

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for Part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191, 33 CFR 1.05–1(g), 6.04–1, 6.04–6 and 160.5; 49 CFR 1.46.

2. Add § 165.170 to read as follows:

§ 165.170 Safety Zone: Triathlon, Ulster Landing, Hudson River, NY.

(a) *Regulated area.* The following area is a safety zone: All waters of the Hudson River, in the vicinity of Ulster Landing, bound by the following points: 42°00'03.7"N, 073°56'43.1"W; thence to 41°59'52.5"N, 073°56'34.2"W; thence to 42°00'15.1"N, 073°56'25.2"W; thence to 42°00'05.4"N, 073°56'41.9"W (NAD 1983); thence along the shoreline to the point of beginning.

(b) *Effective period.* This section is in effect annually from 6 a.m. until 9 a.m. on the first Sunday after July 4th.

(c) *Regulations.* (1) The general regulations contained in 33 CFR 165.23 apply.

(2) No vessels will be allowed to transit the safety zone without the permission of the Captain of the Port, New York.

(3) All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port or the designated on-scene patrol personnel. These personnel comprise commissioned, warrant, and petty officers of the Coast Guard. Upon being hailed by a U.S. Coast Guard vessel by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed.

Dated: May 14, 2001.

R.E. Bennis,

Rear Admiral, U.S. Coast Guard, Captain of the Port, New York.

[FR Doc. 01–13643 Filed 5–30–01; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 4

RIN 2900–AK12

Schedule for Rating Disabilities: Disabilities of the Liver

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

SUMMARY: This document amends the Department of Veterans Affairs (VA) Schedule for Rating Disabilities (38 CFR part 4) by revising the portion of the Digestive System that addresses

disabilities of the liver. The intended effect of this action is to update this portion of the rating schedule to ensure that it uses current medical terminology and unambiguous criteria, and that it reflects medical advances that have occurred since the last review.

DATES: *Effective Date:* This rule is effective July 2, 2001.

FOR FURTHER INFORMATION CONTACT: Carol McBrine, M.D., Consultant, Regulations Staff (211A), Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Ave., NW., Washington DC 20420, (202) 273–7210.

SUPPLEMENTARY INFORMATION: As part of its review of the Schedule for Rating Disabilities (38 CFR part 4), VA published a proposal to amend that portion of the Schedule pertaining to liver disabilities. The proposed rule was published in the **Federal Register** on August 7, 2000 (65 FR 48205). Interested persons were invited to submit written comments on or before October 6, 2000. We received comments from the Disabled American Veterans and one VA employee.

In the preamble of the proposed rule, we proposed to delete diagnostic code 7313 but inadvertently did not include this change in the amendatory instructions portion of the document. No comment was made on this proposed change which is now reflected in the final rule.

One commenter questioned our proposal to provide percentage evaluation levels of 10, 30, 50, 70, and 100% for diagnostic code 7312 (cirrhosis of the liver, primary biliary cirrhosis, or cirrhotic phase of sclerosing cholangitis) and levels of zero, 10, 20, 40, 60, and 100% for diagnostic codes 7345 (chronic liver disease without cirrhosis (including hepatitis B, chronic active hepatitis, autoimmune hepatitis, hemochromatosis, drug-induced hepatitis, etc., but excluding bile duct disorders and hepatitis C)) and 7354 (hepatitis C (or non-A, non-B hepatitis)). The commenter felt all of these conditions should have the same evaluation levels because the symptom criteria are almost identical.

We do not adopt the comment for the following reasons. The symptom criteria for cirrhotic and non-cirrhotic liver diseases are not nearly identical. The evaluation criteria proposed for cirrhotic diseases (diagnostic code 7312) are based on largely objective signs, symptoms, and complications of cirrhosis, such as jaundice, weakness, weight loss, ascites, hepatic encephalopathy, and hemorrhage. The

evaluation levels for cirrhotic diseases have not been changed, except for the addition of the 10 percent rating recommended by our consultants. The evaluation criteria proposed for non-cirrhotic diseases (diagnostic codes 7345 and 7354) are based primarily on specific signs and symptoms of hepatitis or other chronic liver disease without cirrhosis, such as fatigue, malaise, nausea, vomiting, anorexia, arthralgia, and right upper quadrant pain.

Alternatively, non-cirrhotic liver disease and hepatitis C may be rated or on an alternative set of criteria based on incapacitating episodes if it will result in a higher evaluation. VA proposed in the **Federal Register** on February 24, 1996 (62 FR 8204) to also rate intervertebral disc syndrome based on incapacitating episodes. To maintain internal consistency in the rating schedule, we are using the same percentage evaluation levels that we proposed for rating intervertebral disc syndrome when it is based on incapacitating episodes. The evaluation levels for cirrhotic diseases, however, are not based on incapacitating episodes. Accordingly, we do not believe using the same levels of evaluation for such diseases is appropriate, and we have not adopted the commenter's suggestion.

The same commenter suggested that we provide criteria for diagnostic code 7312 based on incapacitating episodes, as we have done for hepatitis or other chronic liver disease without cirrhosis.

Cirrhosis results in liver scarring and progressive liver damage that eventually leads to liver decompensation with the complications of hemorrhage, encephalopathy, ascites, or jaundice. Treatment is aimed at preventing the progression of liver damage, but it cannot reverse it, because it is permanent. Since cirrhosis does not have an overall episodic course, although its complications may occur intermittently once it has reached the decompensated stage, an alternative set of criteria based on incapacitating episodes is not appropriate, and we have not adopted this suggestion.

Section 4.112 currently addresses weight loss in general terms for purposes of application to § 4.114. We proposed to revise this section by defining these terms in more detail and referencing them to the individual's "baseline weight." For example, we proposed to define "substantial weight loss," as meaning a loss of greater than 20 percent of the individual's baseline weight, sustained for three months or longer. One commenter recommended that we include some guidance for determining baseline weight because a

small variation in the way the baseline weight is determined could make a material difference in the disability rating assigned.

In response to this comment, we have added a sentence to § 4.112 defining "baseline weight" as the average weight for the two-year-period preceding onset of the disease. This will assure that the usual weight over a reasonable period of time before the disease began is the basis of determining subsequent weight loss.

We proposed to revise the criteria for evaluating residuals of injury to the liver (diagnostic code 7311) from rating under the criteria for peritoneal adhesions to rating as adhesions of peritoneum (diagnostic code 7301), cirrhosis of liver (diagnostic code 7312), or chronic liver disease without cirrhosis (diagnostic code 7345), depending on the specific residuals. One commenter stated that individuals may have both liver damage and peritoneal adhesions, and that we should therefore indicate that these residuals should be separately evaluated and then combined, rather than evaluating based on only one type of residual.

We agree that this should be clarified, and have revised the criteria to "Depending on the specific residuals, separately evaluate as adhesions of peritoneum (diagnostic code 7301), cirrhosis of liver (diagnostic code 7312), and chronic liver disease without cirrhosis (diagnostic code 7345)."

One commenter suggested we alter the order of presentation of the criteria and punctuation for diagnostic code 7312 at the 100-percent evaluation level from "With one of the following refractory to treatment: ascites, hepatic encephalopathy, or hemorrhage from varices or portal gastropathy (erosive gastritis), or; with persistent jaundice, generalized weakness, and substantial weight loss" to "With persistent jaundice, generalized weakness, and substantial weight loss; or with one of the following refractory to treatment: ascites, hepatic encephalopathy, hemorrhage from varices or portal gastropathy (erosive gastritis)." The commenter recommended similar punctuation changes under diagnostic codes 7345 and 7354.

For the sake of clarity, we have rearranged the order of the criteria under diagnostic code 7312, but prefer to retain the comma and semicolon to distinguish the criteria. We have used this method of punctuation in other sections of the rating schedule (e.g. 38 CFR 4.88b, diagnostic code 6314 and 38 CFR 4.104, diagnostic code 7000) to emphasize a clear separation of

alternative criteria and wish to be consistent in punctuation. A change here might imply a difference in meaning that we do not intend. We have not adopted the suggested punctuation changes for diagnostic codes 7345 and 7354 for the same reasons.

One commenter felt that, in the proposed criteria for a 100-percent evaluation under diagnostic code 7312, it was unclear whether the word "persistent" modifies all 3 manifestations in the phrase "persistent jaundice, generalized weakness, and substantial weight loss," and suggested that we clarify.

There was no intent that "persistent" modify all three nouns. To assure clarity, we have revised that phrase each time it appears to read "generalized weakness, substantial weight loss, and persistent jaundice."

One commenter expressed concerns about the criteria under diagnostic codes 7345 and 7354 for a 100-percent evaluation. The criteria we proposed are: "Near-constant incapacitating symptoms (such as fatigue, malaise, nausea, vomiting, anorexia, arthralgia, and right upper quadrant pain)." For a 60-percent evaluation, we proposed: "Incapacitating episodes (with symptoms such as fatigue, malaise, nausea, vomiting, anorexia, arthralgia, and right upper quadrant pain) having a total duration of at least six weeks during the past 12-month period, but not occurring constantly, or; with daily fatigue, malaise, and anorexia, with substantial weight loss (or other indication of malnutrition), and hepatomegaly." The commenter felt that the term "incapacitating symptoms" under the 100-percent evaluation criteria has essentially the same meaning as "incapacitating episodes" at other levels of evaluation, and that a veteran would have to be bedridden to meet the criteria for a 100-percent evaluation. The commenter said this does not conform to 38 U.S.C. 1155, which states that the rating schedule must be based on the average impairment of earning capacity.

A note under diagnostic codes 7345 and 7354 in the proposed rule defines the term "incapacitating episodes" for purposes of those codes. That definition is necessary because there is no generally understood meaning of "incapacitating episodes" as it is used for evaluation purposes. We have therefore defined the term to mean episodes of sudden onset and limited duration, but severe enough to require bed rest and treatment by a physician. As used in the rating schedule, the term "near-constant incapacitating symptoms" refers to symptoms that,

because of their severity and persistence, render the average individual unable to work. The word "incapacitating" is defined as "to make unable or unfit; esp., to make incapable of normal activity; disable." (Webster's New World Dictionary, Third College Edition, 681). Therefore, the term "incapacitating symptoms" does not require bed rest. To eliminate any possible confusion, however, we have changed the term "near-constant incapacitating symptoms" at the 100-percent level to "near-constant debilitating symptoms." Use of the analogous term "debilitating" will eliminate any possible confusion that might arise from the use of the terms "incapacitating episodes" and "incapacitating symptoms."

The same commenter objected to the retrospective nature of the criteria for diagnostic codes 7345 and 7354 when evaluation is based on incapacitating episodes on the grounds that a veteran might have to endure financial hardship for twelve months or more before being adequately compensated.

In the great majority of cases, veterans with non-cirrhotic liver disease will be evaluated using the criteria based on signs and symptoms of liver disease. Using those criteria does not require a 12-month period of observation before assigning an evaluation because they are based on current medical evidence of the chronic severity of the disease. The criteria based on incapacitating episodes, although they will be used infrequently, provide an avenue for a potentially higher evaluation. It will often not be necessary to wait 12 months in order to rate a veteran based upon incapacitating episodes if, for example, the medical evidence of record indicates how many episodes the veteran has experienced in the previous 12 months, or if there are incapacitating episodes of sufficient duration to allow the assignment of a higher evaluation than one based on symptoms, even though they have occurred over a less than 12-month period. However, in order to indicate more clearly that using signs and symptoms is the primary method of evaluating the severity of these diseases, we have reversed the order of the two sets of alternative criteria for diagnostic codes 7345 and 7354 so that signs and symptoms, *i.e.*, the primary basis of evaluation, comes first.

As an extension of the comment objecting to the retrospective nature of the criteria for diagnostic codes 7345 and 7354, the same commenter said that more frequent ratings would be needed in these cases in order to achieve stable evaluations.

As we explained above, most veterans will be rated on the basis of the signs and symptoms of liver disease, and these are not likely to change rapidly because the course of these liver diseases is commonly slow and prolonged, at least until the latter stages of disease. Most persons with non-cirrhotic liver disease and hepatitis C experience a steadily declining course. Periods of incapacitating episodes followed by substantial improvement or rapid decline would be very unusual. Given the course of these diseases, it is unlikely that re-evaluations would be needed more frequently than with other disabilities, and we have made no change based on this comment.

The same commenter urged that a better way (other than using incapacitating episodes as the basis of evaluation) be found to evaluate the severity of diseases that are characterized by recurring exacerbations. The commenter suggested no alternative method of evaluating recurring exacerbations. We believe that evaluating them based on incapacitating episodes is a fair and reasonable way to assess them, and will promote consistency across the rating schedule, in that different diseases will be rated at the same level if they result in the same duration of periods of incapacitation.

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 proposed rule, is adopted with the changes noted above.

Paperwork Reduction Act

This document contains no provisions constituting a collection of information under the Paperwork Reduction Act (44 U.S.C. 3501–3520).

Regulatory Flexibility Act

The Secretary hereby certifies that this regulatory amendment will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612. The reason for this certification is that this amendment would not directly affect any small entities. Only VA beneficiaries could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this amendment is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Executive Order 12866

This regulatory amendment has been reviewed by the Office of Management and Budget under the provisions of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993.

(The Catalog of Federal Domestic Assistance program numbers are 64.104 and 64.109.)

List of Subjects in 38 CFR Part 4

Disability benefits, Individuals with disabilities, Pensions, Veterans.

Approved: March 5, 2001.

Anthony J. Principi,
Secretary of Veterans Affairs.

For the reasons set out in the preamble, 38 CFR part 4, subpart B, is amended as set forth below:

PART 4—SCHEDULE FOR RATING DISABILITIES

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

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

2. Section 4.112 is revised to read as follows:

§ 4.112 Weight Loss.

For purposes of evaluating conditions in § 4.114, the term “substantial weight loss” means a loss of greater than 20 percent of the individual’s baseline weight, sustained for three months or longer; and the term “minor weight loss” means a weight loss of 10 to 20 percent of the individual’s baseline weight, sustained for three months or longer. The term “inability to gain weight” means that there has been substantial weight loss with inability to regain it despite appropriate therapy. “Baseline weight” means the average weight for the two-year-period preceding onset of the disease.

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

- 3. Section 4.114 is amended by:
 - A. Revising diagnostic codes 7311, 7312, 7343, 7344, and 7345.
 - B. Removing diagnostic code 7313.
 - C. Adding diagnostic codes 7351 and 7354.
 - D. Adding a new authority citation at the end of the section.

The revisions and additions read as follows:

§ 4.114 Schedule of ratings-digestive system.

* * * * *

	<i>Rating</i>
7311 Residuals of injury of the liver: Depending on the specific residuals, separately evaluate as adhesions of peritoneum (diagnostic code 7301), cirrhosis of liver (diagnostic code 7312), and chronic liver disease without cirrhosis (diagnostic code 7345)	
7312 Cirrhosis of the liver, primary biliary cirrhosis, or cirrhotic phase of sclerosing cholangitis: Generalized weakness, substantial weight loss, and persistent jaundice, or; with one of the following refractory to treatment: ascites, hepatic encephalopathy, hemorrhage from varices or portal gastropathy (erosive gastritis)	100
History of two or more episodes of ascites, hepatic encephalopathy, or hemorrhage from varices or portal gastropathy (erosive gastritis), but with periods of remission between attacks	70
History of one episode of ascites, hepatic encephalopathy, or hemorrhage from varices or portal gastropathy (erosive gastritis)	50
Portal hypertension and splenomegaly, with weakness, anorexia, abdominal pain, malaise, and at least minor weight loss	30
Symptoms such as weakness, anorexia, abdominal pain, and malaise	10
Note: For evaluation under diagnostic code 7312, documentation of cirrhosis (by biopsy or imaging) and abnormal liver function tests must be present. * * * * *	
7343 Malignant neoplasms of the digestive system, exclusive of skin growths	100
Note: A rating of 100 percent shall continue beyond the cessation of any surgical, X-ray, antineoplastic chemotherapy or other therapeutic procedure. 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 local recurrence or metastasis, rate on residuals.	
7344 Benign neoplasms, exclusive of skin growths: Evaluate under an appropriate diagnostic code, depending on the predominant disability or the specific residuals after treatment	
7345 Chronic liver disease without cirrhosis (including hepatitis B, chronic active hepatitis, autoimmune hepatitis, hemochromatosis, drug-induced hepatitis, etc., but excluding bile duct disorders and hepatitis C): Near-constant debilitating symptoms (such as fatigue, malaise, nausea, vomiting, anorexia, arthralgia, and right upper quadrant pain)	100
Daily fatigue, malaise, and anorexia, with substantial weight loss (or other indication of malnutrition), and hepatomegaly, or; incapacitating episodes (with symptoms such as fatigue, malaise, nausea, vomiting, anorexia, arthralgia, and right upper quadrant pain) having a total duration of at least six weeks during the past 12-month period, but not occurring constantly	60

Daily fatigue, malaise, and anorexia, with minor weight loss and hepatomegaly, or; incapacitating episodes (with symptoms such as fatigue, malaise, nausea, vomiting, anorexia, arthralgia, and right upper quadrant pain) having a total duration of at least four weeks, but less than six weeks, during the past 12-month period	40
Daily fatigue, malaise, and anorexia (without weight loss or hepatomegaly), requiring dietary restriction or continuous medication, or; incapacitating episodes (with symptoms such as fatigue, malaise, nausea, vomiting, anorexia, arthralgia, and right upper quadrant pain) having a total duration of at least two weeks, but less than four weeks, during the past 12-month period	20
Intermittent fatigue, malaise, and anorexia, or; incapacitating episodes (with symptoms such as fatigue, malaise, nausea, vomiting, anorexia, arthralgia, and right upper quadrant pain) having a total duration of at least one week, but less than two weeks, during the past 12-month period	10
Nonsymptomatic	0
Note (1): Evaluate sequelae, such as cirrhosis or malignancy of the liver, under an appropriate diagnostic code, but do not use the same signs and symptoms as the basis for evaluation under DC 7354 and under a diagnostic code for sequelae. (See § 4.14.)	
Note (2): For purposes of evaluating conditions under diagnostic code 7345, "incapacitating episode" means a period of acute signs and symptoms severe enough to require bed rest and treatment by a physician.	
Note (3): Hepatitis B infection must be confirmed by serologic testing in order to evaluate it under diagnostic code 7345.	
* * * * *	
7351 Liver transplant:	
For an indefinite period from the date of hospital admission for transplant surgery	100
Minimum	30
Note: A rating of 100 percent shall be assigned as of the date of hospital admission for transplant surgery and shall continue. One year following discharge, 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.	
7354 Hepatitis C (or non-A, non-B hepatitis):	
With serologic evidence of hepatitis C infection and the following signs and symptoms due to hepatitis C infection:	
Near-constant debilitating symptoms (such as fatigue, malaise, nausea, vomiting, anorexia, arthralgia, and right upper quadrant pain)	100
Daily fatigue, malaise, and anorexia, with substantial weight loss (or other indication of malnutrition), and hepatomegaly, or; incapacitating episodes (with symptoms such as fatigue, malaise, nausea, vomiting, anorexia, arthralgia, and right upper quadrant pain) having a total duration of at least six weeks during the past 12-month period, but not occurring constantly	60
Daily fatigue, malaise, and anorexia, with minor weight loss and hepatomegaly, or; incapacitating episodes (with symptoms such as fatigue, malaise, nausea, vomiting, anorexia, arthralgia, and right upper quadrant pain) having a total duration of at least four weeks, but less than six weeks, during the past 12-month period	40
Daily fatigue, malaise, and anorexia (without weight loss or hepatomegaly), requiring dietary restriction or continuous medication, or; incapacitating episodes (with symptoms such as fatigue, malaise, nausea, vomiting, anorexia, arthralgia, and right upper quadrant pain) having a total duration of at least two weeks, but less than four weeks, during the past 12-month period	20
Intermittent fatigue, malaise, and anorexia, or; incapacitating episodes (with symptoms such as fatigue, malaise, nausea, vomiting, anorexia, arthralgia, and right upper quadrant pain) having a total duration of at least one week, but less than two weeks, during the past 12-month period	10
Nonsymptomatic	0
Note (1): Evaluate sequelae, such as cirrhosis or malignancy of the liver, under an appropriate diagnostic code, but do not use the same signs and symptoms as the basis for evaluation under DC 7354 and under a diagnostic code for sequelae. (See § 4.14.)	
Note (2): For purposes of evaluating conditions under diagnostic code 7354, "incapacitating episode" means a period of acute signs and symptoms severe enough to require bed rest and treatment by a physician.	

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

[FR Doc. 01-13626 Filed 5-30-01; 8:45 am]

BILLING CODE 8320-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[IN132-1a; FRL-6985-3]

Approval and Promulgation of Implementation Plans; Indiana

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The EPA is approving revisions to particulate matter (PM) emissions regulations for Illinois Cereal Mills, Incorporated (Illinois Cereal Mills). This facility is located in Marion County, Indiana. The Indiana Department of Environmental Management (IDEM) submitted the revised regulations on August 2, 2000 as an amendment to its State Implementation Plan (SIP). The revisions consist of the relaxation of one annual emission limit and the tightening of another limit. These SIP

revisions should result in no change in the overall particulate emissions. Analysis showed that air quality will not be harmed from this change in particulate emissions.

DATES: This rule is effective on July 30, 2001, unless the EPA receives relevant adverse written comments by July 2, 2001. If adverse comment is received, the EPA will publish a timely withdrawal of the rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: You should mail written comments to: J. Elmer Bortzer, Chief, Regulation Development Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

You may inspect copies of Indiana's submittal at: Regulation Development Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Matt Rau, Environmental Engineer, Regulation Development Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency,

Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, Telephone: (312) 886-6524, E-Mail: rau.matthew@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document wherever "we," "us," or "our" are used we mean the EPA.

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I. What Is the EPA Approving?

The EPA is approving revisions to the particulate matter emissions regulations for Illinois Cereal Mills in Marion County, Indiana. IDEM submitted the revised regulation on August 2, 2000 as an amendment to its SIP.

The revisions are the relaxation of one annual emission limit for a boiler and the tightening of another limit for the head house portion of a grain elevator. These SIP revisions result in no change in the overall PM emissions from the