F3e. We explain how this form of Kaposi sarcoma differs from other forms of the condition and what we would require to establish the diagnosis of PKS.

We propose to remove the guidance on HIV infection manifestations specific to women in current section 14.00F4 for two reasons. First, the proposed HIV infection listings do not contain criteria that are gender-specific. We would evaluate the manifestations of HIV infection using the same criteria regardless of a person's gender. Second, while we recognize that manifestations of HIV infection may still affect a person's ability to function, we believe that the guidance in the following sections instruct our adjudicators to consider signs, symptoms, and effects of treatment when evaluating the severity of a person's HIV infection and resulting functional limitations.

- Current section 14.00G5, *How we evaluate the effects of treatment for HIV infection on your ability to function.*
- Current section 14.00H, *How do we consider your symptoms, including your pain, severe fatigue, and malaise?*

We would add information in proposed section 14.00F4 that reflects proposed new listing 14.11F. We explain that we would need one measurement of the absolute CD4 count to evaluate HIV infection under the proposed listing. We explain that we would require the absolute CD4 count to occur within the period we are considering in connection with an application or continuing disability review. We also explain that if there were more than one measurement of the absolute CD4 count within this period, we would use the lowest one to evaluate HIV infection under the proposed listing.

We propose to remove the guidance in current section 14.00F5 that explains how we evaluate involuntary weight loss for the purposes of current listing 14.08H for HIV wasting syndrome. We propose to remove this listing based on recommendations from the IOM report; therefore, we would no longer need the guidance in current section 14.00F5. Our adjudicators, however, would continue to consider involuntary weight loss resulting from HIV infection under our listing for repeated manifestations of HIV infection (proposed listing 14.11I, which is redesignated from current listing 14.08K). We also propose to remove the guidance in this section, which explains that we can evaluate HIV infection affecting the digestive system under current listing 5.08. It is redundant since we have similar guidance in current section 14.00J2e.

We would add information in proposed section 14.00F5 that reflects proposed new listing 14.11G. We explain how we would use a CD4 measurement (absolute count or percentage) and either a measurement of body mass index (BMI) or hemoglobin to evaluate HIV infection under the proposed listing. We also explain that we would require the measurements of CD4 (absolute count or percentage) and BMI or hemoglobin to occur within the period we are considering in connection with an application or continuing disability review. We also explain that if there is more than one measurement of CD4 (absolute count or percentage), BMI, or hemoglobin within this period, we would use the lowest one to evaluate HIV infection under the proposed listing.

We propose to add information in new section 14.00F6 on how to evaluate complications of HIV infection requiring hospitalization under proposed listing 14.11H. We provide examples of complications that may result in hospitalization in proposed section 14.00F6a. We explain in proposed section 14.00F6b our requirements for evaluating hospitalizations under the proposed listing.

We propose to add information in new section 14.00F7 describing HIV-associated dementia (HAD). We explain that we evaluate HAD under current listing 12.02.

**Section 14.00I—How do we use the functional criteria in these listings?**

We propose to revise current section 14.00I by making a minor change to reflect the redesignation of current listing 14.08K as proposed listing 14.11I and clarifying what we mean by ''marked'' in proposed section 14.00I5.

We would remove the description of ''marked'' as ''more than moderate but less than extreme'' and replace it with an explanation based on the language

[11] *Id.*

describing the rating scale for mental disorders in current §§ 404.1520a(c)(4) and 416.920a(c)(4). This rating scale describes ''marked'' as the fourth point on a five-point rating scale. We explain that we would not require our adjudicators to use such a scale, but that ''marked'' would be the fourth point on a scale of ''no limitation, mild limitation, moderate limitation, marked limitation, and extreme limitation.'' With this guideline, it would be unnecessary to state that ''marked'' falls between ''moderate'' and ''extreme.''

**What changes are we proposing to the immune system disorders listings for adults?**

We propose to make the following changes to the HIV infection listing for adults:

- Remove current listings 14.08A–J;
- Add proposed listings 14.11A–H; and
- Redesignate and revise current listing 14.08K as proposed listing 14.11I.

We are proposing to remove current listings 14.08A–J based on our program experience, advances in medical knowledge, and recommendations from the IOM report. They are substantially the same listings that we published in 1993 and, as a result of advances in the treatment of HIV infection, some of the current listings no longer describe impairments that are of listing-level severity. This includes current HIV infection listings 14.08A, 14.08B, 14.08C, 14.08D, 14.08F, and 14.08J that the IOM report recommended we remove from the listings.

The IOM report recommended that we evaluate malignant neoplastic diseases associated with HIV infection, other than primary central nervous system lymphoma, primary effusion lymphoma, and pulmonary Kaposi sarcoma, under the malignant neoplastic diseases listings in 13.00. We, therefore, propose to remove current listing 14.008E for evaluating malignant neoplasms associated with HIV infection and to add proposed listings 14.11B for primary central nervous system lymphoma, 14.11C for primary effusion lymphoma, and 14.11E for pulmonary Kaposi sarcoma. We also propose to revise our guidance in current section 13.00A to indicate how we evaluate malignant neoplastic diseases associated with HIV infection in proposed section 13.00A.

We propose to remove current listing 14.08G for evaluating HIV encephalopathy, also known as HAD, which we would evaluate under current listing 12.02. We also propose to add the revision ''neurocognitive limitation (including dementia not meeting the criteria in 12.02)'' in proposed listing 14.11I. We would add this revision to indicate that we may consider neurocognitive limitations associated with HIV infection that do not satisfy the criteria in current listing 12.02 under proposed listing 14.11I.

We propose to remove current listings 14.08H for HIV wasting syndrome and 14.08I for diarrhea for the same reason. As noted in the IOM report, it is uncommon that these manifestations alone are predictive of disability, but they may be persistent and result in a marked level of limitation(s) in activities of daily living, maintaining social functioning, or completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace. We consider these areas of functioning under current listing 14.08K that we propose to redesignate as listing 14.11I. We therefore propose to remove current listings 14.08H and 14.08I and evaluate these manifestations under proposed listing 14.11I.

We describe proposed HIV infection listings 14.11A–I for adults below.

*Listings 14.11A–E*

*We propose to add listings for the following HIV-associated disorders:*

- Multicentric Castleman disease (14.11A);
- Primary central nervous system lymphoma (14.11B);
- Primary effusion lymphoma (14.11C);
- Progressive multifocal leukoencephalopathy (14.11D); and
- Pulmonary Kaposi sarcoma (14.11E).

Even with the advances in HIV treatment, there are people with HIV infection who continue to develop very aggressive and generally untreatable conditions. We propose, therefore, to add listings 14.11A–E for these conditions due to their aggressive nature and lack of response to treatment that result in loss of function consistent with a listing-level impairment when associated with HIV infection.

In addition to the proposed listings, we added these disorders to our list of Compassionate Allowances (CAL) conditions. CAL are a way of quickly identifying diseases and other medical conditions that invariably qualify under the Listings of Impairments based on minimal objective medical information. For more information about CAL, please visit our Web site at *http://www.ssa.gov/compassionateallowances/.*

*Listing 14.11F, Absolute CD4 Count of 50 Cells/mm³ or Less*

We propose to add listing 14.11F for absolute CD4 count of 50 cells/mm³ or less because it is predictive of disease progression, morbidity, and mortality that is consistent with a listing-level impairment when associated with HIV infection. We would require one absolute CD4 count of 50 cells/mm³ or less to satisfy this listing.

*Listing 14.11G, Absolute CD4 Count of Less Than 200 Cells/mm³, or CD4 Percentage of Less Than 14 Percent*

We propose to add listing 14.11G with criteria for specific combinations of values (either absolute CD4 count or CD4 percentage, and either BMI or hemoglobin measurement) because either of these combinations of values is indicative of a loss of function that is consistent with a listing-level impairment when associated with HIV infection. We would require only one set of values at the specified listing-level to satisfy this listing.

*Listing 14.11H, Complication(s) of HIV Infection Requiring at Least Three Hospitalizations*

We propose to add listing 14.11H to provide criteria that recognize the medical severity of complications of HIV infection that lead to at least three hospitalizations in a 12-month period. Each hospitalization would need to last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization, with at least 30 days between hospitalizations. We would require that each hospitalization last at least 48 hours because we believe this period is indicative of a severe complication of HIV infection. 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.

*Listing 14.11I, Repeated Manifestations of HIV Infection*

We propose to redesignate and revise current listing 14.08K as proposed listing 14.11I. We would revise the listing to reflect the changes that we have made in proposed listings 14.11A–H. We would also expand our guidance on manifestations we evaluate under the listing by adding ''distal sensory polyneuropathy,'' ''infections (bacterial, fungal, parasitic, or viral),'' ''lipodystrophy (lipoatrophy or lipohypertrophy),'' and ''osteoporosis'' as new examples based on recommendations from the IOM report

and our program experience. In addition, we would revise ''cognitive or other mental limitation'' used in current listing 14.08K to ''neurocognitive limitation (including dementia not meeting the criteria in 12.02).'' We would do this because it is a better description of the limitation associated with HIV infection and to indicate that we may consider neurocognitive limitations associated with HIV infection that do not satisfy the criteria in current listing 12.02 under proposed listing 14.11I.

**What changes are we proposing to the introductory text of the immune system disorders listings for children?**

The same basic rules for evaluating immune system disorders in adults also apply to children. Except for minor editorial changes to make the text specific to children, we have repeated much of the introductory text of proposed section 14.00 in the introductory text of proposed section 114.00. Since we have already described these proposed rules under the explanation of proposed section 14.00, we describe here only the significant sections of the proposed rules that are unique to children or that require further explanation.

In proposed section 114.00F1a(iii), we clarify that the HIV p24 antigen test is a definitive laboratory test for documentation of HIV infection for any child age 1 month or older.

We propose to remove current section 114.00F1a(vi) because the immunoglobulin serological assay that we list in this section is no longer used to document HIV infection.

We propose to remove current section 114.00F1b because the laboratory tests and findings described in this section no longer represent the current standard of medical practice for documenting HIV infection and have been supplanted by the laboratory tests listed in proposed section 114.00F1a.

In proposed section 114.00F4, we explain that we will require one measurement of an absolute CD4 count for children from age 5 to attainment of age 18, or CD4 percentage for children from birth to attainment of age 5, to evaluate HIV infection under proposed listing 114.11F.

We propose to add section 114.00F5. We explain we would evaluate linear growth failure under the growth impairment listing in 100.00. We also explain that if a child's growth failure does not meet or medically equal a listing in 100.00, we will consider whether the child's HIV infection meets or medically equals the criteria of a listing in another body system. We provide an example of when we would evaluate a child's HIV infection under the digestive system listing in 105.00.

We propose to move and revise the guidance in current section 114.00F4 to proposed section 114.00F7. We would remove the examples of onset and HIV manifestations at different ages in current section 114.00F4a. This information was useful when we first published the HIV infection listings in 1993. Our adjudicators, however, no longer need this information based on our extensive program experience evaluating HIV infection under our listings. We would revise the information about neurological and growth abnormalities under proposed sections 114.00F5 and 114.00F7.

We propose to redesignate and revise current section 114.00F4b as proposed section 114.00F7. We would primarily retain the information in the current section with editorial changes for clarity. We would explain, however, that the loss of acquired developmental milestones in infants and young children is also known as developmental regression. We would also explain that we evaluate developmental delays without regression under 111.00.

We would remove current section 114.00F4c because it provides information on evaluating bacterial infections under current listing 114.08A4 and pelvic inflammatory disease under current listing 114.08A5. We would no longer need this information because we are proposing to remove both of the listings.

**What changes are we proposing to the immune system disorders listings for children?**

The following is a description of the significant proposed changes to the immune system disorders listings for children when they are different from the changes we propose for adults or require additional explanation.

We propose to remove current listing 114.08H for evaluating growth disturbance with an involuntary weight loss (or failure to gain weight at an appropriate rate for age) that meets specified criteria. We would remove this listing because, as we explain in proposed section 114.00F5, we would evaluate this impairment under a growth impairment listing in 100.00 or a digestive system listing in 105.00.

We propose to remove current listing 114.08J for evaluating lymphoid interstitial pneumonia/pulmonary lymphoid hyperplasia (LIP/PLH complex). We propose to remove this listing based on the recommendation in the IOM report that LIP/PLH complex no longer describes an impairment of listing-level severity.

*Listing 114.11F, Absolute CD4 Count or CD4 Percentage*

Proposed listing 114.11F for children is similar to proposed listing 14.11F for adults, except for the CD4 percentage requirement for children from birth to the attainment of age 5. We would require a CD4 percentage in proposed listing 114.11F1 since it fluctuates less than absolute CD4 counts for children prior to the attainment of age 5 and is a more consistent and reliable measurement of immune suppression. We would require the same absolute CD4 count of 50 cells/$mm^3$ or less for children age 5 to the attainment of age 18 in proposed listing 114.11F2 as for adults in proposed 14.11F because children in that age range have CD4 counts comparable to those levels found in adults.

*Listing 114.11H, A Neurological Manifestation of HIV Infection*

We propose to redesignate and revise current listing 114.08G as proposed listing 114.11H. In proposed listing 114.11H1, we would remove ''marked delay in achieving'' developmental milestones because we evaluate infants and young children with serious developmental delays without regression under 111.00. We would also add ''documented on two examinations at least 60 days apart'' to the loss of previously acquired developmental milestones or intellectual ability (including the sudden onset of a new learning disability) in proposed listing 114.11H1. This chronicity supports the severity of a listing-level impairment.

We propose to redesignate and revise current listing 114.08G3 as proposed listing 114.11H2. We would add ''documented on two examinations at least 60 days apart'' for the same reason as in proposed listing 114.11H1.

We propose to redesignate and revise current listing 114.08G2 as proposed listing 114.11H3 for microcephaly and H4 for brain atrophy. In proposed listing 114.11H3, we change ''acquired microcephaly'' used in current listing 114.08G2 to ''microcephaly'' because ''acquired'' is unnecessary. We would evaluate any finding of microcephaly associated with HIV infection under this listing for children. We also specify the percentile of head circumference that would establish listing-level severity and add the same requirement of ''documented on two examinations at least 60 days apart'' as in the proposed listings 114.11H1 and H2 for the same reason.

In proposed listing 114.11H4, we clarify that we document brain atrophy by appropriate medically acceptable imaging.

**Why are we not proposing a listing with functional criteria for children with HIV infection?**

On August 19, 2010, we published a Notice of Proposed Rulemaking (NPRM) for evaluating mental disorders.[12] We proposed in the NPRM to remove each of the current listings in 114.00 of the immune system disorders that cross-refer to the functional criteria in current listings 112.02 and 112.12. We proposed to remove these listings without replacement, including current listing 114.08L for HIV infection.

Under current listing 114.08L, we use the functional criteria in the childhood mental disorders listings to evaluate both physical and mental limitations that result from HIV infection. Due to the changes that we are proposing in the mental disorders listing, it would no longer be appropriate to cross-refer to the criteria in them. Moreover, we may find children disabled under the Supplemental Security Income program based on functional equivalence to the listings. Functional equivalence considers their functional limitations in domains that we designed to cover all childhood physical and mental functioning.

We are not proposing a similar change to current adult listing 14.08K because it contains specific criteria for evaluating functioning without cross-referring to the mental disorders listings. We are still considering the comments that we received in response to the NPRM for evaluating mental disorders and we will address them in the final rules.

*Other Changes*

We also propose conforming changes to current sections 5.00D4a(i), 5.00D4b(i) and (ii), 105.00D4a(i), and 105.00D4b(i) and (ii) of the digestive disorders listings. We would revise these sections to clarify how comorbid disorders may affect the clinical course of viral hepatitis infection(s) and to provide information on diagnostic tests and treatments for chronic hepatitis B infections.

We also propose to revise current sections 8.00D3 and 108.00D3 of the skin disorders listings to indicate that we evaluate HIV infection under proposed listings 14.11 and 114.11.

Finally, we propose to revise current sections 13.00A and 113.00A of the malignant neoplastic diseases listings. We would revise these sections to indicate that we evaluate primary central nervous system lymphoma, primary effusion lymphoma, and pulmonary Kaposi sarcoma associated with HIV infection under proposed listings 14.11B, C, or E and 114.11B, C, or E. We also propose to evaluate all other malignant neoplasms associated with HIV infection under the current listings for the malignant neoplastic diseases body system or under proposed listings 14.11F–I and 114.11F–H of the immune system disorders body system.

**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.[13]

**How long would these 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 have 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, and was subject to OMB review.

*Regulatory Flexibility Act*

We certify that these proposed 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 proposed rules do not create any new or affect any existing collections, and therefore, do not require OMB approval under the Paperwork Reduction Act.

**References**

We consulted the following references when we developed these proposed rules. Some of the references include a DOI name. You can access a reference with a DOI name by typing the DOI name in the DOI finder at *http://dx.doi.org.*

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[12] 75 FR 51336.

[13] 42 U.S.C. 405(a), 902(a)(5), and 1383(d)(1).

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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: February 18, 2014.

**Carolyn W. Colvin,**

*Acting Commissioner of Social Security.*

For the reasons set out in the preamble, we propose to amend 20 CFR chapter III, 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 15 of the introductory text before part A;

■ b. Adding a sentence to paragraph 5.00D4a(i) of part A;

■ c. Revising paragraph 5.00D4b of part A;

■ d. Revising the last sentence of paragraph 8.00D3 of part A;

■ e. Revising paragraph 13.00A of part A;

■ f. Revising paragraphs 14.00A4, 14.00F, 14.00I1, and 14.00I5 of part A;

■ g. Removing and reserving paragraph 14.08 of part A;

■ h. Adding paragraph 14.11 to part A;

■ i. Adding a sentence to paragraph 105.00D4a(i) of part B;

■ j. Revising paragraph 105.00D4b of part B;

■ k. Revising the last sentence of paragraph 108.00D3 of part B;

■ l. Revising paragraph 113.00A of part B;

■ m. Revising paragraphs 114.00A4 and 114.00F of part B, and

■ n. Removing and reserving paragraph 114.08 of part B; and

■ o. Adding paragraph 114.11 to part B.

The revisions and additions read as follows:

## APPENDIX 1 TO SUBPART P OF PART 404—LISTING OF IMPAIRMENTS

* * * * *

15. Immune System Disorders (14.00 and 114.00): [date 5 years from the effective date of the final rule].

* * * * *

*Part A*

* * * * *

**5.00 DIGESTIVE SYSTEM**

* * * * *

D. *How do we evaluate chronic liver disease?*

* * * * *

4. *Chronic viral hepatitis infections.*

a. *General.*

(i) * * * Comorbid disorders, such as HIV infection, may accelerate the clinical course of viral hepatitis infection(s) or may result in a poorer response to medical treatment.

* * * * *

b. *Chronic hepatitis B virus (HBV) infection.*

(i) *Chronic HBV infection* can be diagnosed by the detection of hepatitis B surface antigen (HBsAg) or hepatitis B virus DNA (HBV DNA) in the blood for at least 6 months. In addition, detection of the hepatitis B e antigen (HBeAg) suggests an increased likelihood of progression to cirrhosis, ESLD, and hepatocellular carcinoma. (HBeAg may also be referred to as ''hepatitis B early antigen'' or ''hepatitis B envelope antigen.'')

(ii) The therapeutic goal of treatment is to suppress HBV replication and thereby prevent progression to cirrhosis, ESLD, and hepatocellular carcinoma. Treatment usually includes interferon injections, oral antiviral agents, or a combination of both. Common adverse effects of treatment are the same as noted in 5.00D4c(ii) for HCV, and generally end within a few days after treatment is discontinued.

* * * * *

**8.00 SKIN DISORDERS**

* * * * *

D. *How do we assess impairments that may affect the skin and other body systems?*

* * * * *

3. * * * We evaluate SLE under 14.02, scleroderma under 14.04, Sjögren's syndrome under 14.10, and HIV infection under 14.11.

* * * * *

**13.00 MALIGNANT NEOPLASTIC DISEASES**

A. *What impairments do these listings cover?* We use these listings to evaluate all malignant neoplasms except certain neoplasms associated with human immunodeficiency virus (HIV) infection. We use the criteria in 14.11B to evaluate primary central nervous system lymphoma, 14.11C to evaluate primary effusion lymphoma, and 14.11E to evaluate pulmonary Kaposi

sarcoma if you also have HIV infection. We evaluate all other malignant neoplasms associated with HIV infection, for example, Hodgkin's lymphoma or non-pulmonary Kaposi sarcoma, under this body system or under 14.11F–I in the immune system disorders body system.

* * * * *

**14.00 IMMUNE SYSTEM DISORDERS**

A. *What disorders do we evaluate under the immune system disorders listings?*

* * * * *

4. *Human immunodeficiency virus (HIV) infection (14.00F).* HIV infection may be characterized by increased susceptibility to common infections as well as opportunistic infections, cancers, or other conditions listed in 14.11.

* * * * *

F. *How do we document and evaluate HIV infection?* Any individual with HIV infection, including one with a diagnosis of acquired immune deficiency syndrome (AIDS), may be found disabled under 14.11 if his or her impairment meets the criteria in that listing or is medically equivalent to the criteria in that listing.

1. *Documentation of HIV infection.*

a. We require positive findings on one or more of the following definitive laboratory tests:

(i) HIV antibody screening test (for example, enzyme immunoassay, or EIA), confirmed by a supplemental HIV antibody test such as the Western blot, an immunofluorescence assay, or an HIV–1/HIV–2 antibody differentiation immunoassay.

(ii) HIV nucleic acid (DNA or RNA) detection test (for example, polymerase chain reaction, or PCR).

(iii) HIV p24 antigen test.

(iv) Isolation of HIV in viral culture.

(v) Other tests that are highly specific for detection of HIV and that are consistent with the prevailing state of medical knowledge.

b. We will make every reasonable effort to obtain the results of your laboratory testing. However, we will not purchase laboratory testing to establish whether you have HIV infection.

c. When we do not have the results of a definitive laboratory test(s), we need a persuasive report from a physician that a positive diagnosis of your HIV infection was confirmed by an appropriate laboratory test(s). To be persuasive, this report must state that you had the appropriate definitive laboratory test(s) for diagnosing your HIV infection and provide the results.

2. *Documentation of the manifestations of HIV infection.*

a. We require positive findings of manifestations of HIV infection on culture, microscopic examination of biopsied tissue or other material (for example, bronchial washings), serologic tests, or on other generally acceptable definitive tests consistent with the prevailing state of medical knowledge and clinical practice.

b. We will make every reasonable effort to obtain the results of your laboratory testing. However, we will not purchase laboratory testing to establish whether you have a manifestation of HIV infection.

c. When we do not have the results of a definitive laboratory test(s), we need a persuasive report from a physician that a positive diagnosis of your manifestation of HIV infection was confirmed by an appropriate laboratory test(s). To be persuasive, this report must state that you had the appropriate definitive laboratory test(s) for diagnosing your manifestation of HIV infection and provide the results.

3. *Disorders associated with HIV infection (14.11A–E).*

a. *Multicentric Castleman disease* (MCD, 14.11A) affects multiple groups of lymph nodes and organs containing lymphoid tissue. This widespread involvement distinguishes MCD from *localized* (or unicentric) Castleman disease, which affects only a single set of lymph nodes. We require characteristic findings on microscopic examination of the biopsied lymph nodes to establish the diagnosis.

b. *Primary central nervous system lymphoma* (PCNSL, 14.11B) originates in the brain, spinal cord, meninges, or eye. Imaging tests (for example, MRI) of the brain, while not diagnostic, may show a single lesion or multiple lesions in the white matter of the brain. We require characteristic findings on microscopic examination of the cerebral spinal fluid or of the biopsied brain tissue to establish the diagnosis.

c. *Primary effusion lymphoma* (PEL, 14.11C) is also known as body cavity lymphoma. We require characteristic findings on microscopic examination of the effusion fluid or of the biopsied tissue from the affected internal organ to establish the diagnosis.

d. *Progressive multifocal leukoencephalopathy* (PML, 14.11D) is a progressive neurological degenerative syndrome caused by the JC virus in immunosuppressed people. Clinical findings of PML include clumsiness, progressive weakness, and visual and speech changes. Personality and cognitive changes may also occur. We require appropriate clinical findings, characteristic white matter lesions on MRI, and a positive PCR test for the JC virus in the cerebral spinal fluid to establish the diagnosis. We also accept a positive brain biopsy for JC virus to establish the diagnosis.

e. *Pulmonary Kaposi sarcoma* (Kaposi sarcoma in the lung, 14.11E) is the most serious form of Kaposi sarcoma (KS). Other internal KS tumors (for example, the gastrointestinal tract) have a more variable prognosis. We require characteristic findings on microscopic examination of the induced sputum or bronchoalveolar lavage washings, or of the biopsied transbronchial tissue, to establish the diagnosis.

4. *CD4 measurement (14.11F).* To evaluate your HIV infection under 14.11F, we require one measurement of your absolute CD4 count (also known as CD4 count or CD4+ T-helper lymphocyte count). This measurement must occur within the period we are considering in connection with your application or continuing disability review. If you have more than one measurement of your absolute CD4 count within this period, we will use your lowest absolute CD4 count.

5. *Measurement of CD4 and either body mass index or hemoglobin (14.11G).* To evaluate your HIV infection under 14.11G, we require one measurement of your absolute CD4 count or CD4 percentage *and* either a measurement of your body mass index (BMI) or hemoglobin. These measurements must occur within the period we are considering in connection with your application or continuing disability review. If you have more than one measurement of your CD4 (absolute count or percentage), BMI, or hemoglobin within this period, we will use the lowest of your CD4 (absolute count or percentage), BMI, or hemoglobin. We calculate your BMI using the formulas in 5.00G2.

6. *Complications of HIV infection requiring hospitalization (14.11H).*

a. Complications of HIV infection may include infections (common or opportunistic), cancers, and other conditions. Examples of complications that may result in hospitalization include: Depression; diarrhea; immune reconstitution inflammatory syndrome; malnutrition; and *Pneumocystis* pneumonia and other severe infections.

b. Under 14.11H, we require three hospitalizations within a 12-month period resulting from a complication(s) of HIV infection. The hospitalizations may be for the same complication or different complications of HIV infection. All three hospitalizations must occur within the period we are considering in connection with your application or continuing disability review.

7. *HIV-associated dementia (HAD).* HAD (also known as AIDS dementia complex, HIV dementia, or HIV encephalopathy) is an advanced neurocognitive disorder, characterized by a significant decline in cognitive functioning. We evaluate HAD under 12.02.

* * * * *

I. *How do we use the functional criteria in these listings?*

1. The following listings in this body system include standards for evaluating the functional limitations resulting from immune system disorders: 14.02B, for systemic lupus erythematosus; 14.03B, for systemic vasculitis; 14.04D, for systemic sclerosis (scleroderma); 14.05E, for polymyositis and dermatomyositis; 14.06B, for undifferentiated and mixed connective tissue disease; 14.07C, for immune deficiency disorders, excluding HIV infection; 14.09D, for inflammatory arthritis; 14.10B, for Sjögren's syndrome; and 14.11I, for HIV infection.

* * * * *

5. *Marked* limitation means that the symptoms and signs of your immune system disorder interfere *seriously* with your ability to function. Although we do not require the use of such a scale, ''marked'' would be the fourth point on a five-point scale consisting of no limitation, mild limitation, moderate limitation, marked limitation, and extreme limitation. * * *

* * * * *

14.01 *Category of Impairments, Immune System Disorders.*

* * * * *

14.11 *Human immunodeficiency virus (HIV) infection.* With documentation as described in 14.00F1 and one of the following:

A. Multicentric Castleman disease (see 14.00F3a). OR

B. Primary central nervous system lymphoma (see 14.00F3b). OR

C. Primary effusion lymphoma (see 14.00F3c). OR

D. Progressive multifocal leukoencephalopathy (see 14.00F3d). OR

E. Pulmonary Kaposi sarcoma (see 14.00F3e). OR

F. Absolute CD4 count of 50 cells/mm$^3$ or less (see 14.00F4). OR

G. Absolute CD4 count of less than 200 cells/mm$^3$ or CD4 percentage of less than 14 percent (see 14.00F5), *and* one of the following:

1. BMI measurement of less than 18.5; or

2. Hemoglobin measurement of less than 8.0 grams per deciliter (g/dL). OR

H. Complication(s) of HIV infection requiring at least three hospitalizations within a 12-month period and at least 30 days apart (see 14.00F6). Each hospitalization must last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization. OR

I. Repeated (as defined in 14.00I3) manifestations of HIV infection, including those listed in 14.11A–H, but without the requisite findings for those listings (for example, Kaposi sarcoma not meeting the criteria in 14.11E), or other manifestations (for example, diarrhea, distal sensory polyneuropathy, glucose intolerance, hepatitis, infections (bacterial, fungal, parasitic, or viral), lipodystrophy (lipoatrophy or lipohypertrophy), muscle weakness, myositis, neurocognitive limitation (including dementia not meeting the criteria in 12.02), oral hairy leukoplakia, osteoporosis, pancreatitis, peripheral neuropathy) resulting in significant, documented symptoms or signs (for example, fever, headaches, insomnia, involuntary weight loss, malaise, nausea, night sweats, pain, severe fatigue, or vomiting) and one of the following at the marked level:

1. Limitation of activities of daily living.

2. Limitation in maintaining social functioning.

3. Limitation in completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace.

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*Part B*

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**105.00 DIGESTIVE SYSTEM**

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D. *How do we evaluate chronic liver disease?*

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4. *Chronic viral hepatitis infections.*

a. *General.*

(i) * * * Comorbid disorders, such as HIV infection, may accelerate the clinical course of viral hepatitis infection(s) or may result in a poorer response to medical treatment.

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b. *Chronic hepatitis B virus (HBV) infection.*

(i) *Chronic HBV infection* can be diagnosed by the detection of hepatitis B surface antigen (HBsAg) or hepatitis B virus DNA (HBV DNA) in the blood for at least 6 months. In addition, detection of the hepatitis B e antigen (HBeAg) suggests an increased likelihood of progression to cirrhosis, ESLD, and hepatocellular carcinoma. (HBeAg may also be referred to as ''hepatitis B early antigen'' or ''hepatitis B envelope antigen.'')

(ii) The therapeutic goal of treatment is to suppress HBV replication and thereby prevent progression to cirrhosis, ESLD, and hepatocellular carcinoma. Treatment usually includes interferon injections, oral antiviral agents, or a combination of both. Common adverse effects of treatment are the same as noted in 105.00D4c(ii) for HCV, and generally end within a few days after treatment is discontinued.

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**108.00 SKIN DISORDERS**

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D. *How do we assess impairments that may affect the skin and other body systems?*

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3. * * * We evaluate SLE under 114.02, scleroderma under 114.04, Sjögren's syndrome under 114.10, and HIV infection under 114.11.

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**113.00 MALIGNANT NEOPLASTIC DISEASES**

A. *What impairments do these listings cover?* We use these listings to evaluate all malignant neoplasms except certain neoplasms associated with human immunodeficiency virus (HIV) infection. If you have HIV infection, we use the criteria in 114.08E to evaluate carcinoma of the cervix, Kaposi sarcoma, lymphoma, and squamous cell carcinoma of the anal canal and anal margin. We use the criteria in 114.11B to evaluate primary central nervous system lymphoma, 114.11C to evaluate primary effusion lymphoma, and 114.11E to evaluate pulmonary Kaposi sarcoma if you also have HIV infection. We evaluate all other malignant neoplasms associated with HIV infection, for example, Hodgkin's lymphoma or non-pulmonary Kaposi sarcoma, under this body system or under 114.11F–I in the immune system disorders body system.

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**114.00 IMMUNE SYSTEM DISORDERS**

A. *What disorders do we evaluate under the immune system disorders listings?*

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4. *Human immunodeficiency virus (HIV) infection (114.00F).* HIV infection may be characterized by increased susceptibility to common infections as well as opportunistic infections, cancers, or other conditions listed in 114.11.

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F. *How do we document and evaluate HIV infection?* Any child with HIV infection, including one with a diagnosis of acquired immune deficiency syndrome (AIDS), may be found disabled under 114.11 if his or her impairment meets the criteria in that listing or is medically equivalent to the criteria in that listing.

1. *Documentation of HIV infection.*

a. We require positive findings on one or more of the following definitive laboratory tests:

(i) HIV antibody screening test (for example, enzyme immunoassay, or EIA), confirmed by a supplemental HIV antibody test such as the Western blot or immunofluorescence assay, for any child age 18 months or older.

(ii) HIV nucleic acid (DNA or RNA) detection test (for example, polymerase chain reaction, or PCR).

(iii) HIV p24 antigen test, for any child age 1 month or older.

(iv) Isolation of HIV in viral culture.

(v) Other tests that are highly specific for detection of HIV and that are consistent with the prevailing state of medical knowledge.

b. We will make every reasonable effort to obtain the results of your laboratory testing. However, we will not purchase laboratory testing to establish whether you have HIV infection.

c. When we do not have the results of a definitive laboratory test(s), we need a persuasive report from a physician that a positive diagnosis of your HIV infection was confirmed by an appropriate laboratory test(s). To be persuasive, this report must state that you had the appropriate definitive laboratory test(s) for diagnosing your HIV infection and provide the results.

2. *Documentation of the manifestations of HIV infection.*

a. We require positive findings of manifestations of HIV infection on culture, microscopic examination of biopsied tissue or other material (for example, bronchial washings), serologic tests, or on other generally acceptable definitive tests consistent with the prevailing state of medical knowledge and clinical practice.

b. We will make every reasonable effort to obtain the results of your laboratory testing. However, we will not purchase laboratory testing to establish whether you have a manifestation of HIV infection.

c. When we do not have the results of a definitive laboratory test(s), we need a persuasive report from a physician that a positive diagnosis of your manifestation of HIV infection was confirmed by an appropriate laboratory test(s). To be persuasive, this report must state that you had the appropriate definitive laboratory test(s) for diagnosing your manifestation of HIV infection and provide the results.

3. *Disorders associated with HIV infection (114.11A–E).*

a. *Multicentric Castleman disease* (MCD, 114.11A) affects multiple groups of lymph nodes and organs containing lymphoid tissue. This widespread involvement distinguishes MCD from *localized* (or unicentric) Castleman disease, which affects only a single set of lymph nodes. We require characteristic findings on microscopic examination of the biopsied lymph nodes to establish the diagnosis.

b. *Primary central nervous system lymphoma* (PCNSL, 114.11B) originates in the brain, spinal cord, meninges, or eye. Imaging tests (for example, MRI) of the brain, while not diagnostic, may show a single lesion or multiple lesions in the white matter

of the brain. We require characteristic findings on microscopic examination of the cerebral spinal fluid or of the biopsied brain tissue to establish the diagnosis.

c. *Primary effusion lymphoma* (PEL, 114.11C) is also known as body cavity lymphoma. We require characteristic findings on microscopic examination of the effusion fluid or of the biopsied tissue from the affected internal organ to establish the diagnosis.

d. *Progressive multifocal leukoencephalopathy* (PML, 114.11D) is a progressive neurological degenerative syndrome caused by the JC virus in immunosuppressed children. Clinical findings of PML include clumsiness, progressive weakness, and visual and speech changes. Personality and cognitive changes may also occur. We require appropriate clinical findings, characteristic white matter lesions on MRI, and a positive PCR test for the JC virus in the cerebral spinal fluid to establish the diagnosis. We also accept a positive brain biopsy for JC virus to establish the diagnosis.

e. *Pulmonary Kaposi sarcoma* (Kaposi sarcoma in the lung, 114.11E) is the most serious form of Kaposi sarcoma (KS). Other internal KS tumors (for example, the gastrointestinal tract) have a more variable prognosis. We require characteristic findings on microscopic examination of the induced sputum or bronchoalveolar lavage washings, or of the biopsied transbronchial tissue, to establish the diagnosis.

4. *CD4 measurement (114.11F).* To evaluate your HIV infection under 114.11F, we require one measurement of your absolute CD4 count (also known as CD4 count or CD4+ T-helper lymphocyte count), for children from age 5 to attainment of age 18, or your CD4 percentage, for children from birth to attainment of age 5. This measurement (absolute CD4 count or CD4 percentage) must occur within the period we are considering in connection with your application or continuing disability review. If you have more than one CD4 measurement within this period, we will use your lowest absolute CD4 count or CD4 percentage.

5. *Growth failure due to HIV immune suppression.* We evaluate linear growth failure under a growth impairment listing in 100.00. If your growth failure does not meet or medically equal the criteria of a listing in 100.00, we will consider whether your HIV infection meets or medically equals the criteria of a listing in another body system. For example, if your HIV infection has resulted in weight loss or a combination of weight loss and linear growth failure, we will evaluate your impairment under a digestive system listing in 105.00.

6. *Complications of HIV infection requiring hospitalization (114.11G).*

a. Complications of HIV infection may include infections (common or opportunistic), cancers, and other conditions. Examples of complications that may result in hospitalization include: Depression; diarrhea; immune reconstitution inflammatory syndrome; malnutrition; and *Pneumocystis* pneumonia and other severe infections.

b. Under 114.11G, we require three hospitalizations within a 12-month period resulting from a complication(s) of HIV infection. The hospitalizations may be for the same complication or different complications of HIV infection. All three hospitalizations must occur within the period we are considering in connection with your application or continuing disability review.

7. *Neurological manifestations specific to children (114.11H).* The methods of identifying and evaluating neurological manifestations may vary depending on a child's age. For example, in an infant, impaired brain growth can be documented by a decrease in the growth rate of the head. In an older child, impaired brain growth may be documented by brain atrophy on a CT scan or MRI. Neurological manifestations in infants and young children may present in the loss of acquired developmental milestones (developmental regression) or, in school-age children and adolescents, the loss of acquired intellectual abilities. A child may demonstrate loss of intellectual abilities by a decrease in IQ scores, by forgetting information previously learned, by inability to learn new information, or by a sudden onset of a new learning disability. When infants and young children present with serious developmental delays (without regression), we evaluate the child's impairment(s) under 111.00.

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114.11 *Human immunodeficiency virus (HIV) infection.* With documentation as described in 114.00F1 and one of the following:

A. Multicentric Castleman disease (see 114.00F3a). OR

B. Primary central nervous system lymphoma (see 114.00F3b). OR

C. Primary effusion lymphoma (see 114.00F3c). OR

D. Progressive multifocal leukoencephalopathy (see 114.00F3d). OR

E. Pulmonary Kaposi sarcoma (see 114.00F3e). OR

F. Absolute CD4 count or CD4 percentage (see 114.00F4):

1. For children from birth to attainment of age 5, CD4 percentage of less than 15 percent; or

2. For children age 5 to attainment of age 18, absolute CD4 count of 50 cells/$mm^3$ or less. OR

G. Complications(s) of HIV infection requiring at least three hospitalizations within a 12-month period and at least 30 days apart (see 114.00F6). Each hospitalization must last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization. OR

H. A neurological manifestation of HIV infection (for example, HIV encephalopathy or peripheral neuropathy) (see 114.00F7) resulting in one of the following:

1. Loss of previously acquired developmental milestones or intellectual ability (including the sudden onset of a new learning disability), documented on two examinations at least 60 days apart; or

2. Progressive motor dysfunction affecting gait and station or fine and gross motor skills, documented on two examinations at least 60 days apart; or

3. Microcephaly with head circumference that is less than the third percentile for age, documented on two examinations at least 60 days apart; or

4. Brain atrophy, documented by appropriate medically acceptable imaging.

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**BILLING CODE 4191–02–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 15

**[Docket No. FDA–2013–N–0402]**

## Generic Drug User Fee Amendments of 2012; Regulatory Science Initiatives; Public Hearing; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification of public hearing; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public hearing that will provide an overview of the current status of regulatory science initiatives for generic drugs and an opportunity for public input on research priorities in this area. FDA is seeking this input from a variety of stakeholders—industry, academia, patient advocates, professional societies, and other interested parties—as it fulfills its commitment under the Generic Drug User Fee Amendments of 2012 (GDUFA) to develop an annual list of regulatory science initiatives specific to generic drugs. FDA will take the information it obtains from the public hearing into account in developing the fiscal year (FY) 2015 Regulatory Science Plan.

**DATES:** The public hearing will be held on May 16, 2014, from 9 a.m. to 5 p.m. The public hearing may be extended or may end early depending on the level of public participation.

**ADDRESSES:** The public hearing will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public hearing participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*.

**FOR FURTHER INFORMATION CONTACT:** Thushi Amini, Center for Drug Evaluation and Research, Food and