

becomes the southern boundary of Cheboygan County, and continuing along the Cheboygan county line to the intersection of the Cheboygan county line with the eastern boundary of Charlevoix County; then

(6) Proceed south then east along the Charlevoix county line to the intersection of the Charlevoix county line with the eastern boundary of Antrim County; then

(7) Proceed south along the Antrim county line to the point where the county line turns due east; then

(8) Proceed west in a straight line to the eastern shoreline of Grand Traverse Bay; then

(9) Proceed north-northeasterly along the shorelines of Grand Traverse Bay, Lake Michigan, Little Traverse Bay, Sturgeon Bay, Trails End Bay, and the Straits of Mackinac, returning to the beginning point.

Signed: July 28, 2015.

John J. Manfreda,
Administrator.

[FR Doc. 2015-19277 Filed 8-5-15; 8:45 am]

BILLING CODE 4810-31-P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 4

RIN 2900-AO19

Schedule for Rating Disabilities: The Hematologic and Lymphatic Systems

AGENCY: Department of Veterans Affairs.
ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend the portion of the VA Schedule for Rating Disabilities (Rating Schedule) that addresses the hematologic and lymphatic systems. The intended effect of this change is to incorporate medical advances that have occurred since the last review, update medical terminology, add medical conditions not currently in the Rating Schedule, and refine criteria for further clarity and ease of rater application.

DATES: Comments must be received by VA on or before October 5, 2015.

ADDRESSES: Written comments may be submitted through www.Regulations.gov; by mail or hand-delivery to the Director, Regulation Policy and Management (02REG), Department of Veterans Affairs, 810 Vermont Ave. NW., Room 1068, Washington, DC 20420; or by fax to (202) 273-9026. Comments should indicate that they are submitted in response to RIN 2900-AO19—Schedule

for Rating Disabilities: The Hematologic and Lymphatic Systems. Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1068, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461-4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at www.Regulations.gov.

FOR FURTHER INFORMATION CONTACT: Nick Olmos-Lau, M.D., Medical Officer (211C), Compensation Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461-9695. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: As part of our ongoing revision of the VA Schedule for Rating Disabilities (Rating Schedule), we are proposing changes to 38 CFR 4.117, Schedule of ratings—hemic and lymphatic systems, and appendices A, B, and C of part 4 pertaining to this section. This section was last updated in 1995. By these revisions, we aim to update medical terminology; add medical conditions not currently in the Rating Schedule; and revise the rating criteria to reflect medical advances and to clarify them for ease of application.

Proposed Title Change: The Hematologic and Lymphatic Systems

“Hemic” is an adjective previously used to describe diseases of or related to the blood. The current medical term for diseases of the blood or blood-forming organs is “hematologic.” In addition, the 2013 National Library of Medicine—Medical Subject Headings (MESH) descriptor advisory discourages the use of the term “hemic” as too general, and recommends instead the use of the term “hematologic” as more specific (http://www.nlm.nih.gov/cgi/mesh/2013/MB_cgi?mode=&index=6154&field=all&HM=&II=&PA=&form=&input=).

VA therefore proposes to edit the header of § 4.117 to “The Hematologic and Lymphatic Systems” and the title of § 4.117 to “Schedule of ratings—hematologic and lymphatic systems.”

Modification and Reorganization of Current Diagnostic Code (DC) 7700 (Anemia, Hypochromic-Microcytic and Megaloblastic, Such as Iron-Deficiency and Pernicious Anemia)

Anemia is predominantly hereditary or secondary, a symptom of another condition. Secondary anemia is corrected by treatment of the underlying

condition. Examples of conditions that cause secondary anemia include osteomyelitis (DC 5000) and hypothyroidism (DC 7903). Anemia is most appropriately evaluated as part of the underlying service-connected disability causing the anemia. VA proposes to address in proposed DCs 7720, 7721, 7722, and 7723 anemias that are neither hereditary nor addressed under DCs for the causative conditions.

The title of current DC 7700 is “Anemia, hypochromic-microcytic and megaloblastic, such as iron-deficiency and pernicious anemia.” This title groups anemias based on red blood cell (RBC) morphology. VA proposes separate DCs and criteria for the major types of anemia. Separation would assist raters in distinguishing amongst and clarifying severity of anemias. Accordingly, VA proposes the removal of DC 7700 from the Rating Schedule, and adding DC 7720 Iron deficiency anemia, 7721 Folic acid deficiency, 7722 Pernicious anemia and Vitamin B₁₂ deficiency anemia, and 7723 Acquired hemolytic anemia.

Anemia is currently rated at levels of 100, 70, 30, 10, and 0-percent, depending on the hemoglobin level and the associated signs and symptoms. It is evaluated at 100-percent for hemoglobin of 5gm/100ml or less, with findings such as high-output congestive heart failure or dyspnea at rest. It is evaluated at 70-percent for hemoglobin of 7gm/100ml or less, with findings such as dyspnea on mild exertion, cardiomegaly, tachycardia (100 to 120 beats per minute) or syncope (three episodes in the last six months). It is evaluated at 30-percent for hemoglobin of 8gm/100ml or less, with findings such as weakness, easy fatigability, headaches, lightheadedness, or shortness of breath. It is evaluated at 10-percent for hemoglobin of 10gm/100ml or less, with findings such as weakness, easy fatigability, or headaches. It is evaluated at 0-percent for hemoglobin of 10gm/100ml or less and asymptomatic.

While there is a high correlation between hemoglobin levels and signs or symptoms of anemia in acute anemia, the correlation is less accurate in chronic anemia. As the duration of the anemia lengthens, the individual becomes more tolerant of lower hemoglobin levels and symptom manifestation decreases. The functional impact of chronic anemia is more accurately measured by mode and frequency of treatment. VA proposes rating criteria based on the specific mode(s) and frequency of treatment.

VA notes that the existing 100 and 70 percent categories for rating anemia are more descriptive of acute rather than

chronic anemia. Acute anemia is usually related to gastrointestinal or uterine bleeding or traumatic injuries with acute hemorrhage. The descriptors in the 100 and 70 percent categories reflect a clinical picture of rapid and extensive blood loss, and their symptoms include high output cardiac failure with hypoxemia due to inability to sustain proper tissue oxygenation, caused by low hemoglobin levels which can lead to shock or collapse. The laboratory values and symptoms described in the 100 and 70 percent categories of the current anemia DC reflect intolerable and life threatening symptoms that require emergency hospitalization and transfusion. See G. Limbruno, "Recommendations for transfusion of red blood cells," 7 Blood Transfusion 49 (2009).

Chronic anemia on the other hand, develops at a more gradual pace, and is usually related to serious medical conditions such as malignancies (cancer) on chemotherapy, infection (osteomyelitis), thyroid disease, hemoglobin disorders (such as sickle-cell disease or thalassemia), renal failure or chronic lower gastrointestinal bleeding. In such cases a slower decline in hemoglobin values allows gradual adjustment. However, even when an individual reaches such low levels as contemplated in the 100 and 70 percent evaluation, such a case reflects acute critical health emergencies that are unsustainable rather than having an ongoing chronic long term disability impairment as with chronic anemia. In those cases where chronic anemia results in urgent hospitalization, VA finds that compensation is more appropriately determined by evaluating the underlying primary medical problem that gave rise to the service-connected chronic anemia. As these more severe cases represent less than 2 percent of the total number of disability awards for anemia in the past years, VA does not anticipate a significant impact on future evaluations based on anemia.

Proposed DC 7720 (Iron Deficiency Anemia)

Iron deficiency anemia is defined as a decrease in total body iron content. Total body iron content is regulated through the balance of iron absorption and loss. Iron deficiency anemia is most commonly due to blood loss, post-hemorrhagic anemia. Iron deficiency anemia due to blood loss would be evaluated under criteria for the causative condition, *e.g.*, duodenal ulcer (DC 7305) or hemorrhoids (DC 7336), rather than under DC 7720. VA proposes to clarify the rating of anemia due to blood loss by adding the following note:

"Do not evaluate iron deficiency anemia due to blood loss under this diagnostic code. Evaluate iron deficiency anemia due to blood loss under the criteria for the condition causing the blood loss."

Iron deficiency anemia can be readily treated by diet or dietary supplements. It is ordinarily short term with mild symptoms and responds to treatment. However, fatigue due to chronic, severe iron deficiency anemia can decrease the ability to perform physical labor. VA proposes rating levels of 30, 10, and 0-percent for iron deficiency anemia not due to blood loss. VA proposes a 30-percent evaluation for iron deficiency anemia requiring intravenous (IV) iron infusions on average 4 or more times per 12-month period; a 10-percent evaluation if requiring continuous treatment with high-dose oral supplementation; and a 0-percent evaluation if asymptomatic or requiring treatment only by dietary modification.

Proposed DC 7721 (Folic Acid Deficiency)

The prevalence of folic acid deficiency has decreased in the United States due to dietary fortification. This form of anemia is amenable to dietary modification and oral supplementation. VA proposes a 10-percent evaluation for folic acid deficiency requiring continuous treatment with high-dose oral supplementation. VA proposes a 0-percent evaluation when asymptomatic or requiring treatment only by dietary modification.

Proposed DC 7722 (Pernicious Anemia and Vitamin B₁₂ Deficiency Anemia)

Pernicious anemia is the most common form of severe Vitamin B₁₂ deficiency. S. Stabler, "Vitamin B₁₂ deficiency," 368(2) *New Eng. J. Med.* 149 (2013). Other causes of Vitamin B₁₂ deficiency that could lead to anemia include: Dietary avoidance (vegetarianism), malabsorption, gastrectomy or gastric bypass, inflammatory bowel disease (IBD), pancreatic insufficiency, use of histamine 2-blockers and proton pump inhibitors. Pernicious anemia is associated with gastric atrophy, due to autoimmune destruction, and a lack of intrinsic factor, a glycoprotein necessary for the absorption of Vitamin B₁₂, in the gastric mucosa. Pernicious anemia requires lifelong treatment with Vitamin B₁₂ injections, sublingual or high-dose oral Vitamin B₁₂ tablets, or Vitamin B₁₂ nasal spray or gel. Since disabilities from nutritional B₁₂ deficiency are consistent with pernicious anemia, nutritional B₁₂ deficiency would be rated under the same diagnostic code as pernicious anemia.

In accordance with the above discussion, VA proposes to evaluate pernicious anemia and other forms of severe B₁₂ deficiency at 100 percent for initial diagnosis requiring transfusion due to severe anemia, or if there are signs or symptoms related to central nervous system impairment, such as encephalopathy, myelopathy, or severe peripheral neuropathy, requiring parenteral B₁₂ therapy. Since certitude of neurologic reversibility cannot be initially determined, and B₁₂ absorption issues may require lifelong supplementation with B₁₂ injections every 1–3 months, VA proposes to re-evaluate at 6 months and rate according to presence of neurologic or gastrointestinal residuals.

If absorption is adequate, lifelong oral or intranasal B₁₂ treatment may be used. VA proposes to evaluate pernicious anemia and other forms of severe Vitamin B₁₂ deficiency at 10 percent if it requires continuous treatment with Vitamin B₁₂ injections, Vitamin B₁₂ sublingual or high-dose oral tablets, or Vitamin B₁₂ nasal spray or gel.

VA proposes to add a note regarding evaluation which states that the 100-percent evaluation for pernicious anemia and Vitamin B₁₂ deficiency shall be assigned as of the date of initial diagnosis requiring transfusion due to severe anemia or parenteral B₁₂ therapy and shall continue with a mandatory VA examination six months following hospital discharge or cessation of continuous parenteral B₁₂ therapy. The note would also state that any reduction in evaluation based upon that or any subsequent examination shall be subject to the provisions of 38 CFR 3.105(e) and that, thereafter, evaluation would be at 10-percent and any residual effects of pernicious anemia, such as neurologic involvement causing peripheral neuropathy, myelopathy, dementia, or related gastrointestinal residuals, would be separately evaluated under the most appropriate diagnostic code.

Proposed 7723 (Acquired Hemolytic Anemia)

There are over 200 causes of hemolytic anemia, including both acquired and hereditary types. The causes of acquired hemolytic anemia include immune disorders, toxic chemicals, medications, physical damage (such as may occur with prosthetic heart valves), and infections. Treatment may include intermittent corticosteroids; other immunosuppressive drugs; immune globulin; monoclonal antibody therapy, such as rituximab; splenectomy; erythropoiesis stimulating agent (ESA) to boost production of RBC;

plasmapheresis (a process similar to dialysis that can remove certain components, such as harmful antibodies, from the blood); blood transfusions; and peripheral blood or bone marrow stem cell transplantation (www.nhlbi.nih.gov/health).

VA proposes to list the evaluation criteria for acquired hemolytic anemia under DC 7723.

VA proposes to rate acquired hemolytic anemia at 100 percent, if requiring a bone marrow transplant or continuous intravenous or immunosuppressive therapy (e.g., prednisone, Cytoxan (cyclophosphamide), azathioprine, or rituximab). VA proposes to rate acquired hemolytic anemia at 60 percent, if requiring immunosuppressive medication an average of 4 or more times per 12-month period. VA proposes to rate acquired hemolytic anemia at 30 percent, if requiring an average of 2–3 courses of immunosuppressive therapy per 12-month period. VA proposes to rate acquired hemolytic anemia at 10 percent, if requiring an average of 1 course of immunosuppressive therapy per 12-month period. VA proposes to evaluate acquired hemolytic anemia at 0 percent if asymptomatic.

VA also proposes to add a Note (1) in relation to this DC, stating that a 100-percent evaluation for bone marrow transplant shall be assigned as of the date of hospital admission and shall continue for six months after hospital discharge with a mandatory VA examination six months following hospital discharge. The note would also state that any reduction in evaluation based upon that or any subsequent examination shall be subject to the provisions of 38 CFR 3.105(e).

To remind rating specialists that there is a separate DC for splenectomy, VA proposes to add a Note (2), which would state that VA will separately evaluate splenectomy under DC 7706 and combine with an evaluation under DC 7723.

DC 7702 (Agranulocytosis, Acute); Proposed DC 7702 (Agranulocytosis, Acquired)

Agranulocytosis, by definition, is an acute condition. Therefore, this disease is better categorized as agranulocytosis, acquired, than as agranulocytosis, acute. VA proposes to list updated evaluation criteria for this condition under DC 7702 with the title “Agranulocytosis, acquired” to reflect current medical terminology.

Acute agranulocytosis is currently evaluated at levels of 100, 60, 30, and 10 percent based on type of treatment or

frequency of episodes of recurring infections. A 100-percent evaluation is currently assigned if requiring bone marrow transplant or transfusion of platelets or red cells at least once every six weeks or if infections recur at least once every six weeks. A 60-percent evaluation is assigned if requiring transfusion of platelets or red cells at least once every three months or if infections recur at least once every three months. A 30-percent evaluation is assigned if requiring transfusion of platelets or red cells at least once per year but less than once every three months or if infections recur at least once per year but less than once every three months. A 10-percent evaluation is assigned if requiring continuous medication for control.

Due to advances in the pharmacological treatment of agranulocytosis and a shift in standard of care, VA proposes the deletion of the number of transfusions as a criterion for rating agranulocytosis. “Granulocyte transfusions have undergone a cycle of popularity followed by disfavor,” although they may be useful in patients with life-threatening infections whose conditions are not responding to antibiotics. A. Distenfeld, M.D., N.Y. Univ. Sch. of Med., “Agranulocytosis,” eMedicine (Updated Jan 9, 2015, by C. Braden). These transfusions are accompanied by many complications, including severe febrile reactions. The use of granulocyte transfusions remains controversial. VA proposes to evaluate agranulocytosis based on type and frequency of treatment or the average number of infections per 12-month period. VA proposes to evaluate agranulocytosis at 100 percent if requiring bone marrow transplant or if infections recur, on average, at least once every six weeks per 12-month period. VA proposes to evaluate agranulocytosis at 60 percent if requiring intermittent myeloid growth factors (granulocyte colony-stimulating factor (G-CSF) or granulocyte-macrophage colony-stimulating factor (GM-CSF)) or continuous immunosuppressive therapy such as cyclosporine to maintain absolute neutrophil count (ANC) greater than 500/ μ l but less than 1000/ μ l, or if infections recur, on average, at least once every three months per 12-month period. VA proposes to evaluate agranulocytosis at 30 percent if requiring intermittent myeloid growth factors to maintain ANC greater than 1000/ μ l or if infections recur, on average, at least once per 12-month period but less than once every three months per 12-month period. VA

proposes to evaluate agranulocytosis at 10 percent if requiring continuous medication (e.g., antibiotics) for control or if requiring intermittent use of a myeloid growth factor to maintain ANC greater than or equal to 1500/ μ l.

VA proposes to preserve the existing note under current DC 7702.

DC 7703 (Leukemia)

One type of leukemia, chronic myelogenous leukemia (CML), is evaluated as a myeloproliferative disorder. CML is a heterogeneous disease with three clinical phases: Chronic, transitional (accelerated), and acute (blast). Most individuals with CML are diagnosed in the chronic phase and with adequate treatment can remain in this phase for several years. However, patients with CML are never “cured” with current therapy, but often have no evidence of the disease at a molecular level. The term used for this state is “complete molecular remission” (CMR). These patients require continuous treatment because otherwise they would relapse. Patients with CML need to be considered as having active disease even when they would otherwise appear to be in remission. Therefore, VA proposes to evaluate CML under separate DC 7719.

Leukemia is currently evaluated at 100 percent for active disease or during a treatment phase. There is also a directive to otherwise rate as anemia (current DC 7700) or aplastic anemia (DC 7716), whichever would result in the greater benefit.

VA proposes to evaluate all forms of active leukemia other than chronic myelogenous leukemia under DC 7703.

VA proposes to retain the 100-percent evaluation “[w]hen there is active disease or during a treatment phase.” For rating purposes, VA considers any diagnosed cancer as “active disease” if medical evidence does not demonstrate the eradication of cancerous cells, if the cancer is not in remission, or when the condition requires continuous treatment since otherwise there would invariably be a relapse.

Since there are numerous residual effects of leukemia and its treatment, which may involve any body system, VA proposes to remove the current directive, which addresses only certain hematologic residuals: “Otherwise rate as anemia (code 7700) or aplastic anemia (code 7716), whichever would result in the greater benefit.” VA proposes another directive, which would read: “Otherwise rate residuals under the appropriate diagnostic code(s).”

One of the four main types of leukemia, chronic lymphocytic

leukemia (CLL), is now often diagnosed at a very early stage when the blood lymphocyte count is high, but the patient does not have enlargement of the lymph nodes, spleen, or liver, and the red blood cells and platelets are normal or nearly so. The average age of patients with this type of leukemia is 70. In the staging system commonly used to assess the severity of CLL, this early stage is known as Rai Stage 0. Occasionally patients are diagnosed instead as having monoclonal B-cell lymphocytosis (MBL). The diagnosis is in a similar category as Rai Stage 0 CLL. Unlike the course of the other major types of leukemia, this early stage of CLL may not progress for many years. The median survival time for this stage of disease is over 12 years. No treatment is required, and it is considered a low risk stage. For individuals with CLL at Rai Stage 0, assigning a 100-percent evaluation would be inappropriate, since antineoplastic treatment is not warranted, and at this early stage, there is little or no effect on a patient's well-being, according to the Leukemia and Lymphoma Society (www.leukemia-lymphoma.org/). Therefore, VA proposes to add a 0-percent evaluation level for asymptomatic low risk level patients with CLL at Rai Stage 0.

Patients with lymphocytosis, enlarged lymph nodes and splenomegaly or hepatomegaly are defined as having an intermediate risk for disease progression (Rai Stages I or II). Patients with hepatomegaly (enlarged liver), anemia (Hemoglobin <11 g/dL), or thrombocytopenia (platelet counts lower than 100,000) are considered to be in the higher risk categories for disease progression (Rai Stages III and IV). Oncologists have developed criteria to determine when to initiate treatment based on the presence of genetic mutation, micro-globulins, lymphocyte doubling times and other markers to help boost the accuracy criteria of the CLL tumor burden along with staging provided by the Rai scale. Patients with newly diagnosed asymptomatic early-stage disease are generally monitored without therapy unless they show signs of disease progression or symptoms. Patients with intermediate risk (Rai Stages I and II) and those with high risk (Rai Stages III or IV) are usually started on treatment.

VA proposes editorial changes to the currently existing note, which would be numbered as Note (1).

Rai Stages I–IV (intermediate and high risk) usually require progressively aggressive therapy, consistent with leukemias and other malignancies. VA proposes addition of notes to clarify

evaluation of CLL that progresses beyond Rai Stage 0.

The proposed Note (2) would read: “Evaluate symptomatic chronic lymphocytic leukemia that is at Rai Stage I, II, III, or IV the same as any other leukemia evaluated under this diagnostic code.”

The proposed Note (3) would read: “Evaluate residuals of leukemia or leukemia therapy under the appropriate diagnostic code(s). Myeloproliferative Disorders: (Diagnostic Codes 7704, 7718, 7719).”

Myeloproliferative Disorders

This section includes: DC 7704 (Polycythemia vera); Proposed DC 7718 (Essential thrombocythemia and primary myelofibrosis); Proposed DC 7719 (Chronic myelogenous leukemia (CML) (chronic myeloid leukemia or chronic granulocytic leukemia)).

Myeloproliferative disorders are a group of slow-growing blood neoplasms in which the bone marrow produces excess numbers of red blood cells, white blood cells, or platelets. Polycythemia vera is one type of myeloproliferative disorder. Other conditions included in this category are essential thrombocythemia, primary idiopathic myelofibrosis, and chronic myelogenous leukemia (CML) (also called chronic myeloid leukemia or chronic granulocytic leukemia) (www.cancer.gov/cancertopics/types/myeloproliferative and www.leukemia-lymphoma.org). These conditions may evolve into acute leukemia.

According to the National Cancer Institute of the U.S. National Institutes of Health, a variety of treatments are used for myeloproliferative disorders. For example, polycythemia vera is commonly treated by phlebotomy (removal of blood, as needed, to decrease the number of red blood cells and platelets). However, other treatments used to achieve appropriate levels of cells and to reduce complications, such as thrombosis, include radioactive phosphorus (which suppresses the overproduction of blood cells), interferon alpha (which boosts the immune system), chemotherapeutic agents (including myelosuppressants, which decrease bone marrow production), and low dose aspirin. Some of these treatments are also used for other myeloproliferative disorders.

Other treatments used for myeloproliferative disorders include: stem cell transplant; platelet apheresis (removal of platelets from the blood in a process similar to dialysis); blood or platelet transfusions (when the bone marrow production is insufficient); periods of hospitalizations to treat

infections (since patients with these conditions are at high risk for serious infections); erythropoiesis-stimulating agents (ESA) to boost production of red blood cells; tyrosine kinase inhibitors such as imatinib (Gleevec) (commonly used to treat chronic myelogenous leukemia) or ruxolitinib (new kinase inhibitor); and androgen-like drugs (which also may stimulate the bone marrow).

Polycythemia vera is the only myeloproliferative disorder, of the above-mentioned disorders, currently evaluated in the Rating Schedule. Therefore, VA proposes the addition of DCs to provide rating criteria for other diseases under the category of myeloproliferative disorders: 7718 Essential thrombocythemia/primary myelofibrosis, and 7719 Chronic myelogenous leukemia (CML) (chronic myeloid leukemia or chronic granulocytic leukemia).

VA proposes to add a note applicable to all myeloproliferative disorders, which would state that if the condition undergoes leukemic transformation, it should be evaluated as leukemia under DC 7703. This note is intended to remind rating specialists that a myeloproliferative disorder may undergo leukemic transformation and warrant evaluation under DC 7703.

VA also proposes to add another note applicable to all myeloproliferative disorders, which would state that a 100-percent evaluation shall be assigned as of the date of hospital admission for peripheral blood or bone marrow stem cell transplant, or during the period of treatment with radioactive phosphorus or chemotherapy (including myelosuppressants), and that six months following hospital discharge or, in the case of radioactive phosphorus or chemotherapy treatment, six months after completion of treatment, the appropriate disability rating shall be determined by mandatory VA examination. The note would also state that any reduction in evaluation based upon that or any subsequent examination shall be subject to the provisions of 38 CFR 3.105(e).

DC 7704 (Polycythemia Vera)

VA proposes a 100-percent evaluation if requiring peripheral blood or bone marrow stem-cell transplant or treatment with radioactive phosphorus or chemotherapy (including myelosuppressants).

VA proposes a 60-percent evaluation if requiring phlebotomy 6 or more times per 12-month period to control RBC count or if requiring radioactive phosphorus treatment, chemotherapy, or targeted agents like ruxolitinib or

imatinib. VA proposes a 30-percent evaluation if requiring phlebotomy 4–5 times per 12-month period or if requiring continuous biologic therapy or myelosuppressive agents to maintain platelet count in the less than 200,000 range or white blood cells (WBC) in the less than 12,000 range. VA proposes a 10-percent evaluation if requiring, on an intermittent basis, phlebotomy, biologic therapy, or interferon, as needed, but less than 4 times per 12-month period.

VA proposes to number the current note for DC 7704 as Note (1). VA proposes the addition of the two notes described above for all myeloproliferative disorders to be added as Notes (2) and (3) after the current note for DC 7704.

Proposed DC 7718 (Essential Thrombocythemia and Primary Myelofibrosis)

VA proposes a 100-percent evaluation if requiring either continuous myelosuppressive therapy or, for six months following hospital admission, any of the following treatments: Peripheral blood or bone marrow stem cell transplant, or treatment with radioactive phosphorus or chemotherapy (including myelosuppressants); a 70 percent evaluation if requiring either continuous or intermittent myelosuppressive therapy to maintain platelet count less than $500 \times 10^9/L$; a 30-percent evaluation if requiring continuous or intermittent myelosuppressive therapy to maintain platelet count of 200,000–400,000 or white blood cell (WBC) count of 4,000–10,000; and a 0-percent evaluation if asymptomatic.

VA proposes the addition of the two notes described above for all myeloproliferative disorders.

Proposed DC 7719 (Chronic Myelogenous Leukemia (CML) (Chronic Myeloid Leukemia or Chronic Granulocytic Leukemia))

VA proposes a 100-percent evaluation if requiring peripheral blood or bone marrow stem cell transplant or requiring continuous myelosuppressive or immunosuppressive therapy. VA proposes a 60-percent evaluation if requiring intermittent myelosuppressive therapy, or targeted therapy with tyrosine kinase inhibitors, or interferon treatment. VA proposes a 30-percent evaluation if in apparent remission on continuous targeted therapy with tyrosine kinase inhibitors.

VA proposes the addition of the two notes described above for all myeloproliferative disorders.

Current DC 7705 (Thrombocytopenia, Primary, Idiopathic or Immune); Proposed DC 7705 (Immune Thrombocytopenia)

Thrombocytopenia is currently evaluated at levels of 100, 70, 30, and 0 percent based on the platelet count, the presence or absence of bleeding episodes, and whether treatment is required. VA proposes to change the title from “Thrombocytopenia, primary, idiopathic or immune” to “Immune thrombocytopenia.”

VA proposes to use the same bases for evaluation of disability, while updating criteria to reflect advances in medical knowledge. A 100-percent evaluation is currently assigned if the platelet count is less than 20,000, with active bleeding, requiring treatment with medication and transfusions. A 70-percent evaluation is currently assigned for a platelet count between 20,000 and 70,000, not requiring treatment, without bleeding. A 30-percent evaluation is currently assigned for a stable platelet count between 70,000 and 100,000, without bleeding. A 0-percent evaluation is currently assigned for a stable platelet count of 100,000 or more, without bleeding. VA proposes to provide evaluation levels of 100, 70, 30, 10 and 0 percent, with criteria based in part on the recommendations of the American Society of Hematology for diagnosis and treatment of idiopathic thrombocytopenic purpura, updated in 2010.

VA proposes to assign a 100-percent evaluation for immune thrombocytopenia requiring chemotherapy for chronic refractory thrombocytopenia or a platelet count from 20,000 to 30,000 despite treatment. VA proposes to assign a 70-percent evaluation if requiring immunosuppressive therapy or for a platelet count higher than 30,000 but not higher than 50,000, with history of hospitalization because of severe bleeding requiring intravenous immune globulin, high-dose parenteral corticosteroids, and platelet transfusions. VA proposes to assign a 30-percent evaluation for a platelet count higher than 30,000 but not higher than 50,000, with either immune thrombocytopenia or mild mucous membrane bleeding which requires oral corticosteroid therapy or intravenous immune globulin. VA proposes to assign a 10-percent evaluation for a platelet count higher than 30,000 but not higher than 50,000, not requiring treatment. VA proposes to assign a 0-percent evaluation for platelet count above 50,000 and asymptomatic, or for

immune thrombocytopenia in remission.

VA also proposes to add a note instructing raters to separately evaluate splenectomy under DC 7706 and combine with an evaluation under this DC. VA proposes to add a second note clarifying re-evaluation following chemotherapy as follows: “A 100-percent evaluation shall continue beyond the cessation of chemotherapy. Six months after discontinuance of such treatment, the appropriate disability rating shall be determined by mandatory VA examination. Any reduction in evaluation based upon that or any subsequent examination shall be subject to the provisions of [38 CFR 3.105(e)].”

DC 7706 (Splenectomy); DC 7707 (Spleen, Injury of, Healed)

VA proposes no change to these DCs except to move the word “separately” in the note following DC 7706 to clarify the meaning.

Current DC 7709 (Hodgkin’s Disease); Proposed DC 7709 (Hodgkin’s Lymphoma)

VA proposes to change the title associated with current DC 7709 from “Hodgkin’s disease” to “Hodgkin’s lymphoma” to be consistent with current medical terminology and knowledge. VA proposes minor editorial changes to the existing note. The following sentence was modified to read as follows at the end of the existing note: “If there has been no local recurrence or metastasis, rate on residuals under the appropriate diagnostic code(s).”

DC 7710 (Adenitis, Tuberculous, Active or Inactive)

VA proposes no changes for this diagnostic code except for the deletion of a section symbol (§).

Proposed DC 7712 (Multiple Myeloma)

VA proposes to add a new DC 7712 for multiple myeloma (MM). MM is a type of systemic, incurable malignancy resulting from the proliferation of abnormal plasma cells in the bone marrow. The overgrowth of these plasma cells results in tumors that are deposited primarily in the bones, but also in the kidneys and other organs. The median age at diagnosis is 65 years, and the average 5-year survival rate is about 30 percent. Survival time depends on many factors, such as age, gender, race, stage of disease at time of diagnosis, and treatment. Recent therapeutic advances have improved the quality of life and length of survival time, but MM remains incurable. Some patients go into remission for various

periods but require maintenance therapy even while in remission.

MM has a wide variety of clinical presentations that can vary between asymptomatic to severely symptomatic.

Asymptomatic (smoldering or indolent) myeloma is a slow-growing, asymptomatic precursor or pre-malignant phase of MM. It is usually not treated until evidence of end organ damage develops. It has a high risk of developing into MM. However, since it is not malignant, is asymptomatic, and does not require treatment, it would not warrant a compensable evaluation under this diagnostic code, and VA proposes to rate it at 0 percent.

Even if smoldering MM is currently regarded as a pre-malignant state, there are subsets of patients with different rates of progression towards MM. No single pathological or molecular feature can be used to distinguish between smoldering and pre-malignant MM with clonal plasma cells from those with clonal malignant plasma cells. A biomarker-based definition that can predict this transformation is needed but is not yet currently available.

Symptomatic multiple myeloma, as further defined in the below proposed notes to new DC 7712, would therefore be rated at 100 percent. VA proposes the following notes to new DC 7712 based on the most recently updated diagnostic criteria staging system of the International Diagnostic Working Group of 2014. See S. Rajkumar, M.D., "International Myeloma Working Group updated criteria for the diagnosis of multiple myeloma," 15(12) *Lancet Oncol.* e538 (2014).

The first note would state the following: "Symptomatic myeloma requires an elevated serum or urine M (monoclonal) protein value (however no specific concentration is required for diagnosis) or presence of increased bone marrow clonal plasma cells $\geq 10\%$. There must be also evidence of related organ tissue impairment (ROTI) due to the plasma cell proliferation. This process is manifested by elevated serum calcium, renal failure, anemia, and bone lesions (CRAB). The corresponding laboratory values are: Serum calcium ≥ 11.5 mg/100 mL, renal insufficiency with creatinine clearance < 40 cc/min or serum creatinine > 1.73 mmol/L, normochromic, normocytic anemia with a hemoglobin value > 2 g/100 mL below the lower limit of normal, or a hemoglobin value < 10 g/100 mL, lytic lesions (one or more osteolytic lesions by radiographic or other imaging system), severe osteopenia, or pathologic bone fractures. A small percentage of patients with symptomatic myeloma have no detectable M-protein

in serum or urine but do have myeloma-related organ impairment ROTI and increased bone marrow plasma cells. Any of the following validated biomarkers of malignancy are acceptable for the diagnosis of MM, including clonal bone marrow plasma cells $\geq 60\%$, serum free light chain ratio ≥ 100 , or free light chain ≥ 100 mg/L, or more than one focal bone or bone marrow lesion on MRI > 5 mm in size."

The second note would state the following: "A nonsecretory myeloma (a variant form of symptomatic myeloma) shows absent M-protein in the serum and urine, bone marrow plasmacytosis, and ROTI. While this group of patients represents a minority of cases (1–2%), this uncommon presentation may lead to delay in diagnosis because of the scarcity of laboratory findings commonly in the face of an isolated bone process such as low back pain."

The third note would state the following: "The diagnostic criteria for asymptomatic (smoldering or indolent) myeloma requires the following two criteria: (1) An elevated serum monoclonal protein (IgG or IgA) > 30 g/L, urine monoclonal protein > 500 mg/24 hrs. or clonal bone marrow plasmal cells 10%–60%, and (2) absence of myeloma defining events or amyloidosis without any related organ or tissue impairment (ROTI) or end-organ damage. There is usually normal serum calcium, hemoglobin, and serum creatinine, and no bone lesions on full skeletal survey and no evidence of amyloidosis or light chain deposition disease."

Multiple myeloma is incurable, and carries a poor prognosis. Therefore, VA proposes Note (4), which would state that the 100-percent evaluation shall continue for five years after the diagnosis of symptomatic multiple myeloma, at which time the appropriate disability evaluation shall be determined by mandatory VA examination. It would also state that any reduction in evaluation based upon that or any subsequent examination shall be subject to the provisions of 38 CFR 3.105(e) and 3.344 (a) and (b).

DC 7714 (Sickle Cell Anemia)

Sickle cell anemia is currently evaluated at levels of 100, 60, 30, and 10 percent. The current 100-percent evaluation criteria are: "With repeated painful crises, occurring in skin, joints, bones or any major organs caused by hemolysis and sickling of red blood cells, with anemia, thrombosis and infarction, with symptoms precluding even light manual labor." VA proposes at the 100-percent level to change the term "painful crises" to "painful

episodes" in keeping with current medical terminology, to insert the word "residual" before the word "symptoms," and to change punctuation to clarify meaning. The 100 percent category would also require at least 4 or more painful episodes in the past 12 months for clarification purposes.

The current 60-percent evaluation criteria are: "With painful crises several times a year or with symptoms precluding other than light manual labor." As in the 100-percent evaluation criteria, VA proposes to change the term "painful crises" to "painful episodes." To remove ambiguity, we also propose replacement of the phrase "With painful crises several times a year" with "Averaging 3 or more painful episodes per 12-month period."

The current 30-percent evaluation criterion is: "Following repeated hemolytic sickling crises with continuing impairment of health." VA proposes to replace "Following repeated hemolytic sickling crises with continuing impairment of health" with "Averaging 1 or 2 painful episodes per 12-month period" in order to make the criterion less ambiguous and promote consistent evaluations. VA proposes no change in the current 10-percent evaluation criteria of "Asymptomatic, established case in remission, but with identifiable organ impairment," and only an editorial change in the note under this DC to reflect the fact that the former Compensation and Pension Service has been reorganized as the Compensation Service and the Pension and Fiduciary Service.

DC 7715 (Non-Hodgkin's Lymphoma)

Currently, non-Hodgkin's lymphoma (NHL), DC 7715, is evaluated at 100 percent for active disease or during a treatment phase. VA proposes to modify the current note under DC 7715 with some non-substantive changes and by extending the allowable time required for mandatory examination from six months to 2 years, as provided in the proposed note to DC 7715. This is based upon current medical information suggesting that recurrences in non-Hodgkin's lymphoma are very high, with common tumor recurrences within or after the period that mandates lowering of disability rating for treatment completion or apparent remission of 6 months. Data on relapsed aggressive NHL: <http://www.texasoncology.com/types-of-cancer/non-hodgkins-lymphoma/intermediate-grade-aggressive-grade-nhl/relapsed-aggressive-nhl/>. VA also proposes to modify the criteria as, "When there is active disease, during treatment phase or with indolent and

non-contiguous phase of low grade NHL." See National Cancer Institute Adult NHL PDQ treatment Update (http://www.cancer.gov/cancertopics/pdq/treatment/adult-non-hodgkins/HealthProfessional/page9#_195_toc) (Dec. 2014).

DC 7716 (Aplastic Anemia)

Aplastic anemia, DC 7716, is currently evaluated at levels of 100, 60, 30, and 10 percent. The current 100-percent evaluation criteria are: "Requiring bone marrow transplant, or; requiring transfusion of platelets or red cells at least once every six weeks, or; infections recurring at least once every six weeks." VA proposes to expand "bone marrow transplant" to "peripheral blood or bone marrow stem cell transplant," as either may be used for treatment. In addition, VA proposes to add the phrase "on average" to the specific numbers of platelet or red cell transfusions required and to the frequency of recurring infections, and to add "per 12-month period" to promote consistent evaluations at the 100-, 60-, and 30-percent levels.

The current 60-percent criteria are: "Requiring transfusion of platelets or red cells at least once every three months, or; infections recurring at least once every three months." Continuous immunosuppressive therapy is currently a standard treatment option for aplastic anemia. A. Bacigalupo, "Diagnosis and treatment of acquired aplastic anemia," 23(2) *Hematol Oncol. Clinical N. Am.* 159 (2009). We therefore propose to add, "using continuous immunosuppressive therapy" as an alternative criterion for the 60-percent level. VA also proposes the changes described above for the 100-percent criteria concerning adding "on average" and "per 12-month period." The current 30-percent evaluation criteria are: "Requiring transfusion of platelets or red cells at least once per year but less than once every three months, or; infections recurring at least once per year but less than once every three months." VA proposes only the changes described above for the 100-percent criteria concerning adding "on average" and "per 12-month period." The current 10-percent criterion is "Requiring continuous medication for control." VA proposes to delete this evaluation level as the medications used to treat aplastic anemia warrant higher levels of evaluation.

VA proposes a change in the note following this DC stating that a 100-percent evaluation will be provided for either peripheral blood or bone marrow stem cell transplant. The remainder of the note is otherwise unchanged.

Proposed DC 7724 (Solitary Plasmacytoma)

Solitary bone or extramedullary (occurring in soft tissue outside of the bone marrow) plasmacytomas are malignant plasma cell neoplasms that are closely related to multiple myeloma. A solitary bone plasmacytoma develops into multiple myeloma in 50 to 60 percent of cases, and into an extramedullary plasmacytoma in 10 to 30 percent of cases. A solitary plasmacytoma that remains solitary has a better prognosis than multiple myeloma and may be curable. VA proposes to rate solitary plasmacytomas similarly to other malignant neoplasms that are potentially curable. VA proposes to rate solitary plasmacytoma at 100 percent when there is active disease or during a treatment phase and to add Note (1) to state that a 100-percent evaluation shall continue beyond the cessation of any surgical therapy, radiation therapy, antineoplastic chemotherapy, or other therapeutic procedures (including autologous stem cell transplantation), and that six months after discontinuance of such treatment, the appropriate disability rating shall be determined by mandatory VA examination. The note would also state that any change in evaluation based upon that or any subsequent examination shall be subject to the provisions of 38 CFR 3.105(e) and that, if there has been no recurrence, to rate residuals under the appropriate diagnostic codes.

VA proposes to add Note (2) to remind rating specialists of the potential for the transformation of solitary plasmacytomas into multiple myeloma. VA also proposes to add Note (3) to remind rating specialists of the residual effects of a solitary plasmacytoma and the adverse effects of medical treatment.

Proposed DC 7725 (Myelodysplastic Syndromes)

VA proposes to add a new DC 7725 for myelodysplastic syndromes because these conditions are relatively common in veterans and do not have a diagnostic code under which they can be appropriately evaluated. These syndromes, sometimes called "pre-leukemia" in the past, are a group of disorders associated with bone marrow dysfunction, in which healthy and mature red blood cells, white blood cells, and platelets are not produced. Therefore, there may be a deficiency of any type of blood cell. About one-third of those with myelodysplastic syndromes progress to acute myelogenous leukemia in months or

years. Some types of myelodysplastic syndromes are primary, in which there is no known cause for the syndromes, and others are secondary types, which develop after treatment with chemotherapy or radiation therapy for other diseases. The classification of these disorders is complex and differs among different medical organizations. Treatment depends in part on the specific disorder but also on many other factors. The mean overall survival time for these conditions is 6 months to 6 years.

VA proposes to evaluate myelodysplastic syndromes based on type and frequency of treatment and number of infections per 12-month period. VA also proposes to include in the evaluation criteria treatment with biologic therapy, either interferon alpha on an ongoing basis or erythropoiesis-stimulating agent (ESA) to boost red blood cell production. These treatments are used in some types of myelodysplastic disorders. VA proposes to provide evaluation levels of 100, 60, and 30 percent. VA proposes to assign 100 percent for either of the following: Requiring peripheral blood or bone marrow stem cell transplant, or requiring chemotherapy (including hypomethylating agents and immunomodulators, e.g., lenalidomide). VA proposes to assign 60 percent for either of the following: Requiring, on average, 4 or more blood or platelet transfusions per 12-month period, or infections requiring hospitalization, on average, 3 or more times per 12-month period. VA proposes to assign 30 percent for any of the following: Requiring, on average, 1 to 3 blood or platelet transfusions per 12-month period, infections requiring hospitalization, on average, 1 to 2 times per 12-month period; or requiring biologic therapy, either interferon alpha on an ongoing basis or erythropoiesis stimulating agent (ESA) for up to 12 weeks per 12-month period.

VA also proposes to add Note (1) stating that if this condition progresses to leukemia, to evaluate it as leukemia under DC 7703 and Note (2) stating that a 100-percent evaluation shall be assigned as of the date of hospital admission for peripheral blood or bone marrow stem cell transplant, or during the period of treatment with chemotherapy and shall continue with a mandatory VA examination six months following hospital discharge or, in the case of radioactive phosphorus or chemotherapy treatment, six months after completion of treatment. Note (2) would also state that any reduction in evaluation based upon that or any subsequent examination shall be subject

to the provisions of 38 CFR 3.105(e) and that, if there has been no recurrence, residuals will be rated under the appropriate diagnostic codes.

Proposed Changes to Appendices A, B, and C to Part 4

VA proposes to amend appendices A, B, and C to reflect the above-noted proposed changes. In appendix A to part 4, § 4.117, remove diagnostic code 7700, revise diagnostic codes 7702–7705, 7709, and 7714–7716, and add diagnostic codes 7718–7725.

In appendix B to part 4, revise the title from “The Hemic and Lymphatic Systems” to “The Hematologic and Lymphatic Systems”, remove diagnostic code 7700 and its disability entry, revise the section heading and the disability entry for diagnostic codes 7702, 7705 and 7709, and add disability codes and disability entries for 7712 and 7718–7725.

In appendix C to part 4, convert the existing entry for “Anemia” into a new section titled “Anemia”, remove diagnostic code 7700 and its disability entry and insert diagnostic codes 7720–7723 and their disability entries in that section; revise the disability entry for diagnostic codes 7702, 7705 and 7709; create a new section titled “Hematologic” and insert diagnostic codes 7705, 7712, 7718, 7724 and 7725 and their disability entries in that section; and convert the existing entry for leukemia into a new section titled “Leukemia” and insert diagnostic codes 7703 and 7719 into that section.

Paperwork Reduction Act

This document contains no provisions constituting a collection of information under the Paperwork Reduction Act (44 U.S.C. 3501–3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This proposed rule would not affect any small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and

benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a “significant regulatory action,” which requires review by the Office of Management and Budget, as “any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive Order.”

The economic, interagency, budgetary, legal, and policy implications of this regulatory action has been examined, and it has been determined not to be a significant regulatory action under Executive Order 12866. VA’s impact analysis can be found as a supporting document at <http://www.regulations.gov>, usually within 48 hours after the rulemaking document is published. Additionally, a copy of this rulemaking and its impact analysis are available on VA’s Web site at <http://www1.va.gov/orpm/>, by following the link for “VA Regulations Published.”

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the

private sector, of \$100 million or more (adjusted annually for inflation) in any year. This proposed rule would have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance Numbers and Titles

The Catalog of Federal Domestic Assistance program numbers and titles for this proposal are 64.104, Pension for Non-Service-Connected Disability for Veterans, and 64.109, Veterans Compensation for Service-Connected Disability.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Robert L. Nabors II, Chief of Staff, Department of Veterans Affairs, approved this document on July 30, 2015, for publication.

List of Subjects in 38 CFR Part 4

Disability benefits, Pensions, Veterans.

Dated: July 31, 2015.

Jeffrey M. Martin,

Office Program Manager, Office of Regulation Policy & Management, Office of the General Counsel, Department of Veterans Affairs.

For the reasons set out in the preamble, VA proposes to amend 38 CFR part 4, subpart B, to read as follows:

PART 4—SCHEDULE FOR RATING DISABILITIES

Subpart B—Disability Ratings

■ 1. The authority citation for part 4 continues to read as follows:

Authority: 38 U.S.C. 1155, unless otherwise noted.

■ 2. Revise the undesignated center heading preceding § 4.117 to read as follows:

The Hematologic and Lymphatic Systems

■ 3. Revise § 4.117 to read as follows:

§ 4.117 Schedule of ratings—hematologic and lymphatic systems.

	Rating
7702 Agranulocytosis, acquired:	
Requiring bone marrow transplant or infections recurring, on average, at least once every six weeks per 12-month period	100
Requiring intermittent myeloid growth factors (granulocyte colony-stimulating factor (G-CSF) or granulocyte-macrophage colony-stimulating factor (GM-CSF)) or continuous immunosuppressive therapy such as cyclosporine to maintain absolute neutrophil count (ANC) greater than 500/ μ l but less than 1,000/ μ l; or infections recurring, on average, at least once every three months per 12-month period	60
Requiring intermittent myeloid growth factors to maintain ANC greater than 1,000/ μ l; or infections recurring, on average, at least once per 12-month period but less than once every three months per 12-month period	30
Requiring continuous medication (e.g., antibiotics) for control; or requiring intermittent use of a myeloid growth factor to maintain ANC greater than or equal to 1,500/ μ l	10
Note: A 100-percent evaluation for bone marrow transplant shall be assigned as of the date of hospital admission and shall continue with a mandatory VA examination six months following hospital discharge. Any change in evaluation based upon that or any subsequent examination shall be subject to the provisions of § 3.105(e) of this chapter.	
7703 Leukemia (except for chronic myelogenous leukemia):	
When there is active disease or during a treatment phase	100
Otherwise rate residuals under the appropriate diagnostic code(s).	
Chronic lymphocytic leukemia or monoclonal B-cell lymphocytosis (MBL), asymptomatic, Rai Stage 0	0
Note (1): A 100-percent evaluation shall continue beyond the cessation of any surgical therapy, radiation therapy, antineoplastic chemotherapy, or other therapeutic procedures. Six months after discontinuance of such treatment, the appropriate disability rating shall be determined by mandatory VA examination. Any change in evaluation based upon that or any subsequent examination shall be subject to the provisions of § 3.105(e) of this chapter. If there has been no recurrence, rate on residuals.	
Note (2): Evaluate symptomatic chronic lymphocytic leukemia that is at Rai Stage I, II, III, or IV the same as any other leukemia evaluated under this diagnostic code.	
Note (3): Evaluate residuals of leukemia or leukemia therapy under the appropriate diagnostic code(s). Myeloproliferative Disorders: (Diagnostic Codes 7704, 7718, 7719).	
7704 Polycythemia vera:	
Requiring peripheral blood or bone marrow stem-cell transplant or treatment with radioactive phosphorus or chemotherapy (including myelosuppressants)	100
Requiring phlebotomy 6 or more times per 12-month period to control RBC count or if requiring radioactive phosphorous treatment, chemotherapy, or targeted agents such as imatinib or ruxolitinib	60
Requiring phlebotomy 4–5 times per 12-month period or if requiring continuous biologic therapy or myelosuppressive agents to maintain platelets <200,000 or white blood cells (WBC) <12,000	30
Requiring phlebotomy, biologic therapy, or interferon on an intermittent basis, as needed, 3 or fewer times per 12-month period ...	10
Note (1): Rate complications such as hypertension, gout, stroke, or thrombotic disease separately.	
Note (2): If the condition undergoes leukemic transformation, evaluate as leukemia under diagnostic code 7703.	
Note (3): A 100-percent evaluation shall be assigned as of the date of hospital admission for peripheral blood or bone marrow stem cell transplant; or during the period of treatment with radioactive phosphorus or chemotherapy (including myelosuppressants). Six months following hospital discharge or, in the case of radioactive phosphorus or chemotherapy treatment, six months after completion of treatment, the appropriate disability rating shall be determined by mandatory VA examination. Any reduction in evaluation based upon that or any subsequent examination shall be subject to the provisions of § 3.105(e) of this chapter.	
7705 Immune thrombocytopenia:	
Requiring chemotherapy for chronic refractory thrombocytopenia or a platelet count from 20,000 to 30,000 despite treatment	100
Requiring immunosuppressive therapy or for a platelet count higher than 30,000 but not higher than 50,000, with history of hospitalization because of severe bleeding requiring intravenous immune globulin, high-dose parenteral corticosteroids, and platelet transfusions	70
Platelet count higher than 30,000 but not higher than 50,000, with either immune thrombocytopenia or mild mucous membrane bleeding which requires oral corticosteroid therapy or intravenous immune globulin	30
Platelet count higher than 30,000 but not higher than 50,000, not requiring treatment	10
Platelet count above 50,000 and asymptomatic, or for immune thrombocytopenia in remission.	0
Note (1): Separately evaluate splenectomy under diagnostic code 7706 and combine with an evaluation under this diagnostic code.	
Note (2): A 100-percent evaluation shall continue beyond the cessation of chemotherapy. Six months after discontinuance of such treatment, the appropriate disability rating shall be determined by mandatory VA examination. Any reduction in evaluation based upon that or any subsequent examination shall be subject to the provisions of § 3.105(e) of this chapter.	
7706 Splenectomy	20
Note: Separately rate complications such as systemic infections with encapsulated bacteria.	
7707 Spleen, injury of, healed.	20
Rate for any residuals.	
7709 Hodgkin's lymphoma:	
With active disease or during a treatment phase	100
Note: A 100-percent evaluation shall continue beyond the cessation of any surgical therapy, radiation therapy, antineoplastic chemotherapy, or other therapeutic procedures. Six months after discontinuance of such treatment, the appropriate disability rating shall be determined by mandatory VA examination. Any reduction in evaluation based upon that or any subsequent examination shall be subject to the provisions of § 3.105(e) of this chapter. If there has been no local recurrence or metastasis, rate on residuals under the appropriate diagnostic code(s).	
7710 Adenitis, tuberculous, active or inactive.	
Rate under § 4.88c or 4.89 of this part, whichever is appropriate.	
7712 Multiple myeloma:	
Symptomatic multiple myeloma	100
Asymptomatic (smoldering or indolent)	0

	Rating
<p>Note (1): Symptomatic myeloma requires, (i) an elevated serum or urine M (monoclonal) protein value (however no specific concentration is required for diagnosis), or (ii) presence of increased bone marrow clonal plasma cells $\geq 10\%$. There must be also evidence of related organ tissue impairment (ROTI) due to the plasma cell proliferation. This process is manifested by elevated serum calcium, renal failure, anemia, and bone lesions (CRAB). The corresponding laboratory values are: Serum calcium ≥ 11.5 mg/100 mL, renal insufficiency with creatinine clearance < 40 cc/min or serum creatinine > 1.73 mmol/L, normochromic, normocytic anemia with a hemoglobin value > 2 g/100 mL below the lower limit of normal, or a hemoglobin value < 10 g/100 mL, lytic lesions (one or more osteolytic lesions by radiographic or other imaging system) severe osteopenia, or pathologic bone fractures. A small percentage of patients with symptomatic myeloma have no detectable M-protein in serum or urine but do have myeloma-related organ impairment ROTI and increased bone marrow plasma cells. Any of the following validated biomarkers of malignancy are acceptable for the diagnosis of MM, including clonal bone marrow plasma cells $\geq 60\%$, serum free light chain ratio of ≥ 100, or free light chain of ≥ 100 mg/L, or more than one focal bone or bone marrow lesion on MRI > 5 mm in size.</p> <p>Note (2): A nonsecretory myeloma (a variant form of symptomatic myeloma) shows absent M-protein in the serum and urine, bone marrow plasmacytosis, and ROTI. While this group of patients represents a minority of cases (1–2%), this uncommon presentation may lead to delay in diagnosis because of the scarcity of laboratory findings commonly in the face of an isolated bone process such as low back pain.</p> <p>Note (3): The diagnostic criteria for asymptomatic (smoldering or indolent) myeloma requires the following two criteria: (1) An elevated serum monoclonal protein (IgG or IgA) > 30 g/L, urine monoclonal protein > 500 mg/24 hrs., or clonal bone marrow plasma cells 10%–60%, and (2) absence of myeloma defining events of amyloidosis without any related organ or tissue impairment (ROTI) or end-organ damage. There is usually normal serum calcium, hemoglobin, and serum creatinine, and no bone lesions on full skeletal survey and no evidence of amyloidosis or light chain deposition disease.</p> <p>Note (4): The 100-percent evaluation shall continue for five years after the diagnosis of symptomatic multiple myeloma, at which time the appropriate disability evaluation shall be determined by mandatory VA examination. Any reduction in evaluation based upon that or any subsequent examination shall be subject to the provisions of § 3.105(e) and § 3.344 (a) and (b) of this chapter.</p>	
<p>7714 Sickle cell anemia:</p> <p>With at least 4 or more painful episodes per 12-month period, occurring in skin, joints, bones, or any major organs, caused by hemolysis and sickling of red blood cells, with anemia, thrombosis, and infarction, with residual symptoms precluding even light manual labor</p> <p>Averaging 3 or more painful episodes per 12-month period or with symptoms precluding other than light manual labor</p> <p>Averaging 1 or 2 painful episodes per 12-month period</p> <p>Asymptomatic, established case in remission, but with identifiable organ impairment</p>	<p>100</p> <p>60</p> <p>30</p> <p>10</p>
<p>Note: Sickle cell trait alone, without a history of directly attributable pathological findings, is not a ratable disability. Cases of symptomatic sickle cell trait will be forwarded to the Director, Compensation Service, for consideration under § 3.321(b)(1) of this chapter.</p>	
<p>7715 Non-Hodgkin's lymphoma:</p> <p>When there is active disease, during treatment phase or with indolent and non-contiguous phase of low grade NHL</p>	<p>100</p>
<p>Note: A 100-percent evaluation shall continue beyond the cessation of any surgical therapy, radiation therapy, antineoplastic chemotherapy, or other therapeutic procedures. Two years after discontinuance of such treatment, the appropriate disability rating shall be determined by mandatory VA examination. Any reduction in evaluation based upon that or any subsequent examination shall be subject to the provisions of § 3.105(e) of this chapter. If there has been no recurrence, rate on residuals under the appropriate diagnostic code(s).</p>	
<p>7716 Aplastic anemia:</p> <p>Requiring peripheral blood or bone marrow stem cell transplant; or requiring transfusion of platelets or red cells, on average, at least once every six weeks per 12-month period; or infections recurring, on average, at least once every six weeks per 12-month period</p> <p>Requiring transfusion of platelets or red cells, on average, at least once every three months per 12-month period; or infections recurring, on average, at least once every three months per 12-month period; or using continuous immunosuppressive therapy ...</p> <p>Requiring transfusion of platelets or red cells, on average, at least once per 12-month period, but less than once every three months per 12-month period; or infections recurring, on average, at least once per 12-month period, but less than once every three months per 12-month period</p>	<p>100</p> <p>60</p> <p>30</p>
<p>Note: A 100-percent evaluation for peripheral blood or bone marrow stem cell transplant shall be assigned as of the date of hospital admission and shall continue with a mandatory VA examination six months following hospital discharge. Any change in evaluation based upon that or any subsequent examination shall be subject to the provisions of § 3.105(e) of this chapter.</p>	
<p>7718 Essential thrombocythemia and primary myelofibrosis</p> <p>Requiring either continuous myelosuppressive therapy or, for six months following hospital admission, peripheral blood or bone marrow stem cell transplant, or treatment with radioactive phosphorus or chemotherapy (including myelosuppressants)</p> <p>Requiring continuous or intermittent myelosuppressive therapy to maintain platelet count $< 500 \times 10^9/L$</p> <p>Requiring continuous or intermittent myelosuppressive therapy to maintain platelet count of 200,000–400,000, or white blood cell (WBC) count of 4,000–10,000</p> <p>Asymptomatic</p>	<p>100</p> <p>70</p> <p>30</p> <p>0</p>
<p>Note (1): If the condition undergoes leukemic transformation, evaluate as leukemia under diagnostic code 7703.</p> <p>Note (2): A 100-percent evaluation shall be assigned as of the date of hospital admission for peripheral blood or bone marrow stem cell transplant; or during the period of treatment with radioactive phosphorus or chemotherapy (including myelosuppressants). Six months following hospital discharge or, in the case of radioactive phosphorus or chemotherapy treatment, six months after completion of treatment, the appropriate disability rating shall be determined by mandatory VA examination. Any reduction in evaluation based upon that or any subsequent examination shall be subject to the provisions of § 3.105(e) of this chapter.</p>	
<p>7719 Chronic myelogenous leukemia (CML) (chronic myeloid leukemia or chronic granulocytic leukemia):</p> <p>Requiring peripheral blood or bone marrow stem cell transplant, or continuous myelosuppressive or immunosuppressive therapy treatment</p> <p>Requiring intermittent myelosuppressive therapy, or targeted therapy with tyrosine kinase inhibitors, or interferon treatment</p> <p>In apparent remission on continuous targeted therapy with tyrosine kinase inhibitors</p>	<p>100</p> <p>60</p> <p>30</p>
<p>Note (1): If the condition undergoes leukemic transformation, evaluate as leukemia under diagnostic code 7703.</p>	

	Rating
<p>Note (2): A 100-percent evaluation shall be assigned as of the date of hospital admission for peripheral blood or bone marrow stem cell transplant; or during the period of treatment with radioactive phosphorus or chemotherapy (including myelosuppressants). Six months following hospital discharge or, in the case of radioactive phosphorus or chemotherapy treatment, six months after completion of treatment, the appropriate disability rating shall be determined by mandatory VA examination. Any reduction in evaluation based upon that or any subsequent examination shall be subject to the provisions of § 3.105 of this chapter.</p>	
7720 Iron deficiency anemia:	
Requiring intravenous iron infusions on average 4 or more times per 12-month period	30
Requiring continuous treatment with high-dose oral supplementation	10
Asymptomatic or requiring treatment only by dietary modification	0
<p>Note: Do not evaluate iron deficiency anemia due to blood loss under this diagnostic code. Evaluate iron deficiency anemia due to blood loss under the criteria for the condition causing the blood loss.</p>	
7721 Folic acid deficiency:	
Requiring continuous treatment with high-dose oral supplementation	10
Asymptomatic or requiring treatment only by dietary modification	0
7722 Pernicious anemia and Vitamin B ₁₂ deficiency anemia:	
For initial diagnosis requiring transfusion due to severe anemia, or if there are signs or symptoms related to central nervous system impairment, such as encephalopathy, myelopathy, or severe peripheral neuropathy, requiring parenteral B ₁₂ therapy	100
Requiring continuous treatment with Vitamin B ₁₂ injections, Vitamin B ₁₂ sublingual or high-dose oral tablets, or Vitamin B ₁₂ nasal spray or gel	10
<p>Note: A 100-percent evaluation for pernicious anemia and Vitamin B₁₂ deficiency shall be assigned as of the date of the initial diagnosis requiring transfusion due to severe anemia or parenteral B₁₂ therapy and shall continue with a mandatory VA examination six months following hospital discharge or cessation of parenteral B₁₂ therapy. Any reduction in evaluation based upon that or any subsequent examination shall be subject to the provisions of § 3.105(e) of this chapter. Thereafter, evaluate at 10-percent and separately evaluate any residual effects of pernicious anemia, such as neurologic involvement causing peripheral neuropathy, myelopathy, dementia, or related gastrointestinal residuals, under the most appropriate diagnostic code.</p>	
7723 Acquired hemolytic anemia:	
Requiring a bone marrow transplant or continuous intravenous or immunosuppressive therapy (e.g., prednisone, Cytoxan, azathioprine, or rituximab)	100
Requiring immunosuppressive medication an average of 4 or more times per 12-month period	60
Requiring an average of 2–3 courses of immunosuppressive therapy per 12-month period	30
Requiring an average of one course of immunosuppressive therapy per 12-month period	10
Asymptomatic	0
<p>Note (1): A 100-percent evaluation for bone marrow transplant shall be assigned as of the date of hospital admission and shall continue for six months after hospital discharge with a mandatory VA examination six months following hospital discharge. Any reduction in evaluation based upon that or any subsequent examination shall be subject to the provisions of § 3.105(e) of this chapter.</p>	
<p>Note (2): Separately evaluate splenectomy under diagnostic code 7706 and combine with an evaluation under diagnostic code 7723.</p>	
7724 Solitary plasmacytoma:	
Solitary plasmacytoma, when there is active disease or during a treatment phase	100
<p>Note (1): A 100-percent evaluation shall continue beyond the cessation of any surgical therapy, radiation therapy, antineoplastic chemotherapy, or other therapeutic procedures (including autologous stem cell transplantation). Six months after discontinuance of such treatment, the appropriate disability rating shall be determined by mandatory VA examination. Any change in evaluation based upon that or any subsequent examination shall be subject to the provisions of § 3.105(e) of this chapter. If there has been no recurrence, rate residuals under the appropriate diagnostic codes.</p>	
<p>Note (2): Rate a solitary plasmacytoma that has developed into multiple myeloma as symptomatic multiple myeloma.</p>	
<p>Note (3): Rate residuals of plasma cell dysplasia (e.g., thrombosis) and adverse effects of medical treatment (e.g., neuropathy) under the appropriate diagnostic codes.</p>	
7725 Myelodysplastic syndromes:	
Requiring peripheral blood or bone marrow stem cell transplant; or requiring chemotherapy	100
Requiring, on average, 4 or more blood or platelet transfusions per 12-month period; or infections requiring hospitalization, on average, 3 or more times per 12-month period	60
Requiring, on average, 1 to 3 blood or platelet transfusions per 12-month period; infections requiring hospitalization, on average, 1 to 2 times per 12-month period; or requiring biologic therapy, either interferon alpha on an ongoing basis or erythropoiesis stimulating agent (ESA) for 12 weeks or less per 12-month period	30
<p>Note (1): If the condition progresses to leukemia, evaluate as leukemia under diagnostic code 7703.</p>	
<p>Note (2): A 100-percent evaluation shall be assigned as of the date of hospital admission for peripheral blood or bone marrow stem cell transplant, or during the period of treatment with chemotherapy and shall continue with a mandatory VA examination six months following hospital discharge or, in the case of radioactive phosphorus or chemotherapy treatment, six months after completion of treatment. Any reduction in evaluation based upon that or any subsequent examination shall be subject to the provisions of § 3.105(e) of this chapter. If there has been no recurrence, residuals will be rated under the appropriate diagnostic codes.</p>	

(Authority: 38 U.S.C. 1155.)

■ 3. Amend appendix A to part 4 by:

- a. Revising the entries for diagnostic codes 7700, 7702 through 7705, 7709, 7712, and 7714 through 7716; and
- b. Adding entries for diagnostic codes 7718 through 7725.

The revisions and additions read as follows:

APPENDIX A TO PART 4—TABLE OF AMENDMENTS AND EFFECTIVE DATES SINCE 1946

Sec.	Diagnostic Code No.	
4.117 ...	7700	Removed [effective date of final rule].
	7702	Evaluation October 23, 1995; title [effective date of final rule]; evaluation [effective date of final rule].
	7703	Evaluation August 23, 1948; criterion October 23, 1995; evaluation [effective date of final rule]; criterion [effective date of final rule].
	7704	Evaluation October 23, 1995; evaluation [effective date of final rule].
	7705	Evaluation October 23, 1995; title [insert effective date of final rule]; evaluation [effective date of final rule]; criterion [effective date of final rule].
	7709	Evaluation March 10, 1976; criterion October 23, 1995; title [effective date of final rule]; criterion [effective date of final rule].
	7712	Added [effective date of final rule].
	7714	Added September 9, 1975; criterion October 23, 1995; criterion [effective date of final rule]
	7715	Added October 26, 1990; criterion [effective date of final rule].
	7716	Added October 23, 1995; evaluation [effective date of final rule]; criterion [effective date of final rule].
	7718	Added [effective date of final rule].
	7719	Added [effective date of final rule].
	7720	Added [effective date of final rule].
	7721	Added [effective date of final rule].
	7722	Added [effective date of final rule].
	7723	Added [effective date of final rule].
	7724	Added [effective date of final rule].
	7725	Added [effective date of final rule].

■ 4. Amend appendix B to part 4 by:
 ■ a. Revising the undesignated center heading immediately preceding diagnostic code 7700;

■ b. Removing the entry for diagnostic code 7700;
 ■ c. Revising the entries for diagnostic codes 7702, 7705 and 7709; and

■ d. Adding entries for diagnostic codes 7712 and 7718 through 7725.
 The revisions and additions read as follows:

APPENDIX B TO PART 4—NUMERICAL INDEX OF DISABILITIES

Diagnostic Code No.	
THE HEMATOLOGIC AND LYMPHATIC SYSTEMS	
7702	Agranulocytosis, acquired.
7705	Immune thrombocytopenia.
7709	Hodgkin's lymphoma.
7712	Multiple myeloma.
7718	Essential thrombocythemia and primary myelofibrosis.
7719	Chronic myelogenous leukemia (CML) (chronic myeloid leukemia or chronic granulocytic leukemia).

APPENDIX B TO PART 4—NUMERICAL INDEX OF DISABILITIES—Continued

Diagnostic Code No.	
7720	Iron deficiency anemia.
7721	Folic acid deficiency.
7722	Pernicious anemia and Vitamin B ₁₂ deficiency anemia.
7723	Acquired hemolytic anemia.
7724	Solitary plasmacytoma.
7725	Myelodysplastic syndromes.

- 5. Amend appendix C to part 4 by:
- a. Revising the entries for Agranulocytosis and Anemia;
 - c. Adding an entry for Hematologic in alphabetical order;
 - d. Removing the entry for Hodgkin’s disease and adding in its place an entry for Hodgkin’s lymphoma;
 - e. Revising the entry for Leukemia;
- The revisions and additions read as follows:

APPENDIX C TO PART 4—ALPHABETICAL INDEX OF DISABILITIES

	Diagnostic Code No.
Agranulocytosis, acquired	7702
Anemia:	
Acquired hemolytic anemia	7723
Folic acid deficiency	7721
Iron deficiency anemia	7720
Pernicious anemia and Vitamin B ₁₂ deficiency anemia	7722
Hematologic:	
Essential thrombocythemia and primary myelofibrosis	7718
Immune thrombocytopenia	7705
Multiple myeloma	7712
Myelodysplastic syndromes	7725
Solitary plasmacytoma	7724
Hodgkin’s lymphoma	7709
Leukemia:	
Chronic myelogenous leukemia (CML) (chronic myeloid leukemia or chronic granulocytic leukemia)	7719
Leukemia	7703

[FR Doc. 2015–19197 Filed 8–5–15; 8:45 am]
 BILLING CODE 8320–01–P

FEDERAL COMMUNICATIONS COMMISSION
47 CFR Parts 0, 2, 15, and 18

[ET Docket No. 15–170; RM–11673; FCC 15–92]

Equipment Authorization and Electronic Labeling for Wireless Devices

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document proposes updates to the rules that govern the evaluation and approval of RF devices. The Commission last comprehensively reviewed its equipment authorization procedures more than fifteen years ago. The RF equipment ecosystem has significantly expanded in that time, and the manner in which today’s RF equipment is now designed, manufactured, and marketed—as well as the sheer number of devices subject to authorization—warrant the proposed rule modifications.

DATES: Comments must be filed on or before September 8, 2015, and reply comments must be filed on or before September 21, 2015.

FOR FURTHER INFORMATION CONTACT: Brian Butler, Office of Engineering and Technology, (202) 418–2702, email: Brian.Butler@fcc.gov, TTY (202) 418–2989.

ADDRESSES: You may submit comments, identified by ET Docket No. 15–170; RM–11673, by any of the following methods:

- Federal Communications Commission’s Web site: <http://apps.fcc.gov/ecfs/>. Follow the instructions for submitting comments.