nature. This proposed rule provides parties with guidance on the timing and process by which to request sampling in the agency's proceedings.

The second alternative, the ''no action'' alternative, would set forth a proposed methodology for sampling in AD and CVD proceedings, without providing regulated parties with any guidance on the timing and process by which to request sampling in the agency's proceedings. This alternative would either create no economic impact, or slightly negative impacts to the regulated community due to the increased confusion generated as a result of the lack of guidance and process for requesting sampling. Although this alternative was considered, it was not selected because it does not serve the Department's objectives of creating certainty and clarity for participants in AD and CVD proceedings.

Paperwork Reduction Act

This rule does not require a collection of information for purposes of the Paperwork Reduction Act of 1980, as amended (44 U.S.C. 3501 *et seq.*).

List of Subjects in 19 CFR Part 351

Administrative practice and procedure, Antidumping, Business and industry, Cheese, Confidential business information, Countervailing duties, Freedom of information, Investigations, Reporting and recordkeeping requirements.

Dated: November 6, 2013.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

For the reasons stated, 19 CFR part 351 is proposed to be amended as follows:

PART 351—ANTIDUMPING AND COUNTERVAILING DUTIES

■ 1. The authority citation for 19 CFR part 351 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 1202 note; 19 U.S.C. 1303 note; 19 U.S.C. 1671 *et seq.;* and 19 U.S.C. 3538.

■ 2. In § 351.301, add new paragraph (d) to read as follows:

§ 351.301 Time limits for submission of factual information.

* * * * *

(d) *Time limits for filing request for sampling in antidumping duty administrative reviews.*

(1) For antidumping duty administrative reviews, all submissions from parties to the proceeding wishing to request that the Department conduct sampling in selecting respondents for individual examination under section 777A(c)(2)(A) of the Act are normally due no later than 7 days after the Department releases to interested parties data from Customs and Border Protection pertaining to entries of merchandise subject to the review. The request for the Department to use sampling in the review must include the following information:

(i) A request that the Department conduct sampling with respect to the exporters subject to the review; and

(ii) Factual information and comment upon whether the factual information presented provides a reasonable basis to believe or suspect that the average export prices and/or dumping margins for the largest exporters differ from such information that would be associated with the remaining exporters subject to the review.

(2) Interested parties wishing to comment on the request for sampling must submit comments within 10 days from the date of receipt of the request for sampling.

(3) Interested parties wishing to submit rebuttal comments addressing comments submitted under paragraph (d)(2) of this section must submit such comments within 5 days from the due date for submitting comments in paragraph (d)(2).

[FR Doc. 2013–27442 Filed 11–18–13; 8:45 am]

BILLING CODE 3510–DS–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404

[Docket No. SSA–2010–0055]

RIN 0960–AF88

Revised Medical Criteria for Evaluating Hematological 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 cases involving hematological disorders in adults and children under titles II and XVI of the Social Security Act (Act). The proposed revisions reflect advances in medical knowledge, our adjudicative experience, and information we received from medical experts and the public.

DATES: To ensure that your comments are considered, we must receive them no later than January 21, 2014.

ADDRESSES: You may submit comments by 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–2010–0055 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 your Social Security number 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–2010–0055. The system will issue 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, 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:

What revisions are we proposing?

We propose to:

- Revise and expand the introductory text to the hematological disorders body system for both adults (section 7.00) and children (section 107.00);
- Revise and reorganize the listings in this body system to update them and to make the adult and childhood rules more consistent; and
- Add criteria to the adult rules for establishing disability under the listings

based on functional limitations associated with hematological disorders.

Why are we proposing to make these changes?

We last issued final rules making comprehensive revisions to the hematological disorders listings on December 6, 1985.[1] Since then, we have generally only extended the effective date of the rules.[2] In the preamble to the 1985 rules, we stated that we would carefully monitor these listings to ensure that they continue to meet program purposes, and that we would revise them if warranted. We are now proposing to update the medical criteria in the current listings and provide more information about how we evaluate hematological disorders. For example:

- We propose to update current listing 7.08, which provides transfusion criteria for spontaneous hemorrhage (bleeding) in hemophilia. It does not reflect the current standard of care, because physicians now use other treatments for this type of bleeding.
- We propose to update current listing 7.17, which addresses bone marrow and stem cell transplantation only for aplastic anemias. Other hematological disorders, such as sickle cell disease, may now be treated with bone marrow or stem cell transplantation.

We are also proposing changes to the current listings to reflect the considerable adjudicative experience we have gained since we issued the 1985 rules. Some of these proposals also reflect information we received at outreach conferences from people who have hematological disorders, their family members, physicians who treat hematological disorders, and advocates who represent people who have these disorders. These proposals also take into consideration recommendations we received in public comments in response to a previous notice of proposed rulemaking (NPRM), which we explain in more detail below.

How did we develop these proposed rules?

On November 27, 2001, we published an NPRM proposing revisions to both the listings for hematological disorders and the listings for malignant neoplastic diseases.[3] We received public comments raising significant issues about the proposed listings for some of the hematological disorders. To obtain more information, on April 18, 2002, we published a notice providing an additional public comment period.[4] We also held meetings on April 8, 2002, April 24, 2002, and August 26, 2002, with medical professionals and representatives of advocacy and legal-services groups. During these meetings, we asked the participants for information about the issues.[5]

Based on the information we received from these activities, we published a notice on November 15, 2004, withdrawing the 2001 proposed rules for hematological disorders.[6] We later hosted a policy conference on sickle cell disease and hemophilia in Boston, MA, on November 18, 2004.[7] At this conference, we heard comments and suggestions for updating and revising the current rules for sickle cell disease and hemophilia from people who have these disorders, their family members, and physicians, advocates, and other professionals. In developing this NPRM, we considered the information we obtained at this conference, our earlier meetings, and the comments we received on the 2001 NPRM.[8]

What general changes are we proposing?

We propose to use only broad categories of hematological disorders in the listings instead of the mixture of specific hematological disorders and broad categories of hematological disorders that are in the current listings. We believe that it would be better to use only broad categories throughout this body system so that we can include more types of hematological disorders. We also propose to remove some of the current listings and revise the criteria of others.

The following chart shows the headings of the current listings for evaluating hematological disorders in adults and the name of the proposed listing, or the proposed listing under which we would evaluate the disorder that is currently listed:

Current listings *	Proposed listings
7.02 *Chronic anemia (hematocrit persisting at 30 percent or less due to any cause).*	Evaluate under the appropriate listing for the underlying hematological disorder or under 7.18.
7.05 *Sickle cell disease, or one of its variants*	7.05 *Hemolytic anemias.*
7.06 *Chronic thrombocytopenia (due to any cause)*	Evaluate under 7.08.
7.07 *Hereditary telangiectasia*	Evaluate under the body system where the bleeding occurs.
7.08 *Coagulation defects (hemophilia or a similar disorder)*	7.08 *Disorders of hemostasis.*
7.09 *Polycythemia vera (with erythrocytosis, splenomegaly, and leukocytosis or thrombocytosis).*	Removed.
7.10 *Myelofibrosis (myeloproliferative syndrome)*	7.10 *Disorders of bone marrow failure.*
7.15 *Chronic granulocytopenia (due to any cause)*	Evaluate under 7.10.
7.17 *Aplastic anemias with bone marrow or stem cell transplantation*	7.17 *Hematological disorders treated by bone marrow or stem cell transplantation.*
	7.18 *Repeated complications of hematological disorders.*

* The listings in this body system are not numbered consecutively. This chart contains the only listings in this body system.

We also propose to replace the current introductory text with updated and expanded guidance that reflects the proposed listings. The following chart shows the headings of the current and proposed sections of the introductory text:

[1] (50 FR 50068)

[2] We published some revisions to the hematological body system on April 24, 2002, and November 15, 2004. See 67 FR 20018 and 69 FR 67017 (corrected at 70 FR 15227). These revisions were not comprehensive; they addressed only specific listings. The current listings will no longer be effective as of July 2, 2012, unless we extend them or revise and issue them again. See 75 FR 33166.

[3] 66 FR 59306.

[4] 67 FR 19138.

[5] You can read the notes from these meetings at *http://www.regulations.gov/#!docketDetail;dct=FR%252BPR%252BN%252BO%252BSR;rpp=10;po=0;D=SSA-2006-0113.*

[6] 69 FR 67039.

[7] You can read the transcript of the November 18, 2004, policy conference at *http://www.regulations.gov/#!docketDetail;dct=FR%252BPR%252BN%252BO%252BSR;rpp=10;po=0;D=SSA-2006-0113.*

[8] You can view the comments we received on the 2001 NPRM by going to *http://www.regulations.gov/#!docketDetail;dct=FR%252BPR%252BN%252BO%252BSR;rpp=10;po=0;D=SSA-2006-0113.*

Current introductory text	Proposed introductory text
7.00A *Impairment caused by anemia*	7.00A *What hematological disorders do we evaluate under these listings?*
7.00B *Chronicity is indicated by*	7.00B *What evidence do we need to document that you have a hematological disorder?*
7.00C *Sickle cell disease*	7.00C *What are hemolytic anemias, and how do we evaluate them under 7.05?*
7.00D *Coagulation defects*	7.00D *What are disorders of hemostasis, and how do we evaluate them under 7.08?*
	7.00E *What are disorders of bone marrow failure, and how do we evaluate them under 7.10?*
	7.00F *How do we evaluate bone marrow or stem cell transplantation under 7.17?*
	7.00G *How do we use the functional criteria in 7.18?*
	7.00H *How do we consider your symptoms, including your pain, severe fatigue, and malaise?*
	7.00I *How do we evaluate episodic events in hematological disorders?*
	7.00J. *How do we evaluate hematological disorders that do not meet one of these listings?*

What specific changes are we proposing to make in the introductory text to the listings for evaluating hematological disorders in adults?

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

Proposed section 7.00A—What hematological disorders do we evaluate under these listings?

In this new section, we explain which hematological disorders we evaluate under these listings and which we evaluate under the listings in other body systems.

Proposed section 7.00B—What evidence do we need to document that you have a hematological disorder?

In this new section, we explain the evidence we need to establish the existence of a hematological disorder. In proposed sections 7.00B1 and B2, we provide two methods for establishing the existence of the disorder when we have a copy of definitive laboratory test results. In proposed section 7.00B3, we provide an additional method for establishing the existence of the disorder when we do not have a copy of definitive laboratory test results.

In proposed section 7.00B1, we explain that a laboratory report of a definitive test that establishes a hematological disorder, signed by a physician, is sufficient to document that you have a hematological disorder. As an alternative, we also explain in proposed section 7.00B2 that, if we have a copy of the laboratory report of a definitive test that establishes a hematological disorder, but a physician has not signed it, we also require a report from a physician confirming that the person has the hematological disorder. We need this statement because our rules require evidence from an ''acceptable medical source'' to establish the existence of a medically determinable impairment, and a physician is the only such source we can accept for hematological disorders.[9] We are proposing these changes only to clarify our current rules and are not proposing that the physician needs to provide any more information to establish the existence of the disorder than we require under our current rules.

In proposed section 7.00B3, we explain how we can establish the existence of a hematological disorder when we do not have a copy of the laboratory report of a definitive test. Under section 7.00B3, we need a persuasive report from a physician that a positive diagnosis of the person's hematological disorder was confirmed by appropriate laboratory analysis or other diagnostic method(s). We also explain that to be persuasive, the report must state that the person has had the appropriate definitive laboratory test or tests for diagnosing the disorder and provide the results, or explain how the diagnosis was established by other diagnostic techniques consistent with the prevailing state of medical knowledge and clinical practice.

We propose to remove the information in current section 7.00B because it primarily discusses medically acceptable imaging techniques. These techniques would apply to the proposed listings primarily to establish the presence of certain complications of hematological disorders, such as blood clots. There are many other types of laboratory tests and clinical findings we may need to establish a hematological disorder and the nature of any complications. We do not believe it would be practical or necessary to include them all in the introductory text of the proposed listings. We propose to remove, rather than expand, the limited guidance in current section 7.00B.

Current section 7.00B also includes two sentences that explain how we establish ''chronicity.'' We would no longer need this rule because we do not use the term ''chronicity'' in any of the proposed listings. Instead, we provide specific criteria in each proposed listing for which we need evidence of chronicity. For example, in some of the proposed listings we require a certain number of events (such as hospitalizations) directly associated with the person's hematological disorder occurring at least 30 days apart and within a 12-month period.

In proposed section 7.00B4, we explain that we will make every reasonable effort to obtain the results of appropriate laboratory testing. We also explain that we will not purchase tests of clotting factors, bone marrow aspirations, or bone marrow biopsies. We will not purchase these tests because obtaining, handling, or evaluating the blood or tissue samples may be too complex, invasive, or costly.

Proposed section 7.00C—What are hemolytic anemias, and how do we evaluate them under 7.05?

In this new section, we describe hemolytic anemias and provide examples of these disorders. We propose to evaluate all hemolytic anemias under listing 7.05 instead of listing only sickle cell disease or its variants.

In proposed section 7.00C2, we address a concern raised at our meetings on sickle cell disease: That some hospitalizations are for complications of sickle cell disease, and that our adjudicators should recognize and consider such hospitalizations when determining whether a person's impairment meets current listing 7.05B. Since we also have requirements for hospitalizations in the proposed listings, we propose to address this concern by providing examples of common complications of hemolytic anemias (including sickle cell disease) that could result in hospitalization. These examples include some of the complications that we term ''major visceral episodes'' in current section 7.00C. We also specify that the hospitalizations do not all have to be for the same complication, such as a painful (vaso-occlusive) crisis. The three hospitalizations we require in proposed

[9] We define the terms ''medically determinable impairment'' and ''acceptable medical source'' in §§ 404.1508, 404.1513, 416.908, and 416.913 of our regulations.

listing 7.05B may be for three different complications of a hemolytic anemia.

In proposed section 7.00C3, we explain that the hemoglobin measurements required in proposed listing 7.05C do not have to occur when the person is free of complications of his or her hemolytic anemia. The frequency of very low hemoglobin measurements required in the proposed listing provides a way for finding disability without considering the person's complications because it would establish a hemoglobin level associated with serious chronic anemia.

We propose a new listing 7.05D for transfusion-dependent beta thalassemia major. In proposed section 7.00C4, we define the term ''transfusion-dependent'' as it is widely used in the medical community to emphasize that transfusion dependency is necessary to sustain life. We exclude prophylactic red blood cell (RBC) transfusion for sickle cell disease because we do not consider this therapy to be of equal medical significance to transfusion-dependent thalassemia.

Proposed section 7.00D—What are disorders of hemostasis, and how do we evaluate them under 7.08?

In this new section, we propose to use a more inclusive term, ''disorders of hemostasis,'' to reflect the criteria in proposed listing 7.08. We provide examples of these disorders, which include coagulation defects.

We propose to remove the guidance in current section 7.00D about prophylactic therapy because this guidance would no longer be applicable in light of proposed listing 7.08. Prophylactic therapy for coagulation defects is usually self-administered and does not reflect the requirement in proposed listing 7.08 that the disorder result in hospitalization.

In proposed section 7.00D2, we provide examples of common complications of disorders of hemostasis that may result in hospitalization or contribute to functional limitations. We explain that surgery is a complication in disorders of hemostasis if it requires treatment with factor infusions or anticoagulant medication to control bleeding or coagulation in connection with the surgery.

Proposed section 7.00E—What are disorders of bone marrow failure, and how do we evaluate them under 7.10?

Proposed listing 7.10, Disorders of bone marrow failure, includes several hematological conditions that we now list separately: Myelofibrosis (current listing 7.10), granulocytopenia (current listing 7.15), and aplastic anemia (current listing 7.17). We name these conditions as examples of disorders of bone marrow failure to emphasize that we still include them in the proposed hematological disorders listings. In proposed section 7.00E2, we provide examples of common complications of disorders of bone marrow failure that may result in hospitalization or contribute to functional limitations. As we do for other hematological disorders that require hospitalizations, we specify in 7.00E2 that the hospitalizations in proposed listing 7.10A do not all have to be for the same complication. We also provide that we will consider other types of systemic infections that may result in hospitalizations. As we explain below in our summary of proposed listing 7.10A, we would include viral and fungal infections because they can have the same impact as bacterial infections required in current listing 7.10B.

Proposed section 7.00F—How do we evaluate stem cell or bone marrow transplantation under 7.17?

In this section, we explain that under proposed listing 7.17, we will consider a person to be disabled for 12 months from the date of bone marrow or stem cell transplantation, or we may consider a person to be disabled for a longer period if he or she has any serious post-transplantation complications, such as graft-versus-host (GVH) disease. The proposed rule is consistent with how we evaluate bone marrow and stem cell transplantation in other body systems.[10]

Proposed section 7.00G—How do we use the functional criteria in 7.18?

We are proposing new listing 7.18 to evaluate repeated complications of hematological disorders, including those complications listed in 7.05, 7.08, and 7.10 that do not have the requisite findings for those listings, or other complications. Under listing 7.18, the complications listed in 7.05, 7.08, and 7.10 that do not have the requisite findings for those listings, or the other complications the person has that are not contained in those specific listings, must result in ''significant, documented symptoms or signs.'' The person must also have a marked limitation in at least one of three broad areas of functioning. We explain each part of this listing in detail in proposed section 7.00G. We modeled listing 7.18 after a number of listings in the immune disorders body system (14.00), and we based the rules in proposed section 7.00G on the rules in section 14.00I of the introductory text of the immune disorders body system.

Proposed listing 7.18 requires a marked limitation of activities of daily living; a marked limitation in maintaining social functioning; or a marked limitation in completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace. In proposed section 7.00G4, we use essentially the same definition of ''marked'' as we use in section 14.00I5, but we are not including the description of ''marked'' as ''more than moderate but less than extreme.'' Instead, we would use an explanation based on the language 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.'' In proposed sections 7.00G5, 7.00G6, and 7.00G7, we explain what we mean by ''activities of daily living,'' ''social functioning,'' and ''completing tasks in a timely manner.'' We based these proposed sections on current sections 14.00I6, 14.00I7, and 14.00I8 in our immune system listings.

Proposed section 7.00H—How do we consider your symptoms, including your pain severe fatigue, and malaise?

In this section, we explain how we consider the effects of the symptoms of hematological disorders on a person's ability to function. Except for a reference to section 7.00 instead of section 14.00, this paragraph would be identical to section 14.00H in our immune system disorders body system.

Proposed section 7.00I—How do we evaluate episodic events in hematological disorders?

Several of our current hematological listings include a requirement for events (pain crises, transfusions, or infections) within the 5 months or 12 months before we adjudicate a claim. We propose similar requirements in several of the proposed hematological listings, but also propose several changes. In proposed section 7.00I, we would explain that under listings 7.05, 7.08, and 7.10A, we require a specific number of events within a consecutive 12-month period and that when we use such criteria, the 12-month period must occur within the period we are considering in

[10] See, for example, section 13.00L4 in the malignant neoplastic diseases body system.

connection with your application or continuing disability review. Our current rules require that the events must take place in a period immediately before we adjudicate a case. This proposed change would be consistent with how we evaluate episodic events in other body systems.[11] We believe this change also is both more logical and fair, and that it would address many adjudicator questions we have received over the years. In some cases, for example, we must determine whether a person was disabled in a period that ended before we adjudicated the claim.

How are we proposing to revise the criteria in the listings for evaluating hematological disorders in adults?

We propose to remove several current hematological listings:

- Current listing 7.02, for chronic anemia. We would evaluate anemia that results from an underlying hematological disorder under the appropriate proposed listing for the disorder or under the functional criteria in proposed listing 7.18. We would also remove the guidance in current section 7.00A for evaluating impairments caused by anemia ''according to the ability of the person to adjust to the reduced oxygen[-]carrying capacity of the blood.'' This guidance does not consider that a person who can adjust to his or her anemia may have other serious complications that could be disabling. We provide examples of these other complications in proposed sections 7.00C, 7.00D, and 7.00E, the sections of the proposed introductory text that describe the major categories of hematological disorders in the proposed listings. As we have already mentioned, some proposed listings establish the presence of chronic anemia that meets the requirement of three hospitalizations within 12 months spaced 30 days apart, essentially replacing the ''chronicity'' requirement in current section 7.00B.
- Current listings 7.05D for sickle cell disease, 7.09 for polycythemia vera, and 7.10A for myelofibrosis with chronic anemia. These listings are reference listings. Reference listings are redundant because they are met by satisfying the criteria of other listings, and we are removing them from our listings as we update the body systems.[12]
- Current listing 7.06, for chronic thrombocytopenia. We would include thrombocytopenia under proposed new listing 7.08, ''Disorders of hemostasis.''
- Current listing 7.07 for hereditary telangiectasia. Hereditary telangiectasia is a disorder that may result in bleeding from defects in the blood vessels in various organs. We believe it is more appropriate to evaluate hereditary telangiectasia under the body system where this bleeding occurs, such as the digestive body system (for example, listing 5.02) or the neurological body system (for example, listing 11.04).
- Current listing 7.10C for myelofibrosis with intractable bone pain. We believe it is more appropriate to evaluate this impairment under the criteria for the affected body system.
- Current listing 7.15, for chronic granulocytopenia. We would include granulocytopenia under proposed new listing 7.10, ''Disorders of bone marrow failure.''

While incorporating the disorders from several of the foregoing listings into other proposed listings, we also propose either to revise the criteria in the current listing or replace it with new criteria. Two changes would be common to several listings that include criteria for episodic events (for example, painful crises or hospitalizations): We would require at least 30 days between these events to ensure that we are evaluating separate events, and we would require that these events occur within a relevant 12-month period, consistent with our rules in other body systems.

The following is a detailed explanation of the changes we are proposing to the hematological disorder listings for evaluating hematological disorders in adults that need further explanation.

Proposed Listing 7.05—Hemolytic Anemias

In addition to expanding the scope of current listing 7.05A, we propose to make the following changes:

We would add a requirement for the treatment of documented painful crises with parenteral (intravenous or intramuscular) narcotic medication. Physicians usually provide this treatment (in outpatient or inpatient settings) only for crises they cannot alleviate with initial treatment, such as oral narcotics or non-narcotic medications. We believe that the proposed requirement for parenteral narcotic medication will confirm the severity of the crisis and provide a more objective measure than the requirement in the current listing.

We would also require at least 6 painful crises treated with parenteral narcotic medication in a 12-month period, instead of the three in the 5-month period prior to adjudication in the current listing. We believe the need for parenteral narcotic medication on such a frequent basis is indicative of recurring severe pain that prevents a person from working for the required 12-month duration. We based the change in frequency of painful crises on our adjudicative experience and the prevailing state of medical knowledge and clinical practice. Although people who have painful crises less frequently than 6 times in a 12-month period may be limited in functioning, we believe they are not precluded from engaging in any gainful activity.

We would consider a person with hemolytic anemia who has less severe painful episodes or other complications that result in functional limitations under proposed listing 7.18, which we describe in detail below.

In addition, people who have severe painful episodes may have impairments that meet proposed listing 7.05B. Proposed listing 7.05B corresponds to current listing 7.05B in that it would include people who have three hospitalizations in a 12-month period because of their hemolytic anemia. We would revise the current listing as follows:

We explain that the hospitalization can be for any complication of hemolytic anemia, which, as we explain in proposed section 7.00C2, would include painful crises. We believe that three hospitalizations in a 12-month period establish hemolytic anemia of listing-level severity because complications of hemolytic anemia that require hospitalization are generally more serious and involve longer recovery periods than those treated solely in outpatient settings. We also specify in the introductory text that the three hospitalizations do not have to be for the same complication.

We would include criteria for hospitalizations similar to current listing 7.05B but specify that each hospitalization must last at least 48 hours. We believe a hospitalization period of at least 48 hours is indicative of a severe complication of hemolytic anemia, and would more clearly define our intent in the current rule for an ''extended hospitalization.'' We would include the hours the person spends in the emergency department immediately before hospital admission as part of his or her hospitalization. We would include these hours in the emergency department because the person is likely to be receiving the same intensity of care as he or she will receive in the hospital.

In proposed listing 7.05C, we would require hemoglobin measurements

[11] See, for example, section 4.00A3e in the cardiovascular system.

[12] Current listing 7.10A also cross-refers to current listing 7.02, which we are proposing to remove.

instead of the current requirement for hematocrit values. Hemoglobin is measured directly. Hematocrit values are calculated, and therefore they are less precise. We would accept the hemoglobin measurements required in proposed listing 7.05C regardless of whether the person was experiencing complications of his or her hemolytic anemia at the time of the measurements.

Current listing 7.05C requires a persistence of a hematocrit of 26 percent or less, which is comparable to a hemoglobin measurement of approximately 8.5 grams per deciliter (g/dL) or less. We believe that hematocrit or hemoglobin at these levels does not necessarily correlate with an inability to do any gainful activity. Instead, the proposed listing would require a hemoglobin measurement of 7.0 g/dL or less. We believe a hemoglobin measurement at this level provides a better description of a listing-level impairment because many people who have this finding will have related problems, such as an abnormal heartbeat, shortness of breath with mild exertion, and significant fatigue. We also believe that the frequency of the hemoglobin measurements in the proposed listing provides a way for finding a person to be disabled without having to consider the person's specific complications since it establishes a hemoglobin level associated with serious chronic anemia.

Even though we are proposing a specific laboratory finding for evaluating anemia in proposed listing 7.05C, we would also consider anemia under proposed new listing 7.18. Proposed listing 7.18 will allow us to make an individualized determination about disability for people whose impairments do not meet proposed listing 7.05.

Proposed Listing 7.08—Disorders of Hemostasis

This proposed listing corresponds to current listing 7.06, ''Chronic thrombocytopenia (due to any cause),'' and current listing 7.08, ''Coagulation defects (hemophilia or similar disorder).'' We would evaluate thrombocytopenia and coagulation defects under this proposed listing because they are both disorders of hemostasis. The proposed listing would also cover any other hypo- or hypercoagulation disorder.

We believe that the criterion in proposed 7.08 for complications requiring at least three hospitalizations within a 12-month period and occurring at least 30 days apart is a more accurate medical description of listing-level thrombocytopenia than the current requirements for platelet counts and spontaneous bleeding. Some people who have thrombocytopenia that satisfies the criteria in the current listing for platelet counts repeatedly below 40,000/mm^3 and one episode of spontaneous bleeding (current listing 7.06A) will have serious limitations in their functioning. Others, however, will not have limitations that prevent them from doing any gainful activity for at least 12 continuous months, the duration requirement in our definition of disability. Some people who have thrombocytopenia with the requisite platelet counts and who experience one episode of intracranial bleeding (current listing 7.06B) also do not have impairments that meet the 12-month duration requirement. Likewise, we believe that the episodes of bleeding we include in the other current listings for disorders of hemostasis, including bleeding episodes resulting from hemophilia, do not necessarily preclude a person from doing any gainful activity for at least 12 months.

The requirement for transfusions in current listing 7.08 is out of date. Instead of blood transfusions, physicians now use blood-clotting factor VIII, factor IX, or other factor components to treat uncontrolled bleeding in hemophilia. A person usually receives intensive treatment with factor in a hospital if he or she cannot control a bleed with factor through outpatient treatment or self-care. We believe that the requirement for hospitalization will confirm the severity of the bleeding episode and provide an objective measure. Similarly, the requirement for hospitalization would be an objective measure for other complications of disorders of hemostasis, such as thromboses (blood clots) that result from a hypercoagulation disorder.

We would use the criteria in proposed listing 7.18 to evaluate hemostasis disorders that do not meet the criteria of proposed listing 7.08 but that cause complications that affect a person's functioning. For example, proposed listing 7.18 would include some people who have joint deformity (arthropathy) from repeated bleeding into a joint. We may also use the criteria in the musculoskeletal listings to evaluate the effects of joint deformity.[13]

Proposed Listing 7.10—Disorders of Bone Marrow Failure

This proposed listing corresponds to current listings 7.10, ''Myelofibrosis (myeloproliferative syndrome),'' 7.15, ''Chronic granulocytopenia (due to any cause),'' and 7.17, ''Aplastic anemias.'' We would evaluate myelofibrosis, granulocytopenia, and aplastic anemias, as well as any other disorder of bone marrow failure, under the proposed listing. We would also evaluate aplastic anemias and other disorders of bone marrow failure treated with bone marrow or stem cell transplantation under proposed listing 7.17.

In proposed listing 7.10A, we would require three hospitalizations within a 12-month period (and occurring at least 30 days apart) for complications of a disorder of bone marrow failure (such as systemic infections). As we noted earlier in our explanation of proposed section 7.00E, in proposed 7.10A we would broaden the criterion in current listing 7.10B to include systemic viral and fungal infections. Systemic viral and fungal infections that must be treated in the hospital are as serious as systemic bacterial infections. People who have episodes of systemic infections that do not meet the requirement in proposed listing 7.10A may qualify under proposed listing 7.18.

We propose to remove current listing 7.10C because intractable bone pain is rare in myelofibrosis. When a person has this symptom, we would be able to evaluate his or her impairment under proposed listing 7.18. We can also use an appropriate listing in the musculoskeletal body system, as we make clear in proposed section 7.00J1.

Proposed Listing 7.17—Hematological Disorders Treated by Bone Marrow or Stem Cell Transplantation

Current listing 7.17 is for aplastic anemias treated with bone marrow or stem cell transplantation. We would broaden this listing to include all hematological disorders treated with these transplantation procedures. We would consider the person disabled until ''at least'' 12 months from the date of transplantation. The phrase ''at least'' would provide our adjudicators with the flexibility to consider the person disabled for a period longer than 12 months from the date of transplantation if the evidence justifies it. After that period, we would evaluate any residual impairment(s) under the criteria for the affected body system.

Proposed Listing 7.18—Repeated Complications of Hematological Disorders

As we have already noted, we propose a new listing based on repeated complications of any hematological disorder together with functional limitations that result from the disorder. We modeled this proposed listing after several listings in our immune disorders

[13] See proposed section 7.00J1.

body system.[14] The proposed listing reflects symptoms, signs, and complications of hematological disorders. Like immune disorders, hematological disorders can be characterized by episodes of complications and symptoms that can significantly affect functioning. For this reason, we believe it is appropriate to have a listing that includes functional limitations for hematological disorders like the listings in the immune disorders body system. We believe these functional criteria would help us more quickly and easily adjudicate some claims.

How are we proposing to change the introductory text and listings for evaluating hematological disorders in children?

With one exception, the proposed childhood introductory text and listings are the same as the proposed adult rules, apart from minor differences such as referring to children instead of adults. The reasons we gave earlier for changing or removing current criteria for adults also apply to the childhood criteria.

We are not proposing a listing for children like proposed listing 7.18 for adults. Instead, we would use our current childhood rules for evaluating functional equivalence to the listings.[15] These rules accomplish the same objective for children as proposed listing 7.18 would for adults.

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

Under the Act, we have full power and authority to make rules and regulations and to establish necessary and appropriate procedures to carry out such provisions.[16]

How long would these proposed rules be effective?

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

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 this NPRM, 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, (for example, 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 relevant comments we received, our responses to them, 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 these proposed rules meet the requirements for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. Thus, OMB reviewed them.

Regulatory Flexibility Act

We certify that these proposed rules would not have a significant economic impact on a substantial number of small entities because they affect only individuals. 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 impose new or affect any existing reporting or recordkeeping requirements and are not subject to OMB clearance.

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[14] See listings 14.02B, 14.03B, 14.04D, 14.05E, 14.06B, 14.07C, 14.08K, 14.09D, and 14.10B.

[15] See § 416.926a.

[16] Sections 205(a), 702(a)(5), and 1631(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 persons 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: November 8, 2013.

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–)

■ 1. The authority citation for subpart P of part 404 is revised 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).

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

■ 2. Amend appendix 1 to subpart P of part 404 by revising:
■ a. Item 8 of the introductory text before part A;
■ b. Section 7.00 of part A;
■ c. Section 13.00K2c(ii) of part A;
■ d. Second sentence of section 13.00K3 of part A; and
■ e. Section 107.00 of part B.

The revisions read as follows:

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

* * * * *

8. Hematological Disorders (7.00 and 107.00): (*Date 5 years from the effective date of the final rules*).

* * * * *

Part A

* * * * *

7.00 HEMATOLOGICAL DISORDERS

A. *What hematological disorders do we evaluate under these listings?*

1. We evaluate non-malignant (non-cancerous) hematological disorders, such as hemolytic anemias (7.05), disorders of hemostasis (7.08), and disorders of bone marrow failure (7.10), which disrupt the normal development and function of white blood cells, red blood cells, platelets, and blood-clotting factors.

2. We evaluate malignant (cancerous) hematological disorders, such as lymphoma, leukemia, and multiple myeloma, under the appropriate listings in 13.00, except for lymphoma associated with human immunodeficiency virus (HIV) infection, which we evaluate under 14.08E.

B. *What evidence do we need to document that you have a hematological disorder?* We need the following evidence to document that you have a hematological disorder:

1. A laboratory report of a definitive test that establishes a hematological disorder, signed by a physician; or

2. A laboratory report of a definitive test that establishes a hematological disorder that is not signed by a physician *and* a report from a physician that states you have the disorder; or

3. When we do not have a laboratory report of a definitive test, a persuasive report from a physician that a positive diagnosis of your hematological disorder was confirmed by appropriate laboratory analysis or other diagnostic method(s). To be persuasive, this report must state that you had the appropriate definitive laboratory test or tests for diagnosing your disorder and provide the results, or explain how your diagnosis was established by other diagnostic method(s) consistent with the prevailing state of medical knowledge and clinical practice.

4. We will make every reasonable effort to obtain the results of appropriate laboratory testing you have had. We will not purchase complex, costly, or invasive tests, such as tests of clotting factors, bone marrow aspirations, or bone marrow biopsies.

C. *What are hemolytic anemias, and how do we evaluate them under 7.05?*

1. *Hemolytic anemias* include an array of disorders that result in premature destruction of red blood cells (RBCs). The diagnosis of hemolytic anemia is based on hemoglobin electrophoresis or analysis of the contents of the RBC (hemoglobin, enzymes) and the envelope (membrane) of the RBC. Sickle cell disease, thalassemia, and their variants are some examples of hemolytic anemias.

2. The hospitalizations in 7.05B do not all have to be for the same complication of the hemolytic anemia. They may be for three different complications of the disorder. Examples of complications of hemolytic anemia that may result in hospitalization include osteomyelitis, painful (vaso-occlusive) crisis, pulmonary infections or infarctions, acute chest syndrome, pulmonary hypertension, chronic heart failure, gallbladder disease, hepatic (liver) failure, renal (kidney) failure, nephrotic syndrome, aplastic crisis, and cerebrovascular accident (stroke).

3. For 7.05C, we do not require hemoglobin to be measured during a period in which you are free of pain or other symptoms of your disorder. We will accept hemoglobin measurements made while you are experiencing complications of your hemolytic anemia.

4. *Transfusion-dependent* in 7.05D refers to the most serious type of beta thalassemia major, in which the bone marrow cannot produce sufficient numbers of RBCs to maintain life. Transfusion dependency requires life-long chronic treatment with RBC transfusions at least once every 6 weeks. We exclude prophylactic RBC transfusions for sickle cell disease (for example, to prevent stroke) because we do not consider them to be of equal medical significance to transfusion-dependent thalassemia.

D. *What are disorders of hemostasis, and how do we evaluate them under 7.08?*

1. *Disorders of hemostasis* are characterized by abnormalities in blood clotting and include both *hypocoagulation* (inadequate blood clotting) and *hypercoagulation* (excessive blood clotting). The diagnosis of a disorder of hemostasis is based on evaluation of plasma clotting factors or platelets. *Hemophilia, von Willebrand disease,* and *thrombocytopenia* are some examples of hypocoagulation disorders. *Protein C* or *protein S deficiency* and *Factor V Leiden* are examples of hypercoagulation disorders.

2. The hospitalizations in 7.08 do not all have to be for the same complication of a disorder of hemostasis. They may be for three different complications of the disorder. Examples of complications that may result in hospitalization include uncontrolled bleeding requiring multiple factor concentrate infusions or platelet transfusions, anemia, thromboses, and embolisms. We will also consider any surgery that you have to be a complication of your disorder of hemostasis if you require treatment with factor infusions or anticoagulant medication to control bleeding or coagulation in connection with your surgery.

E. *What are disorders of bone marrow failure, and how do we evaluate them under 7.10?*

1. *Disorders of bone marrow failure* are characterized by bone marrow that does not make enough healthy RBCs, granulocytes (specialized types of white blood cells), platelets, or a combination of these cell types. The diagnosis is based on bone marrow aspirations or bone marrow biopsies. Myelodysplastic syndromes, aplastic anemia, granulocytopenia, and myelofibrosis are some examples of disorders of bone marrow failure.

2. The hospitalizations in 7.10A do not all have to be for the same complication of bone marrow failure. They may be for three different complications of the disorder. Examples of complications that may result in hospitalization include uncontrolled bleeding, anemia, and systemic bacterial, viral, or fungal infections.

3. For 7.10B, *transfusion-dependent* for myelodysplastic syndromes or aplastic anemias has the same meaning as it does for beta thalassemia major. (See 7.00C4.)

F. *How do we evaluate bone marrow or stem cell transplantation under 7.17?* We will consider you to be disabled for 12 months from the date of bone marrow or stem cell transplantation, or we may consider you to be disabled for a longer period if you are experiencing any serious post-transplantation complications, such as graft-versus-host (GVH) disease, frequent infections after immunosuppressive therapy, or significant deterioration of organ systems. We do not restrict our determination of the onset of disability to the date of the transplantation in 7.17. We may establish an earlier onset date of disability due to your transplantation if evidence in your case record supports such a finding.

G. *How do we use the functional criteria in 7.18?*

1. When we use the functional criteria in 7.18, we consider all relevant information in your case record to determine the impact of your hematological disorder on your ability to function independently, appropriately, effectively, *and* on a sustained basis in a work setting. Factors we will consider when we evaluate your functioning under 7.18 include, but are not limited to: Your symptoms, the frequency and duration of complications of your hematological disorder, periods of exacerbation and remission, and the functional impact of your treatment, including the side effects of your medication.

2. *Repeated complications* means that the complications occur on an average of three times a year, or once every 4 months, each lasting 2 weeks or more; or the complications do not last for 2 weeks but occur substantially more frequently than three times in a year or once every 4 months; or they occur less frequently than an average of three times a year or once every 4 months but last substantially longer than 2 weeks. Your impairment will satisfy this criterion regardless of whether you have the same kind of complication repeatedly, all different complications, or any other combination of complications; for example, two of the same kind of complication and a different one. You must have the required number of complications with the frequency and duration required in this section. Additionally, the complications must occur within the period we are considering in connection with your application or continuing disability review.

3. To satisfy the functional criteria in 7.18, your hematological disorder must result in a ''marked'' level of limitation in one of three general areas of functioning: Activities of daily living, social functioning, or difficulties in completing tasks due to deficiencies in concentration, persistence, or pace. Functional limitation may result from the impact of the disease process itself on your mental functioning, physical functioning, or both your mental and physical functioning. This limitation could result from persistent or intermittent symptoms, such as pain, severe fatigue, or malaise, resulting in a limitation of your ability to do a task, to concentrate, to persevere at a task, or to perform the task at an acceptable rate of speed. (*Severe fatigue* means a frequent sense of exhaustion that results in significant reduced physical activity or mental function. *Malaise* means frequent feelings of illness, bodily discomfort, or lack of well-being that result in significantly reduced physical activity or mental function.) You may also have limitations because of your treatment and its side effects.

4. *Marked* limitation means that the symptoms and signs of your hematological 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. We do not define ''marked'' by a specific number of different activities of daily living or different behaviors in which your social functioning is impaired, or a specific number of tasks that you are able to complete, but by the nature and overall degree of interference with your functioning. You may have a marked limitation when several activities or functions are impaired, or even when only one is impaired. Additionally, you need not be totally precluded from performing an activity to have a marked limitation, as long as the degree of limitation interferes seriously with your ability to function independently, appropriately, and effectively. The term ''marked'' does not imply that you must be confined to bed, hospitalized, or in a nursing home.

5. *Activities of daily living* include, but are not limited to, such activities as doing household chores, grooming and hygiene, using a post office, taking public transportation, or paying bills. We will find that you have a ''marked'' limitation in activities of daily living if you have a serious limitation in your ability to maintain a household or take public transportation because of symptoms such as pain, severe fatigue, anxiety, or difficulty concentrating, caused by your hematological disorder (including complications of the disorder) or its treatment, even if you are able to perform some self-care activities.

6. *Social functioning* includes the capacity to interact with others independently, appropriately, effectively, and on a sustained basis. It includes the ability to communicate effectively with others. We will find that you have a ''marked'' limitation in maintaining

social functioning if you have a serious limitation in social interaction on a sustained basis because of symptoms such as pain, severe fatigue, anxiety, or difficulty concentrating, or a pattern of exacerbation and remission, caused by your hematological disorder (including complications of the disorder) or its treatment, even if you are able to communicate with close friends or relatives.

7. *Completing tasks in a timely manner* involves the ability to sustain concentration, persistence, or pace to permit timely completion of tasks commonly found in work settings. We will find that you have a ''marked'' limitation in completing tasks if you have a serious limitation in your ability to sustain concentration or pace adequate to complete work-related tasks because of symptoms, such as pain, severe fatigue, anxiety, or difficulty concentrating caused by your hematological disorder (including complications of the disorder) or its treatment, even if you are able to do some routine activities of daily living.

H. *How do we consider your symptoms, including your pain, severe fatigue, and malaise?* Your symptoms, including pain, severe fatigue, and malaise, may be important factors in our determination whether your hematological disorder(s) meets or medically equals a listing, or in our determination whether you are otherwise able to work. We cannot consider your symptoms unless you have medical signs or laboratory findings showing the existence of a medically determinable impairment(s) that could reasonably be expected to produce the symptoms. If you have such an impairment(s), we will evaluate the intensity, persistence, and functional effects of your symptoms using the rules throughout 7.00 and in our other regulations. (See §§ 404.1528, 404.1529, 416.928, and 416.929 of this chapter.) Additionally, when we assess the credibility of your complaints about your symptoms and their functional effects, we will not draw any inferences from the fact that you do not receive treatment or that you are not following treatment without considering all of the relevant evidence in your case record, including any explanations you provide that may explain why you are not receiving or following treatment.

I. *How do we evaluate episodic events in hematological disorders?* Some of the listings in this body system require a specific number of events within a consecutive 12-month period. (See 7.05, 7.08, and 7.10A.) When we use such criteria, the 12-month period must occur within the period we are considering in connection with your application or continuing disability review.

J. *How do we evaluate hematological disorders that do not meet one of these listings?*

1. These listings are only examples of common hematological disorders that we consider severe enough to prevent a person from doing any gainful activity. If your disorder does not meet the criteria of any of these listings, we must consider whether you have a disorder that satisfies the criteria of a listing in another body system. For example, we will evaluate hemophilic joint deformity or bone or joint pain from myelofibrosis under 1.00; polycythemia vera under 3.00, 4.00, or 11.00; chronic iron overload resulting from repeated RBC transfusion (transfusion hemosiderosis) under 3.00, 4.00, or 5.00; and the effects of intracranial bleeding under 11.00 or 12.00.

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.) Hematological 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, 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. We use the rules in §§ 404.1594, 416.994, and 416.994a of this chapter, as appropriate, when we decide whether you continue to be disabled.

7.01 Category of Impairments, Hematological Disorders

7.05 *Hemolytic anemias (including sickle cell disease, thalassemia, and their variants)* (see 7.00C), with:

A. Documented painful (vaso-occlusive) crises requiring parenteral (intravenous or intramuscular) narcotic medication, occurring at least six times within a 12-month period with at least 30 days between crises.

OR

B. Complications of hemolytic anemia requiring at least three hospitalizations within a 12-month period and occurring at least 30 days apart. Each hospitalization must last at least 48 hours, which can include hours in a hospital emergency department immediately before the hospitalization. (See 7.00C2).

OR

C. Hemoglobin measurements of 7.0 grams per deciliter (g/dL) or less, occurring at least three times within a 12-month period with at least 30 days between measurements.

OR

D. Transfusion-dependent beta thalassemia major (see 7.00C4).

7.08 *Disorders of hemostasis* (including hemophilia and thrombocytopenia) (see 7.00D), with complications requiring at least three hospitalizations within a 12-month period and occurring at least 30 days apart. Each hospitalization must last at least 48 hours, which can include hours in a hospital emergency department immediately before the hospitalization. (See 7.00D2.)

7.10 *Disorders of bone marrow failure* (including myeloproliferative syndrome, aplastic anemia, and granulocytopenia) (see 7.00E), with:

A. Complications of bone marrow failure requiring at least three hospitalizations within a 12-month period and occurring at least 30 days apart. Each hospitalization must last at least 48 hours, which can include hours in a hospital emergency department immediately before the hospitalization. (See 7.00E2.)

OR

B. Transfusion-dependent myelodysplastic syndromes or aplastic anemias (see 7.00C4).

7.17 *Hematological disorders treated by bone marrow or stem cell transplantation* (see 7.00F). Consider under a disability for at least 12 months from the date of transplantation. After that, evaluate any residual impairment(s) under the criteria for the affected body system.

7.18 *Repeated complications of hematological disorders* (see 7.00G2), including those complications listed in 7.05, 7.08, and 7.10 but without the requisite findings for those listings, or other complications (for example, anemia, osteonecrosis, retinopathy, skin ulcers, silent central nervous system infarction, cognitive or other mental limitation, or limitation of joint movement), resulting in significant, documented symptoms or signs (for example, pain, severe fatigue, malaise, fever, night sweats, headaches, joint or muscle swelling, or shortness of breath), and one of the following at the marked level (see 7.00G4):

A. Limitation of activities of daily living (see 7.00G5).

B. Limitation in maintaining social functioning (see 7.00G6).

C. Limitation in completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace (see 7.00G7).

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13.00 Malignant Neoplastic Diseases

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K. *How do we evaluate specific malignant neoplastic diseases?*

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2. *Leukemia.*

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c. *Chronic lymphocytic leukemia.*

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ii. We evaluate the complications and residual impairment(s) from chronic lymphocytic leukemia (CLL) under the appropriate listings, such as 13.05A2 or an appropriate listing in 7.00.

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3. *Macroglobulinemia or heavy chain disease.* * * * We evaluate the resulting impairment(s) under the criteria of 7.00 or any other affected body system.

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Part B

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107.00 HEMATOLOGICAL DISORDERS

A. *What hematological disorders do we evaluate under these listings?*

1. We evaluate non-malignant (non-cancerous) hematological disorders, such as hemolytic anemias (107.05), disorders of hemostasis (107.08), and disorders of bone marrow failure (107.10), which disrupt the normal development and function of white blood cells, red blood cells, platelets, and blood-clotting factors.

2. We evaluate malignant (cancerous) hematological disorders, such as lymphoma, leukemia, and multiple myeloma under the appropriate listings in 113.00, except for lymphoma associated with human

immunodeficiency virus (HIV) infection, which we evaluate under 114.08E.

B. *What evidence do we need to document that you have a hematological disorder?* We need the following evidence to document that you have a hematological disorder:

1. A laboratory report of a definitive test that establishes a hematological disorder, signed by a physician; or

2. A laboratory report of a definitive test that establishes a hematological disorder that is not signed by a physician *and* a report from a physician that states you have the disorder; or

3. When we do not have a laboratory report of a definitive test, a persuasive report from a physician that a positive diagnosis of your hematological disorder was confirmed by appropriate laboratory analysis or other diagnostic method(s). To be persuasive, this report must state that you had the appropriate definitive laboratory test or tests for diagnosing your disorder and provide the results, or explain how your diagnosis was established by other diagnostic method(s) consistent with the prevailing state of medical knowledge and clinical practice.

4. We will make every reasonable effort to obtain the results of appropriate laboratory testing you have had. We will not purchase complex, costly, or invasive tests, such as tests of clotting factors, bone marrow aspirations, or bone marrow biopsies.

C. *What are hemolytic anemias, and how do we evaluate them under 107.05?*

1. *Hemolytic anemias* include an array of disorders that result in premature destruction of red blood cells (RBCs). The diagnosis of hemolytic anemia is based on hemoglobin electrophoresis or analysis of the contents of the RBC (hemoglobin, enzymes) and the envelope (membrane) of the RBC. Sickle cell disease, thalassemia, and their variants are some examples of hemolytic anemias.

2. The hospitalizations in 107.05B do not all have to be for the same complication of the hemolytic anemia. They may be for three different complications of the disorder. Examples of complications of hemolytic anemia that may result in hospitalization include dactylitis, osteomyelitis, painful (vaso-occlusive) crisis, pulmonary infections or infarctions, acute chest syndrome, pulmonary hypertension, chronic heart failure, gallbladder disease, hepatic (liver) failure, renal (kidney) failure, nephrotic syndrome, aplastic crisis, and cerebrovascular accident (stroke).

3. For 107.05C, we do not require hemoglobin to be measured during a period in which you are free of pain or other symptoms of your disorder. We will accept hemoglobin measurements made while you are experiencing complications of your hemolytic anemia.

4. *Transfusion-dependent* in 107.05D refers to the most serious type of beta thalassemia major, in which the bone marrow cannot produce sufficient numbers of RBCs to maintain life. Transfusion dependency requires life-long chronic treatment with RBC transfusions at least once every 6 weeks. We exclude prophylactic RBC transfusions for sickle cell disease (for example, to prevent stroke) because we do not consider them to be of equal medical significance to transfusion-dependent thalassemia.

D. *What are disorders of hemostasis, and how do we evaluate them under 107.08?*

1. *Disorders of hemostasis* are characterized by abnormalities in blood clotting and include both *hypocoagulation* (inadequate blood clotting) and *hypercoagulation* (excessive blood clotting). The diagnosis of a disorder of hemostasis is based on evaluation of plasma clotting factors or platelets. *Hemophilia, von Willebrand disease,* and *thrombocytopenia* are some examples of hypocoagulation disorders. *Protein C* or *protein S deficiency* and *Factor V Leiden* are examples of hypercoagulation disorders.

2. The hospitalizations in 107.08 do not all have to be for the same complication of a disorder of hemostasis. They may be for three different complications of the disorder. Examples of complications that may result in hospitalization include uncontrolled bleeding requiring multiple factor concentrate infusions or platelet transfusions, anemia, thromboses, and embolisms. We will also consider any surgery that you have to be a complication of your disorder of hemostasis if you require treatment with factor infusions or anticoagulant medication to control bleeding or coagulation in connection with your surgery.

E. *What are disorders of bone marrow failure, and how do we evaluate them under 107.10?*

1. *Disorders of bone marrow failure* are characterized by bone marrow that does not make enough healthy RBCs, granulocytes (specialized types of white blood cells), platelets, or a combination of these cell types. The diagnosis is based on bone marrow aspirations or bone marrow biopsies. Myelodysplastic syndromes, aplastic anemia, granulocytopenia, and myelofibrosis are some examples of disorders of bone marrow failure.

2. The hospitalizations in 107.10A do not all have to be for the same complication of bone marrow failure. They may be for three different complications of the disorder. Examples of complications that may result in hospitalization include uncontrolled bleeding, anemia, and systemic bacterial, viral, or fungal infections.

3. For 107.10B, *transfusion-dependent* for myelodysplastic syndromes or aplastic anemias has the same meaning as it does for beta thalassemia major. (See 107.00C4.)

F. *How do we evaluate bone marrow or stem cell transplantation under 107.17?* We will consider you to be disabled for 12 months from the date of bone marrow or stem cell transplantation, or we may consider you to be disabled for a longer period if you are experiencing any serious post-transplantation complications, such as graft-versus-host (GVH) disease, frequent infections after immunosuppressive therapy, or significant deterioration of organ systems. We do not restrict our determination of the onset of disability to the date of the transplantation in 107.17. We may establish an earlier onset of disability due to your transplantation if evidence in your case record supports such a finding.

G. *How do we consider your symptoms, including your pain, severe fatigue, and malaise?* Your symptoms, including pain, severe fatigue, and malaise, may be important factors in our determination whether your hematological disorder meets or medically equals a listing, or in our determination whether you otherwise have marked and severe functional limitations. We cannot consider your symptoms unless you have medical signs or laboratory findings showing the existence of a medically determinable impairment(s) that could reasonably be expected to produce the symptoms. If you have such an impairment(s), we will evaluate the intensity, persistence, and functional effects of your symptoms using the rules throughout 107.00 and in our other regulations. (See §§ 416.928 and 416.929 of this chapter.) Additionally, when we assess the credibility of your complaints about your symptoms and their functional effects, we will not draw any inferences from the fact that you do not receive treatment or that you are not following treatment without considering all of the relevant evidence in your case record, including any explanations you provide that may explain why you are not receiving or following treatment.

H. *How do we evaluate episodic events in hematological disorders?* Some of the listings in this body system require a specific number of events within a consecutive 12-month period. (See 107.05, 107.08, and 107.10A.) When we use such criteria, the 12-month period must occur within the period we are considering in connection with your application or continuing disability review.

I. *How do we evaluate hematological disorders that do not meet one of these listings?*

1. These listings are only examples of common hematological disorders that we consider severe enough to result in marked and severe functional limitations. If your disorder does not meet the criteria of any of these listings, we must consider whether you have a disorder that satisfies the criteria of a listing in another body system. For example, we will evaluate hemophilic joint deformity under 101.00; polycythemia vera under 103.00, 104.00, or 111.00; chronic iron overload resulting from repeated RBC transfusion (transfusion hemosiderosis) under 103.00, 104.00, or 105.00; and the effects of intracranial bleeding under 111.00 or 112.00.

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.) Hematological 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.

107.01 Category of Impairments, Hematological Disorders

107.05 *Hemolytic anemias* (including sickle cell disease, thalassemia, and their variants) (see 107.00C), with:

A. Documented painful (vaso-occlusive) crises requiring parenteral (intravenous or

intramuscular) narcotic medication, occurring at least six times within a 12-month period with at least 30 days between crises.

OR

B. Complications of hemolytic anemia requiring at least three hospitalizations within a 12-month period and occurring at least 30 days apart. Each hospitalization must last at least 48 hours, which can include hours in a hospital emergency department immediately before the hospitalization. (See 107.00C2.)

OR

C. Hemoglobin measurements of 7.0 grams per deciliter (g/dL) or less, occurring at least three times within a 12-month period with at least 30 days between measurements.

OR

D. Transfusion-dependent beta thalassemia major (see 107.00C4).

107.08 *Disorders of hemostasis* (including hemophilia and thrombocytopenia) (see 107.00D), with complications requiring at least three hospitalizations within a 12-month period and occurring at least 30 days apart. Each hospitalization must last at least 48 hours, which can include hours in a hospital emergency department immediately before the hospitalization. (See 107.00D2.)

107.10 *Disorders of bone marrow failure (including myeloproliferative syndrome, aplastic anemia, and granulocytopenia)* (see 107.00E), with:

A. Complications of bone marrow failure requiring at least three hospitalizations within a 12-month period and occurring at least 30 days apart. Each hospitalization must last at least 48 hours, which can include hours in a hospital emergency department immediately before the hospitalization. (See 107.00E2.)

OR

B. Transfusion-dependent myelodysplastic syndromes or aplastic anemias (see 107.00C4).

107.17 *Hematological disorders treated by bone marrow or stem cell transplantation* (see 107.00F). Consider under a disability for at least 12 months from the date of transplantation. After that, evaluate any residual impairment(s) under the criteria for the affected body system.

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DEPARTMENT OF EDUCATION

34 CFR Part 200

[Docket ID ED–2013–OESE–0018]

Title I—Improving the Academic Achievement of the Disadvantaged

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice of proposed rulemaking; notice to reopen the public comment period.

SUMMARY: On August 23, 2013, we published in the **Federal Register** (78 FR 52467) a notice of proposed rulemaking regarding modified academic achievement standards and alternate assessments based on those modified academic achievement standards. This notice established an October 7, 2013, deadline for the submission of written comments. We are reopening the public comment period for seven days.

DATES: For the proposed rule published on August 23, 2013 (78 FR 52467), written submissions must be received by the Department on or before November 26, 2013.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via U.S. mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* to submit your comments electronically. Information on using *Regulations.gov,* including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under ''Are you new to the site?''
- *U.S. Mail, Commercial Delivery, or Hand Delivery:* If you mail or deliver your comments about the proposed amendments, address them to Monique Chism, Director, Student Achievement and School Accountability Programs, Office of Elementary and Secondary Education, Attention: AA–MAAS NPRM, U.S. Department of Education, 400 Maryland Avenue SW., Room 3W224, Washington, DC 20202–6132.

Privacy Note: The Department's policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov.* Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: Carlos Martinez, U.S. Department of Education, 400 Maryland Avenue SW., Room 3W104, Washington, DC 20202–6132. Telephone: 202–260–1440.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Background: On August 23, 2013, we published a notice of proposed rulemaking in the **Federal Register** (78 FR 52467), proposing to amend the regulations governing Title I, Part A of the Elementary and Secondary Education Act of 1965, as amended (ESEA) (the ''Title I regulations''), to no longer authorize a State, in satisfying ESEA accountability requirements, to define modified academic achievement standards and develop alternate assessments based on those modified academic achievement standards. These proposed amendments would permit, as a transitional measure and for a limited period of time, States that administered alternate assessments based on modified academic achievement standards in the 2012–13 school year to continue to administer alternate assessments based on modified academic achievement standards and include the results in adequate yearly progress (AYP) calculations, subject to limitations on the number of proficient scores that may be counted for AYP purposes. The notice of proposed rulemaking established an October 7, 2013, deadline for the submission of written comments. Though the Federal eRulemaking Portal was in operation during the recent government shutdown, which included the final seven days of the original public comment period, we recognize that interested parties reasonably may have believed that the government shutdown resulted in a shutdown of the public comment period. To ensure that all interested parties are provided the opportunity to submit comments, we are reopening the public comment period for seven days.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or compact disc) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

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