

significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the bridge may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Government

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and

responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.ID, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule simply promulgates the operating regulations or procedures for drawbridges. This action is categorically excluded from further review, under figure 2–1, paragraph (32)(e), of the Instruction. A preliminary Record of Environmental Consideration and a Memorandum for the Record are not required for this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

- 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

- 2. From 12:01 a.m. on date of publication, through 12:01 a.m. on

December 31, 2018, in § 117.723, suspend paragraph (b) and temporarily add paragraph (k) to read as follows:

§ 117.723 Hackensack River.

* * * * *

(k) The draw of the PATH Bridge, mile 3.0, at Jersey City, shall open on signal provided at least a two-hour advance notice is provided by calling the number posted at the bridge. The draw need not open for the passage of vessel traffic Monday through Friday, except Federal holidays, from 6 a.m. to 10 a.m. and from 4 p.m. to 8 p.m.; and from 12:01 a.m. Saturday to 12:01 a.m. Monday. Weekdays additional bridge openings shall be provided for commercial vessels from 6 a.m. to 7:20 a.m.; 9:20 a.m. to 10 a.m.; 4 p.m. to 4:30 p.m. and from 6:50 p.m. to 8 p.m. provided at least a two-hour advance notice is given by calling the number posted at the bridge.

Dated: October 12, 2018.

A.J. Tionsgon,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

[FR Doc. 2018–23596 Filed 10–26–18; 8:45 am]

BILLING CODE 9110–04–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: Final rule.

SUMMARY: This document amends the Department of Veterans Affairs (VA) Schedule for Rating Disabilities (VASRD) by revising the section of the Rating Schedule that addresses the hematologic and lymphatic systems. This action will ensure VA uses current medical terminology and provides detailed and updated criteria for evaluating conditions pertaining to the hematologic and lymphatic systems.

DATES: This rule is effective on December 9, 2018.

FOR FURTHER INFORMATION CONTACT: Ioulia Vvedenskaya, M.D., M.B.A., Medical Officer, Part 4 VASRD Regulations Staff (211C), Compensation Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 461–9700. (This is not a toll-free telephone number.)

SUPPLEMENTARY INFORMATION: VA published a proposed rule in the **Federal Register** at 80 FR 46888 on August 6, 2015, to amend the portion of the VASRD dealing with the hematologic and lymphatic systems. VA provided a 60-day public comment period and invited interested persons to submit written comments, suggestions, or objections on or before October 5, 2015. VA received 11 comments.

I. Purpose of the Final Rule

VA revises the section of the VASRD that addresses the hematologic and lymphatic systems. This final rule updates medical terminology, adds certain hematologic diseases, and provides detailed and updated criteria for evaluating conditions pertaining to the hematologic and lymphatic systems.

II. Technical Corrections

In the proposed rule, VA proposed a new diagnostic code (DC) 7720, Iron deficiency anemia. In its review of the final rule, VA realized that the proposed text for 10 percent disability rating contained an error. Namely, VA required continuous treatment with high-dose oral supplementation for a 10 percent disability rating, rather than intravenous iron infusions at least 1 time but less than 4 times per 12-month period, or continuous treatment with oral supplementation. This document corrects this error by amending the proposed text to read as follows: "Requiring intravenous iron infusions at least 1 time but less than 4 times per 12-month period, or requiring continuous treatment with oral supplementation." The proposed rule specified that a zero-percent rating would be warranted if the condition is asymptomatic or treatable by dietary restrictions only. Implicit in the proposed rule was the premise that, if the condition requires intravenous treatment less often than required for a 30-percent rating, then a 10 percent rating would be warranted. This final rule makes that premise explicit in DC 7720.

In the proposed rule, VA introduced amended criteria for the 100 percent evaluation in DC 7702 based on the requirement for bone marrow transplant or infections recurring at least once every six weeks per 12-month period. Upon further review, VA inadvertently omitted a semicolon between these two criteria, which could lead to confusion as to the application of the 100 percent criteria. To clarify that these two criteria are separate and distinct and that only one is required to establish a 100 percent evaluation, VA is inserting a semicolon after "transplant";

In the proposed rule, VA introduced criteria for DCs 7714, 7720, 7723, and 7725 which measured the occurrence of infections (7725), painful episodes (7714), transfusions (7725), infusions (7720), or medication usage (7723) based on the "average" number of episodes per 12-month period. Upon further review, VA determined that including "average" in calculating the number of episodes required by the given criteria will result in unclear guidance and inconsistent application of the VASRD, in direct conflict with one of the stated goals of the VASRD revisions. Additionally, references to the average number of episodes per 12-month period might suggest that evaluations should in all instances be based on the average frequency of the episodes over an unspecified number of years. Although VA must evaluate conditions "in relation to [their] history," 38 CFR 4.1, there may be instances where there has been a discernible change in the severity of a condition and it is more appropriate to evaluate the disability primarily on current manifestations than on an average of the manifestations over a number of prior years. Accordingly, to increase consistency in the application of the criteria, promote clarity in the requirements for each evaluation level, and to ensure that evaluations may reflect changes in a condition's severity and the frequency of episodes, VA will remove the reference to "average" from the criteria in DCs 7714, 7720, 7723, and 7725 and replace it with a quantifiable range at each criteria level. This change to the language does not result to any substantive changes to the criteria in the identified DCs.

Additionally, in DC 7705, VA inadvertently omitted semicolons between these distinct criteria in the 100, 70, and 0 percent evaluations, which could lead to confusion as to the application of these evaluation levels. To reiterate and clarify that the criteria in these evaluation levels are separate and distinct, and that only one is required to establish a given evaluation, VA is inserting a semicolon between the criteria for clarification purposes. No substantive change to the evaluation criteria results from this change.

In the proposed rule, VA introduced several changes to DC 7704, Polycythemia vera, including a revision for a 30 percent disability rating. Namely, for a 30 percent disability rating, VA required phlebotomy 4–5 times per 12-month period or continuous biologic therapy or myelosuppressive agents to maintain platelets <200,000 or white blood cells (WBC) <12,000. VA would like to clarify

that myelosuppressive agents, which are used to maintain platelets <200,000 or white blood cells (WBC) <12,000, include interferon. This document includes this clarification by amending the proposed text to read as follows: "Requiring phlebotomy 4–5 times per 12-month period, or if requiring continuous biologic therapy or myelosuppressive agents, to include interferon, to maintain platelets <200,000 or white blood cells (WBC) <12,000." VA also makes a clarifying change in the proposed text for 60 percent disability amending the reference to "targeted agents such as imatinib or ruxolitinib" to "molecularly targeted therapy," which includes imatinib, ruxolitinib, and other agents. Upon further review, VA has determined that including the "chemotherapy" reference in the evaluation criteria at both the 60 percent and 100 percent levels in the proposed rule would create a conflict such that the criteria could not be applied consistently and accurately, potentially resulting in over- and under-evaluation. Accordingly, to increase consistency in the application of the criteria, promote clarity in the requirements for each evaluation level, and to ensure the VASRD criteria do not conflict with the guidance set forth in Note 3, VA will remove the reference to "chemotherapy" from the criteria in proposed DC 7704 for the 60 percent rating criteria. Because the requirement for chemotherapy supports a 100 percent rating, this change to the criteria for the lower 60 percent rating will not affect any claims but will eliminate potential confusion. Additionally, VA made an editorial change to the proposed language. Namely, VA clarified the 60 percent disability rating criteria to read as follows: "Requiring phlebotomy 6 or more times per 12-month period or molecularly targeted therapy for the purpose of controlling RBC count." This change to the language does not result in any substantive changes to the criteria in the identified DC.

VA also corrects the spelling of "myelosuppressive," which was misspelled in the proposed regulatory text.

Additionally, VA realized that the proposed text for 10 percent disability rating under DC 7704 contained a grammatical error that would have made the rule more confusing and difficult to apply than VA intended. Namely, VA identified a 10 percent disability rating in the proposed rule as: "Requiring phlebotomy, biologic therapy, or interferon on an intermittent basis, as needed, 3 or fewer times per 12-month

period.” VA did not intend to apply two different frequency standards—*i.e.*, “on an intermittent basis” and “3 or fewer times per 12-month period”—to the same events, but the proposed text could suggest that both standards apply to each of the listed events. Rather, consistent with the requirements for the 60 percent and 30 percent ratings, VA intended that the “3 or fewer times per 12-month period” requirement would apply only to phlebotomy, and that the “on an intermittent basis” requirement would apply to the other listed treatments. In order to increase consistency in the application of the criteria and promote clarity in the requirements for each evaluation level, VA has included additional reference to the outcome of the treatment for polycythemia vera for 10 percent and 100 percent evaluation levels. This document corrects the above-referenced grammatical error and includes additional guidance by amending the proposed text for 10 percent evaluation to read as follows: “Requiring phlebotomy 3 or fewer times per 12-month period or if requiring biologic therapy or interferon on an intermittent basis as needed to maintain all blood levels at reference range levels.” Additionally, VA amends the proposed text for 100 percent evaluation to read as follows: “Requiring peripheral blood or bone marrow stem-cell transplant or chemotherapy (including myelosuppressants) for the purpose of ameliorating the symptom burden.”

In the proposed rule, VA proposed several changes to DC 7705, including criteria based on platelet counts. VA specifically proposed to assign a 100 percent evaluation for platelet count below 30,000. However, for the 70 percent criteria, which apply in circumstances involving a platelet count higher than 30,000, VA omitted criteria for when platelet count is at 30,000. Accordingly, VA has changed the 100 percent criteria to read “platelet count 30,000 or below” to avoid a gap in the platelet count range considered in the evaluation criteria.

In the proposed rule, VA introduced several changes to DC 7716, Aplastic anemia, including a revision for a 60 percent disability rating. Namely, for a 60 percent rating, VA required the use of continuous immunosuppressive therapy. In order to capture the full range of therapeutic agents that are used to treat this condition, VA makes a clarifying change that amends the proposed text to reference the use of “newer platelet stimulating factors” in the evaluation criteria. Additionally, VA has added an explanatory note (2) regarding the definition of “newer

platelet stimulating factors” for clarification purposes and redesignated the existing note as note (1).

In the proposed rule, VA introduced several changes to DC 7718, Essential thrombocythemia and primary myelofibrosis, including revisions for 70 and 30 percent disability ratings. Namely, for 70 and 30 percent ratings, VA required the use of continuous or intermittent myelosuppressive therapy. In order to capture the full range of therapeutic agents that are used to treat these conditions, VA makes a clarifying change that amends the proposed text for 70 percent disability rating to read as follows: “Requiring continuous or intermittent myelosuppressive therapy, or chemotherapy, or interferon treatment to maintain platelet count $< 500 \times 10^9/L$.” VA makes a clarifying change that amends the proposed text for 30 percent disability rating to read as follows: “Requiring continuous or intermittent myelosuppressive therapy, or chemotherapy, or interferon treatment to maintain platelet count of 200,000–400,000, or white blood cell (WBC) count of 4,000–10,000.”

In the proposed rule, VA introduced several changes to DC 7719, Chronic myelogenous leukemia (CML) (chronic myeloid leukemia or chronic granulocytic leukemia), including revisions for 60 and 30 percent disability ratings. Namely, for 60 and 30 percent ratings, VA required the use of targeted therapy with tyrosine kinase inhibitors. In order to capture the full range of targeted therapy agents that are used to treat these conditions, VA makes a clarifying change that amends the proposed text for 60 percent disability rating to read as follows: “Requiring intermittent myelosuppressive therapy, or molecularly targeted therapy with tyrosine kinase inhibitors, or interferon treatment when not in apparent remission.” VA makes a clarifying change that amends the proposed text for 30 percent disability rating to read as follows: “In apparent remission on continuous molecularly targeted therapy with tyrosine kinase inhibitors.”

III. Public Comments

One commenter asked why the hematological system did not include Lyme disease. Lyme disease is an infectious disease evaluated under 38 CFR 4.88b. DC 6319 specifically addresses Lyme disease and its residuals. Therefore, VA makes no changes based on this comment.

One commenter urged VA to include in the rating schedule the debilitating side effects of daily tyrosine kinase inhibitors (TKIs) therapy for chronic

myelogenous leukemia (CML). In the proposed rule, DC 7719 assigns a 60 percent evaluation for intermittent myelosuppressive therapy, or targeted therapy with TKIs, such as ruxolitinib, and a 100 percent evaluation for continuous myelosuppressive or immunosuppressive therapy. However, in cases of debilitating side effects of therapy for a service-connected disease, such as CML, VA may grant service connection on a secondary basis for disabilities that are proximately due to, or aggravated by, service-connected disease or injury pursuant to 38 CFR 3.310. Therefore, VA makes no changes based on this comment.

Another commenter suggested separating evaluations for pernicious anemia from evaluations for Vitamin B₁₂ deficiency anemia. Pernicious anemia is caused by too little Vitamin B₁₂; it is one form of Vitamin B₁₂ deficiency anemia. VA recognizes the importance of separating pernicious anemia from Vitamin B₁₂ deficiency anemia for diagnosis and treatment. However, for disability compensation, VA evaluates common signs and symptoms and functional impairment of Vitamin B₁₂ deficiency, also seen in pernicious anemia, under one diagnostic code. Therefore, VA makes no changes based on this comment.

The same commenter noted that anemia secondary to autoimmune pernicious anemia is not corrected but maintained by Vitamin B₁₂ injections. VA agrees. In the proposed rule, DC 7722 provides a 10 percent evaluation for pernicious anemia and other forms of severe Vitamin B₁₂ deficiency if it requires continuous treatment with Vitamin B₁₂ injections, Vitamin B₁₂ sublingual or high-dose oral tablets, or Vitamin B₁₂ nasal spray or gel. Therefore, VA makes no changes based on this comment.

The same commenter suggested including all body systems sequelae of pernicious anemia into hematologic system evaluations. In cases when debilitating effects of pernicious anemia affect other body systems, VA may grant service connection on a secondary basis for disabilities that are proximately due to, or aggravated by, service-connected disease or injury, pursuant to 38 CFR 3.310. Therefore, VA makes no changes based on this comment.

The same commenter suggested VA conduct a study to determine whether the degree of neurologic or gastrointestinal residuals correlates with treatment variations. While VA appreciates this comment, it is beyond the scope of this rulemaking. Therefore, VA makes no changes based on it.

The same commenter expressed concern regarding the application of 38 CFR 3.105(e), which governs reduction in evaluation, to evaluate the debilitating residual effects of pernicious anemia. However, VA may grant service connection on a secondary basis for disabilities that are proximately due to, or aggravated by, service-connected disease or injury pursuant to 38 CFR 3.310. Therefore, VA makes no changes based on this comment.

One commenter discussed his current treatment for chronic myeloid leukemia and its side effects. The commenter did not offer any specific suggestions or recommendations for this rulemaking. Therefore, VA makes no changes based on this comment.

Another commenter urged the Federal Communications Commission (FCC) to reconsider regulating open-source software. This comment is beyond the scope of this rulemaking, so VA makes no changes based on it.

Two commenters indicated that security and privacy issues are important to them. The commenters did not offer any specific suggestions or recommendations for this rulemaking. Therefore, VA makes no changes based on these comments.

One commenter discussed his brother's diagnosis of chronic myeloid leukemia and military service in Vietnam. The commenter did not offer any specific suggestions or recommendations for this rulemaking. Therefore, VA makes no changes based on this comment.

Another commenter discussed his diagnosis of chronic myeloid leukemia, its side effects, and his military service in Vietnam. The commenter expressed his satisfaction with updates to the hematologic section of the rating schedule, which includes evaluations for chronic myeloid leukemia. The commenter did not offer any specific suggestions or recommendations for this rulemaking. Therefore, VA makes no changes based on this comment.

One commenter was supportive of many of the changes and additions made to the hematologic and lymphatic sections of the VASRD, which include new diagnostic codes for common disorders, clarifying notes on residuals affecting other body systems, and recognizing common side effects of various treatments. The commenter offered two minor suggestions regarding rating criteria for multiple myeloma (DC 7712) and acquired hemolytic anemia (DC 7723).

The commenter suggests deleting Note 2, Note 3, and part of Note 1 under DC 7712 in order to simplify the rating

process. VA agrees and removes the references to specific laboratory values by deleting Note (2) and Note (3). VA edits Note (1) by removing the references to specific laboratory values and replaces them with more general references to what are acceptable for the diagnosis of multiple myeloma as defined by the American Society of Hematology (ASH) and International Myeloma Working Group. Lastly, VA renumbers the proposed Note (4) to become Note (2).

The same commenter suggested including two additional treatment modalities for acquired hemolytic anemia under DC 7723. The commenter noted that, according to guidelines of the National Institutes of Health, the National Heart, Lung, and Blood Institute, and ASH, treatments for symptomatic acquired hemolytic anemia may include blood transfusion or plasmapheresis. VA identifies four levels of disability for symptomatic acquired hemolytic anemia, each of which includes blood transfusion or plasmapheresis. The defining feature for each level of disability is the frequency of immunosuppressive therapy or the need for a bone marrow transplant. Therefore, VA makes no changes based on this comment.

Another commenter noted that further revisions are needed for hematologic and lymphatic section of the VASRD to ensure its congruency with current understanding of hematologic diseases. The commenter offered multiple recommendations on selected diagnostic codes.

The commenter recommended deleting the references to obsolete or never used treatments. VA agrees and removes all references to treatment with radioactive phosphorus (DCs 7704, 7718, 7719, and 7725), imantib (DC 7704), interferon alpha (DC 7725), and multiple references to outdated laboratory values under DCs 7705 and 7712, Note (1). Proposed DC 7705 referred to a platelet count range from 20,000 to 30,000 despite treatment under a 100-percent rating level. The final rule revises this value to include all platelet counts of 30,000 or below.

The commenter noted that various anemia sections (DCs 7714, 7716, 7720, 7722, and 7723) did not link to comorbidities, such as cardiac disease and chronic obstructive pulmonary disease. The commenter advised VA to revise anemia DCs to include comorbidities because different hemoglobin levels might have vastly different implications in patients with cardiac disease, chronic obstructive pulmonary disease, or other significant comorbid conditions. As the

hematopoietic system supports other cells or organs of the body, VA assigns disability ratings resulting from identifiable defects in these organs due to hematologic disease. The hematologic rating does not generally include the physiologic effects on the function of other end-organs. For example, very severe anemia can reduce oxygen delivery to the point where the individual suffers a myocardial infarction. The disability ratings for both the anemia and the myocardial infarction would be rated separately and then combined. VA may grant service connection on a secondary basis for disabilities that are proximately due to, or aggravated by, service connected disease or injury pursuant to 38 CFR 3.310. Therefore, VA makes no changes based on this comment.

The commenter noted that current practice infrequently transplants bone marrow to treat agranulocytosis (DC 7702). Additionally, current medical protocol never uses platelet and red cell transfusions. Even though use of bone marrow transplants may be infrequent, the fact that it is still used for cases that do not respond to other types of treatment justifies including it as part of the 100 percent rating criteria. Additionally, the proposed rule does not refer to platelet and red cell transfusions for the treatment of agranulocytosis. Therefore, VA makes no changes based on this comment.

The commenter indicated that current practice does not use radioactive phosphorus or interferon alpha to treat myelodysplastic syndromes (DC 7725). VA agrees and removes all references to such treatment from this DC.

The commenter suggested editing platelet count reference for a 100 percent evaluation under DC 7705, Immune thrombocytopenia. ASH guidelines for immune thrombocytopenia recommend treatment for patients with platelet counts below 30,000. VA agrees and replaces the reference to "a platelet count from 20,000 to 30,000" under DC 7705 with "a platelet count 30,000 or below despite treatment".

The commenter noted that the 100 percent evaluation under DC 7705 included chemotherapy but the relevance of immunosuppressive therapy to this evaluation was unclear. However, VA did not intend to include immunosuppressive therapy as part of a 100 percent evaluation. VA includes immunosuppressive therapy as part of a 70 percent evaluation. Therefore, VA makes no changes based on this comment.

The commenter noted that recent advances in medicine have identified

conditions called monoclonal gammopathy of undetermined significance (MGUS) and smoldering myeloma, which are not acute myeloma but may indicate a future need for treatment. The commenter suggested removing an outdated reference to indolent myeloma from DC 7712 and replacing it with MGUS. VA agrees and removes the reference to indolent myeloma from DC 7712 and replaces the reference with MGUS.

VA appreciates the comments submitted in response to the proposed rule. Based on the rationale stated in the proposed rule and in this document, the final rule is adopted with the changes noted.

We are additionally adding updates to 38 CFR part 4, Appendices A, B, and C, to reflect changes to the hematologic and lymphatic systems rating criteria made by this rulemaking. VA designs the appendices for users of the VASRD. They do not contain substantive content regarding disability evaluations.

Executive Orders 12866, 13563 and 13771

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” requiring review by the Office of Management and Budget (OMB), unless OMB waives such review, 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 have 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 website at <http://www.va.gov/orpm/>, by following the link for “VA Regulations Published From FY 2004 Through Fiscal Year to Date.”

This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This final rule will not affect any small entities. Only certain VA beneficiaries could be directly affected. 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.

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 one year. This final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

This final rule contains provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). Specifically, this final rule is associated with information collections related to the filing of disability claims (VA Form 21–526EZ) as well as Disability Benefits Questionnaires (DBQs) which enable a claimant to gather the necessary information from his or her treating physician as to the current symptoms and severity of a disability. Both information collections are currently approved by the Office of Management

and Budget (OMB) and have been assigned OMB control Numbers 2900–0749 and 2900–0779, respectively. There are no changes to any of these information collections and, thus, no incremental costs associated with this rulemaking.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance program numbers and titles for this rule are 64.104, Pension for Non-Service-Connected Disability for Veterans; 64.109, Veterans Compensation for Service-Connected Disability; and 64.110, Veterans Dependency and Indemnity Compensation for Service-Connected Death.

List of Subjects in 38 CFR Part 4

Disability benefits, Pensions, Veterans.

Signing Authority

The Secretary of Veterans Affairs 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. Wilkie, Secretary, Department of Veterans Affairs, approved this document on October 23, 2018, for publication.

Dated: October 23, 2018.

Jeffrey M. Martin,

Assistant Director, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

For the reasons set out in the preamble, the Department of Veterans Affairs amends 38 CFR part 4, subpart B 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. Amend § 4.117 by:

■ a. Removing the entry for diagnostic code 7700;

■ b. Revising the entries for diagnostic codes 7702 through 7706, 7709, 7710 and 7714 through 7716;

■ c. Adding, in numerical order, an entry for diagnostic code 7712 and 7718 through 7725.

The revisions, and additions 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/microliter (µl) but less than 1000/µl; 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 1000/µl; 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 1500/µl ..	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
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 chemotherapy (including myelosuppressants) for the purpose of ameliorating the symptom burden ..	100
Requiring phlebotomy 6 or more times per 12-month period or molecularly targeted therapy for the purpose of controlling RBC count ..	60
Requiring phlebotomy 4–5 times per 12-month period, or if requiring continuous biologic therapy or myelosuppressive agents, to include interferon, to maintain platelets <200,000 or white blood cells (WBC) <12,000 ..	30
Requiring phlebotomy 3 or fewer times per 12-month period or if requiring biologic therapy or interferon on an intermittent basis as needed to maintain all blood values at reference range levels ..	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 chemotherapy (including myelosuppressants). Six months following hospital discharge or, in the case of 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 30,000 or below 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.	
* * * * *	
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

	Rating
Asymptomatic, smoldering, or monoclonal gammopathy of undetermined significance (MGUS)	0
<p>Note (1): Current validated biomarkers of symptomatic multiple myeloma and asymptomatic multiple myeloma, smoldering, or monoclonal gammopathy of undetermined significance (MGUS) are acceptable for the diagnosis of multiple myeloma as defined by the American Society of Hematology (ASH) and International Myeloma Working Group (IMWG).</p> <p>Note (2): 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>	
7714 Sickle cell anemia:	
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	100
With 3 painful episodes per 12-month period or with symptoms precluding other than light manual labor	60
With 1 or 2 painful episodes per 12-month period	30
Asymptomatic, established case in remission, but with identifiable organ impairment	10
<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>	
7715 Non-Hodgkin's lymphoma:	
When there is active disease, during treatment phase, or with indolent and non-contiguous phase of low grade NHL	100
<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>	
7716 Aplastic anemia:	
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	100
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 therapy with immunosuppressive agent or newer platelet stimulating factors	60
Requiring transfusion of platelets or red cells, on average, at least once per 12-month period; or infections recurring, on average, at least once per 12-month period	30
<p>Note (1): 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>Note (2): The term "newer platelet stimulating factors" includes medication, factors, or other agents approved by the United States Food and Drug Administration.</p>	
* * * * *	
7718 Essential thrombocythemia and primary myelofibrosis:	
Requiring either continuous myelosuppressive therapy or, for six months following hospital admission, peripheral blood or bone marrow stem cell transplant, or chemotherapy, or interferon treatment	100
Requiring continuous or intermittent myelosuppressive therapy, or chemotherapy, or interferon treatment to maintain platelet count <500 × 10 ⁹ /L	70
Requiring continuous or intermittent myelosuppressive therapy, or chemotherapy, or interferon treatment to maintain platelet count of 200,000–400,000, or white blood cell (WBC) count of 4,000–10,000	30
Asymptomatic	0
<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 chemotherapy (including myelosuppressants). Six months following hospital discharge or, in the case of 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>	
7719 Chronic myelogenous leukemia (CML) (chronic myeloid leukemia or chronic granulocytic leukemia):	
Requiring peripheral blood or bone marrow stem cell transplant, or continuous myelosuppressive or immunosuppressive therapy treatment	100
Requiring intermittent myelosuppressive therapy, or molecularly targeted therapy with tyrosine kinase inhibitors, or interferon treatment when not in apparent remission	60
In apparent remission on continuous molecularly targeted therapy with tyrosine kinase inhibitors	30
<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 chemotherapy (including myelosuppressants). Six months following hospital discharge or, in the case of 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 4 or more times per 12-month period	30
Requiring intravenous iron infusions at least 1 time but less than 4 times per 12-month period, or requiring continuous treatment with oral supplementation	10
Asymptomatic or requiring treatment only by dietary modification	0

	Rating
<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:	
<p>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</p>	
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	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 4 or more times per 12-month period	60
Requiring at least 2 but less than 4 courses of immunosuppressive therapy per 12-month period	30
Requiring 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 4 or more blood or platelet transfusions per 12-month period; or infections requiring hospitalization 3 or more times per 12-month period	60
Requiring at least 1 but no more than 3 blood or platelet transfusions per 12-month period; infections requiring hospitalization at least 1 but no more than 2 times per 12-month period; or requiring biologic therapy 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 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>	

■ 3. Amend Appendix A to Part 4 by:
 ■ a. Revising the entries for diagnostic codes 7700, 7702 through 7706, 7709 through 7710, and 7714 through 7716;

■ b. Adding, in numerical order, an entry for diagnostic code 7712 and 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 December 9, 2018.
*	*	*
	7702	Evaluation October 23, 1995; title December 9, 2018; evaluation December 9, 2018.
*	*	*

Sec.	Diagnostic code No.
	7703 Evaluation August 23, 1948; criterion October 23, 1995; evaluation December 9, 2018; criterion December 9, 2018.
	7704 Evaluation October 23, 1995; evaluation December 9, 2018.
	7705 Evaluation October 23, 1995; title December 9, 2018; evaluation December 9, 2018; criterion December 9, 2018.
	7706 Evaluation October 23, 1995; note December 9, 2018; criterion October 23, 1995.
*	*
	7709 Evaluation March 10, 1976; criterion October 23, 1995; title December 9, 2018; criterion December 9, 2018.
	7710 Criterion October 23, 1995; criterion December 9, 2018.
	7712 Added December 9, 2018.
	7714 Added September 9, 1975; criterion October 23, 1995; criterion December 9, 2018.
	7715 Added October 26, 1990; criterion December 9, 2018.
	7716 Added October 23, 1995; evaluation December 9, 2018; criterion December 9, 2018.
*	*
	7718 Added December 9, 2018.
	7719 Added December 9, 2018.
	7720 Added December 9, 2018.
	7721 Added December 9, 2018.
	7722 Added December 9, 2018.
	7723 Added December 9, 2018.
	7724 Added December 9, 2018.
	7725 Added December 9, 2018.
*	*

■ 4. Amend Appendix B to Part 4 by:
 ■ a. Revising the undesignated center heading immediately preceding diagnostic code 7700.

■ b. Revising the entries for diagnostic codes 7700, 7702, 7705, and 7709.
 ■ c. Adding, in numerical order, 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
7700 [Removed]
* * * * *
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).
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 revising the entries for Agranulocytosis, Anemia, Hodgkin's lymphoma, and

Leukemia and adding in alphabetical order, a new entry for Hematologic to 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

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0334; FRLc-9983-29]

Pyoxasulfone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyoxasulfone in or on multiple commodities which are identified and discussed later in this document. In addition, the established pyoxasulfone tolerance on cotton, undelinted seed is removed.

Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 29, 2018. Objections and requests for hearings must be received on or before December 28, 2018, and must be filed in accordance with the instructions provided in 40 CFR part

178 (see also Unit I.C. of the SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2017-0334, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDfRNNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.