Rules and Regulations

Federal Register
Vol. 74, No. 192
Tuesday, October 6, 2009

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SMALL BUSINESS ADMINISTRATION

13 CFR Parts 120 and 124

RIN 3245–AF64

Agency Titling Procedure Revision; Nomenclature Changes; Correction

AGENCY: U.S. Small Business Administration.

ACTION: Notice of correcting amendment; correction.

SUMMARY: The U.S. Small Business Administration (SBA) published in the **Federal Register** of September 4, 2009, a document correcting the titles of certain SBA officials. Some sections were inadvertently amended and another contained an error. This document corrects those amendments.

DATES: Effective on October 6, 2009.

FOR FURTHER INFORMATION CONTACT: Dean R. Koppel, Office of Government Contracting, Small Business Administration, 409 3rd Street, SW., Washington, DC 20416. Tel: (202) 205–6460 and e-mail: *dean.koppel@sba.gov.*

SUPPLEMENTARY INFORMATION: The SBA published a document in the **Federal Register** of August 30, 2007 which amended several SBA titles. On September 4, 2009, in the **Federal Register** (74 FR 45754), § 120.433; § 120.472 and § 120.473 were inadvertently amended. This correction removes the amendments to § 120.433; § 120.472 and § 120.473 published on September 4, 2009. Additionally, § 124.1008 (a) was identified as amended when the reference should have been § 124.1008(e).

In 74 FR 45754 published on September 4, 2009, make the following corrections.

§§ 120.433, 120.472 and 120.473 [Corrected]

■ 1. On page 45753, in the first column, remove the amendments to § 120.433; § 120.472 and § 120.473.

§ 124.1008 [Corrected]

■ 2. On page 45754, in the first column, correct the amendment to § 124.1008 by removing the reference to ''paragraph (a)'' and adding a reference to ''paragraph (e)'' in its place.

Dated: September 29, 2009.

Joseph G. Jordan,

Associate Administrator, Office of Government Contracting and Business Development.

[FR Doc. E9–24040 Filed 10–5–09; 8:45 am]

BILLING CODE 8025–01–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Docket No. SSA–2007–0066]

RIN 0960–AG57

Revised Medical Criteria for Evaluating Malignant Neoplastic Diseases

AGENCY: Social Security Administration.

ACTION: Final rule.

SUMMARY: We are revising some of the criteria in the Listing of Impairments (the listings) that we use to evaluate claims involving malignant neoplastic diseases (cancer) [1] under titles II and XVI of the Social Security Act (Act). The revisions reflect our adjudicative experience, advances in medical knowledge, diagnosis, and treatment, and public comments we received in response to a Notice of Proposed Rulemaking (NPRM).

DATES: This rule is effective November 5, 2009.

FOR FURTHER INFORMATION CONTACT: Mark Kuhn, Office of Medical Listings Improvement, Social Security Administration, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, (410) 965–1020. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213, or TTY 1–800–325–0778, or visit our Internet Web site, Social Security Online, at *http://www.socialsecurity.gov*.

SUPPLEMENTARY INFORMATION:

[1] ''Malignant neoplastic disease'' is commonly known as ''cancer.'' We use both terms interchangeably in this document because we continue to use the technical medical term in the listings.

Electronic Version

The electronic file of this document is available on the date of publication in the **Federal Register** at *http://www.gpoaccess.gov/fr/index.html.*

Background

We are revising and making final the rules for evaluating malignant neoplastic diseases we proposed in an NPRM published in the **Federal Register** on April 24, 2008 (73 FR 22871). The preamble to the NPRM discussed the changes from the current rules and our reasons for making those changes. Since we are largely adopting the proposed rules as published, we are not repeating that information here. Interested readers may refer to the preamble to the NPRM, available at *http://www.regulations.gov*.

We are making a few changes from the NPRM as a result of public comments. We explain those changes in our summary of the public comments and our responses later in this preamble.

Why are we revising the listings for malignant neoplastic diseases?

We developed these final rules as part of our ongoing review of the cancer body system. When we last revised this body system in final rules published on November 15, 2004,[2] we indicated that we would monitor and update the listings in this body system as needed.

When will we use these final rules?

We will use these final rules beginning on their effective date. We will continue to use the current listings until the date these final rules become effective. We will apply the final rules to new applications filed on or after the effective date of the final rules and to claims that are pending on and after the effective date.[3]

[2] *See* 69 FR 67018, corrected at 70 FR 15227.

[3] This means that we will use these final rules on and after their effective date in any case in which we make a determination or decision. We expect that Federal courts will review our final decisions using the rules that were in effect at the time we issued the decisions. If a court reverses the Commissioner's final decision and remands a case for further administrative proceedings after the effective date of these final rules, we will apply these final rules to the entire period at issue in the decision we make after the court's remand.

How long will the rules in the malignant neoplastic diseases body system be in effect?

We are extending the effective date of the malignant neoplastic diseases body system in parts A and B of the listings until 8 years after the effective date of these final rules. The rules will remain in effect only until that date unless we extend them. We will continue to monitor the rules and may revise them before the end of the 8-year period.

Public Comments on the NPRM

In the NPRM, we provided the public with a 60-day comment period, which ended on June 27, 2008. We received five public comment letters. The comments came from a national cancer advocacy group, a national group representing disability examiners in the State agencies that make disability determinations for us, a national group representing directors of those State agencies, and two individual State agencies.

We provide our responses below to the significant comments that were relevant to this rulemaking. A few of the comments were on subjects that were not related to the proposed rules. For example, commenters suggested changes to the introductory text of this body system and some suggested that we add new listings in sections for which we had not proposed rules. Other commenters made suggestions that involved the steps of our sequential evaluation process coming after the listing step. Although we read and considered these comments, we do not summarize or respond to them below because they are outside the scope of this rulemaking proceeding.

We have summarized the relevant comments below, but have tried to present the commenters' concerns and suggestions accurately and completely.

Sections 13.00I and 113.00I—What do we mean by the following terms?

We adopted a comment that suggested we include the term ''multimodal'' or the phrase ''multimodal therapy'' in the list of defined terms in sections 13.00I and 113.00I. The commenter also requested that we provide additional clarification of multimodal therapy. We adopted this comment by moving the definition of ''multimodal therapy'' from current sections 13.00E2 and 113.00E2 to final sections 13.00I3 and 113.00I2. We also revised the definitions in these sections to make them clearer.

Since we added a new definition in final sections 13.00I and 113.00I, we renumbered the definitions that follow. We also changed the headings of these sections. In the NPRM, we used the heading ''*What do these terms in the listings mean?''* for sections 13.00I and 113.00I, and we included only terms that were actually included in the listings. We use the term ''multimodal'' in current listings 13.02 and 13.11, and final listing 13.14; however, we do not use it in any of the listings in part B. Since we do not use the terms ''multimodal'' or ''multimodal therapy'' in any of the listings in part B, we changed the headings in both parts.

We did not adopt a suggestion that we include in final section 13.00I a definition of the term ''first treatment,'' which is a term we use only when we refer to an autologous bone marrow transplant in current listing 13.28B. The commenter thought that we defined this term only in an internal instruction. In fact, we already define ''first treatment'' in current section 13.00L3b, where we explain how to use listing 13.28. Moreover, listing 13.28 refers to section 13.00L3b. We think it will be easier for our adjudicators to find the definition if we leave it where it is.

We also did not adopt a comment that recommended that we add a definition for ''satellite lesions.'' We use this term only in one section of the listing for melanoma (a kind of skin cancer), and we define it there. See final listing 13.03B2c.

Listing 13.02—Soft Tissue Tumors of the Head and Neck

We did not adopt a comment recommending that we provide general guidance for evaluating bilateral neuroblastomas under current listing 13.02A. We consider bilateral neuroblastomas to be tumors of the central nervous system, which we evaluate under listing 13.13.

The same commenter suggested that we emphasize in the introductory text of the malignant neoplastic diseases body system how to evaluate soft tumors of the head and neck under current listing 13.02A. We did not adopt this comment because the listing requires such tumors to be either ''inoperable'' or ''unresectable'' and we already define those terms in final section 13.00I.

We did, however, adopt a third comment from this commenter recommending that we explain how we evaluate a recurrence that occurs more than 3 years after remission in connection with listing 13.02 and another listing. In response to this comment, we revised the second sentence of current sections 13.00H2 and 113.00H2, which referred only to the ''original'' tumor and any metastases, to also include recurrences and relapses. We also added a sentence at the end of final sections 13.00H3 and 113.00H3 to indicate that, if there is a recurrence or relapse after 3 years or another period specified in a listing in this body system, the impairment may again meet or medically equal the requirements of a cancer listing. These changes are only a clarification of our current rules, and ensure that we will not incorrectly find that people with recurrent tumors are no longer disabled.

Listing 13.03—Skin

One commenter suggested that we include criteria in listing 13.03 for melanomas with ulcerative features. The commenter believed that the description of these melanomas in the current American Joint Committee on Cancer (AJCC) staging manual indicates listing-level severity. We disagree with the commenter and have not adopted the comment. While the AJCC staging manual does indicate that melanomas with ulceration have a worse prognosis than non-ulcerated melanomas, it also indicates that many ulcerated melanomas have good prognoses. Therefore, we do not believe that the AJCC staging manual describes an impairment of listing-level severity, and it would be inappropriate for us to find that all people with this condition have a listing-level impairment.

The same commenter recommended that we add criteria for melanoma with in-transit spread; that is, metastasis along the lymph channels. We did not adopt the comment because the final listings already address the disabling effects of in-transit spread. We will evaluate in-transit spread that affects the lymph nodes under final listing 13.03B2a or 13.03B2b. We will evaluate in-transit spread that results in metastases to adjacent skin or distant sites under final listing 13.03B2c.

Listing 13.09—Thyroid Gland

In response to a comment, we added final listing 113.09C, for medullary carcinoma of the thyroid gland with metastases beyond the regional lymph nodes. Final listing 113.09C is identical to final listing 13.09C. The commenter referred to our statement in proposed 113.00K4 that we did not include a specific listing for children because the condition is rare in children, but did not believe the listings are meant to exclude cancers simply because they are rare. Since our listings do include some rare disorders, we agreed to add this listing in response to the comment. We currently find all such children with the cancer described in final listing 113.09C disabled based on medical equivalence to listing 113.09B.

In the NPRM, we explained in proposed section 113.00K4 that we would use listing 13.09C for children with this type of cancer. Because we are adding listing 113.09C, we did not include that paragraph in these final rules.

Listing 13.10—Breast

One commenter recommended that we include a listing for people with locally advanced breast cancer who receive multimodal therapy. The commenter recommended that we consider these people disabled for either 12 or 18 months from the date of diagnosis. The commenter noted that we have other listings that recognize the difficulties faced by patients during initial treatment of their cancers, even though they have good prognoses, and believed that we could have a similar listing for some people with breast cancer. The commenter indicated that there are treatment regimens that last for at least 7 to 12 months that may have many side effects and that, as treatment progresses, the side effects worsen.

We did not adopt this comment. While we agree with the commenter that there may be some people who are disabled from multimodal therapy for breast cancer and its adverse effects, we do not believe that we can uniformly describe those people medically, as required for a listing. Many people who undergo such therapy are not unable to work for 12 continuous months.

Another commenter recommended that we add a criterion for metastatic breast cancer to an axillary lymph node(s) with perforation of the capsule (that is, tumor extension beyond the capsule),[4] with or without nodal matting (fusion). We did not adopt this comment because, while perforation of the capsule, with or without matting, increases the risk of tumor recurrence, this finding alone does not usually represent the level of severity intended by the listings. We cannot have a listing based only on a risk of recurrence because people cannot qualify for disability benefits before they actually become unable to work (or for children under title XVI, meet the definition of disability for children). When there is recurrence, we will evaluate it under listing 13.10C.

Listing 13.13—Nervous System

One commenter recommended that we rewrite listing 13.13 to separate neoplasms that require metastases from those that do not. The commenter provided a suggested revision, but we did not adopt it for two reasons. First, the revisions we proposed to the listing did separate the neoplasms that require metastases from those that do not. As we explained in the preamble to the NPRM:

> We propose to make a minor editorial change to current listing 13.13A1 for highly malignant central nervous system neoplasms to clarify that the requirement for documented metastases applies only to medulloblastoma or other primitive neuroectodermal tumors (PNETs), and not to grades III and IV astrocytomas, glioblastoma multiforme, and ependymoblastoma. This is what we intend in the current rule, but we want[ ] to make the current sentence structure clearer. Therefore, we propose to reorganize the sentence for clarity.[5]

Second, and more importantly, the language the commenter proposed could have been misinterpreted to include under this listing medulloblastomas and other PNETs that have not metastasized. This interpretation would have been contrary to our intent, as we explained when we last made comprehensive revisions to the malignant neoplastic diseases body system in 2004.[6] In that final rule, we explained that we could evaluate medulloblastomas or other PNETs that have not metastasized under listing 13.13A2.

Listing 13.23—Cancers of the Female Genital Tract

One commenter pointed out that we have no listing for cancer of the vagina, nor do we provide guidance in the introductory text on how adjudicators should evaluate this malignancy. The commenter suggested that we revise listing 13.23C to include cancer of the vagina or that we explain which listing to use to evaluate this condition. We adopted this comment by including cancer of the vagina in listing 13.23C. The criteria for listing-level cancer of the vulva are also appropriate for cancer of the vagina. Under the prior rules, we would have found medical equivalence to this listing in such cases.

Two commenters expressed concern about our proposal to remove prior listing 13.23E1c, for ovarian cancer with ruptured ovarian capsule, tumor on the serosal surface, ascites with malignant cells, or positive peritoneal washings. One comment letter said that the medical literature with which the commenters were familiar showed that ovarian cancer with these findings has a high mortality rate. However, in the NPRM we cited current medical literature indicating that therapy has significantly improved the prognosis for women who have ovarian cancer with these findings.[7] Based on this medical literature, we believe that most women who have ovarian cancer with the findings in prior listing 13.23E1c have a good prognosis.

The other commenter, a national advocacy group for women with ovarian cancer, agreed with us that the prognosis for these cases has improved significantly, but recommended that we keep the listing to recognize the length and side effects of treatment. The commenter pointed out that women with these findings may undergo the same or similar surgery and chemotherapy as women with more advanced disease and that this treatment substantially limits those women's ability for gainful activity.

While we appreciate the second commenter's concerns—and we agree that some women with the findings in the prior listing will be disabled—we did not adopt the recommendation to keep the listing, primarily because many women with the findings in prior listing 13.23E1c will not be unable to work for at least 12 months. Even though they may be debilitated while they undergo treatment and for some time afterward, many of these women will have only minimal functional limitations 12 months after diagnosis. Therefore, it would be inappropriate for us to keep the prior listing, which would require us to find that all women with the listed criteria are disabled. We must evaluate these cases on an individual basis.

Finally, two commenters recommended that we not remove the listing 13.23E1c because there may be a recurrence of the disease, and a recurrence generally has a poor prognosis. We agree that recurrent ovarian cancer has a poor prognosis, but we already include it in final listing 13.23E1c, our criterion for recurrent ovarian cancer. As we have already noted, we cannot have a listing based only on a risk of recurrence.

Listing 13.24—Prostate Gland

We did not adopt a suggestion that we clarify in the introductory text how our adjudicators should use the Gleason grading scale[8] in connection with listing 13.24 because the listing criteria are not based on this scale. The listing requires that the tumor not respond to initial hormonal treatment or that it metastasize to internal organs. The

[4] The capsule is a membrane of fibrous tissue that encases the lymph node.

[5] *See* 73 FR at 22873.

[6] *See* 69 FR at 67024.

[7] For the list of references we consulted, see 73 FR at 22875.

[8] The Gleason grades and scores are used to help evaluate the prognosis of men with prostate cancer.

Gleason grade does not indicate whether the tumor meets these criteria.

Other Changes From the NPRM

We made a number of editorial corrections and changes in the final rules from the language of the NPRM. For example, we changed some sentences from passive into active voice. These changes are only for clarity, consistency, and to correct minor grammatical errors in the NPRM; none are substantive.

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

Under the Act, we have full power and authority to make rules and regulations and to establish necessary and appropriate procedures to carry out such provisions. Sections 205(a), 702(a)(5), and 1631(d)(1).

Regulatory Procedures

Executive Order 12866

We have consulted with the Office of Management and Budget (OMB) and determined that these final rules meet the requirements for a significant regulatory action under Executive Order 12866 and were subject to OMB review.

Regulatory Flexibility Act

We certify that these final rules have no significant economic impact on a substantial number of small entities because they affect only individuals. Therefore, a regulatory flexibility analysis was not required under the Regulatory Flexibility Act, as amended.

Paperwork Reduction Act

This rule does not create any new or affect any existing collections and, therefore, does not require Office of Management and Budget approval under the Paperwork Reduction Act.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security—Disability Insurance; 96.002, Social Security—Retirement Insurance; 96.004, Social Security—Survivors Insurance; and 96.006, Supplemental Security Income)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Dated: July 30, 2009.

Michael J. Astrue,

Commissioner of Social Security.

■ For the reasons set out in the preamble, we amend appendix 1 to subpart P of part 404 of chapter III of title 20 of the Code of Federal Regulations as set forth below:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

■ 1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a), (b), and (d)–(h), 216(i), 221(a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)–(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189; sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

■ 2. Amend appendix 1 to subpart P of Part 404 as follows:
■ a. Revise item 14 of the introductory text before part A of appendix 1.
■ b. Revise paragraph E2 of section 13.00 of part A of appendix 1.
■ c. Revise the second sentence of paragraph H2 and add a new second sentence to paragraph H3 of section 13.00 of part A of appendix 1.
■ d. Revise paragraph I of section 13.00 of part A of appendix 1.
■ e. Amend paragraph K of section 13.00 of part A of appendix 1 by revising K1a, K1b, the third sentence of K2a, and K6.
■ f. Revise listing 13.02C of part A of appendix 1.
■ g. Revise listing 13.03B2 of part A of appendix 1.
■ h. Amend listing 13.05 of part A of appendix 1 by revising the listing 13.05A.
■ i. Amend listing 13.09 of part A of appendix 1 by adding the word ''OR'' after listing 13.09B and adding listing 13.09C.
■ j. Revise listing 13.10B of part A of appendix 1.
■ k. Revise the heading of listing 13.11 of part A of appendix 1.
■ l. Revise listing 13.13A of part A of appendix 1.
■ m. Amend listing 13.14 of part A of appendix 1 by adding the word ''OR'' after listing 13.14B and adding listing 13.14C.
■ n. Revise listings 13.23C and 13.23E1 of part A of appendix 1.
■ o. Revise listing 13.24B of part A of appendix 1.
■ p. Revise listing 13.27 of part A of appendix 1.
■ q. Revise paragraph E2 of section 113.00 of part B of appendix 1.
■ r. Revise the second sentence of paragraph H2 and add a new second sentence to paragraph H3 of section 113.00 of part B of appendix 1.
■ s. Revise paragraph I of section 113.00 of part B of appendix 1.
■ t. Amend paragraph K of section 113.00 of part B of appendix 1 by revising K1a, the third sentence of K2a, and K4.
■ u. Amend listing 113.09 of part B of appendix 1 by adding the word ''OR'' after listing 113.09B and adding listing 113.09C.
■ v. Revise listing 113.13 of part B of appendix 1.

The revised text is set forth as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

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14. Malignant Neoplastic Diseases (13.00 and 113.00): November 5, 2017

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Part A

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13.00 MALIGNANT NEOPLASTIC DISEASES

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E. *When do we need longitudinal evidence?*

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2. *Other malignancies.* When there are no distant metastases, many of the listings require that we consider your response to initial antineoplastic therapy; that is, the initial planned treatment regimen. This therapy may consist of a single modality or a combination of modalities; that is, multimodal therapy (see 13.00I3).

* * * * *

H. *How long do we consider your impairment to be disabling?*

* * * * *

2. * * * When the impairment(s) has been in complete remission for at least 3 years, that is, the original tumor or a recurrence (or relapse) and any metastases have not been evident for at least 3 years, the impairment(s) will no longer meet or medically equal the criteria of a listing in this body system.

3. * * * If you have a recurrence or relapse of your malignancy, your impairment may meet or medically equal one of the listings in this body system again.

* * * * *

I. *What do we mean by the following terms?*

1. *Inoperable:* Surgery is thought to be of no therapeutic value or the surgery cannot be performed; for example, when you cannot tolerate anesthesia or surgery because of another impairment(s), or you have a tumor that is too large or that has invaded crucial structures. This term does not include situations in which your tumor could have been surgically removed but another method of treatment was chosen; for example, an attempt at organ preservation. Your physician may determine whether a tumor is inoperable before or after you receive neoadjuvant therapy. *Neoadjuvant therapy* is antineoplastic therapy, such as chemotherapy or radiation, given before surgery in order to reduce the size of the tumor.

2. *Metastases:* The spread of tumor cells by blood, lymph, or other body fluid. This term does not include the spread of tumor cells by direct extension of the tumor to other tissues or organs.

3. *Multimodal therapy:* A combination of at least two types of treatment modalities given in close proximity as a unified whole and usually planned before any treatment has begun. There are three types of treatment modalities: Surgery, radiation, and systemic drug therapy (chemotherapy, hormonal therapy, and immunotherapy).

Examples of multimodal therapy include:

a. Surgery followed by chemotherapy or radiation.

b. Chemotherapy followed by surgery.

c. Chemotherapy and concurrent radiation.

4. *Persistent:* Failure to achieve a complete remission.

5. *Progressive:* The malignancy becomes more extensive after treatment.

6. *Recurrent, relapse:* A malignancy that was in complete remission or entirely removed by surgery has returned.

7. *Unresectable:* Surgery was performed, but the malignant tumor was not removed. This term includes situations in which your tumor is incompletely resected or the surgical margins are positive. It does not include situations in which a tumor is completely resected but you are receiving adjuvant therapy. Adjuvant therapy is antineoplastic therapy, such as chemotherapy or radiation, given after surgery in order to eliminate any remaining cancer cells and lessen the chance of recurrence.

* * * * *

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

1. *Lymphoma.*

a. Many indolent (non-aggressive) lymphomas are controlled by well-tolerated treatment modalities, although the lymphomas may produce intermittent symptoms and signs. Therefore, we may defer adjudicating these cases for an appropriate period after therapy is initiated to determine whether the therapy will achieve its intended effect, which is usually to stabilize the disease process. (See 13.00E3.) When your disease has been stabilized, we will assess severity based on the extent of involvement of other organ systems and residuals from therapy.

b. A change in therapy for indolent lymphomas is usually an indicator that the therapy is not achieving its intended effect. However, your impairment will not meet the requirements of 13.05A2 if your therapy is changed solely because you or your physician choose to change it, not because of a failure to achieve stability.

* * * * *

2. *Leukemia.*

a. *Acute leukemia.* * * * Recurrent disease must be documented by peripheral blood, bone marrow, or cerebrospinal fluid examination, or by testicular biopsy. * * *

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6. *Brain tumors.* We use the criteria in 13.13 to evaluate malignant brain tumors. We consider a brain tumor to be malignant if it is classified as grade II or higher under the World Health Organization (WHO) classification of tumors of the central nervous system (*WHO Classification of Tumours of the Central Nervous System*, 2007). We evaluate any complications of malignant brain tumors, such as resultant neurological or psychological impairments, under the criteria for the affected body system. We evaluate benign brain tumors under 11.05.

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13.02 *Soft tissue tumors of the head and neck* (*except salivary glands—13.08—and thyroid gland—13.09*).

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C. Recurrent disease following initial antineoplastic therapy, except recurrence in the true vocal cord.

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13.03 *Skin.*

* * * * *

B. Melanoma, as described in 1 or 2.

* * * * *

2. With metastases as described in a, b, or c:

a. Metastases to one or more clinically apparent nodes; that is, nodes that are detected by imaging studies (excluding lymphoscintigraphy) or by clinical examination.

b. If the nodes are not clinically apparent, with metastases to four or more nodes.

c. Metastases to adjacent skin (satellite lesions) or distant sites.

* * * * *

13.05 *Lymphoma* (*excluding T-cell lymphoblastic lymphoma—13.06*). (*See* 13.00K1 and 13.00K2c.)

A. Non-Hodgkin's lymphoma, as described in 1 or 2:

1. Aggressive lymphoma (including diffuse large B-cell lymphoma) persistent or recurrent following initial antineoplastic therapy.

2. Indolent lymphoma (including mycosis fungoides and follicular small cleaved cell) requiring initiation of more than one antineoplastic treatment regimen within a consecutive 12-month period. Consider under a disability from at least the date of initiation of the treatment regimen that failed within 12 months.

* * * * *

13.09 *Thyroid gland.*

B. * * *

OR

C. Medullary carcinoma with metastases beyond the regional lymph nodes.

13.10 *Breast* (*except sarcoma—13.04*). (*See* 13.00K4.)

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B. Carcinoma with metastases to the supraclavicular or infraclavicular nodes, to 10 or more axillary nodes, or with distant metastases.

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13.11 *Skeletal system*—sarcoma.

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13.13 *Nervous system.* (*See* 13.00K6.)

A. Central nervous system malignant neoplasms (brain and spinal cord), as described in 1 or 2:

1. Highly malignant tumors, such as medulloblastoma or other primitive neuroectodermal tumors (PNETs) with documented metastases, grades III and IV astrocytomas, glioblastoma multiforme, ependymoblastoma, diffuse intrinsic brain stem gliomas, or primary sarcomas.

2. Progressive or recurrent following initial antineoplastic therapy.

OR

* * * * *

13.14 *Lungs.*

B. * * *

OR

C. Carcinoma of the superior sulcus (including Pancoast tumors) with multimodal antineoplastic therapy. Consider under a disability until at least 18 months from the date of diagnosis. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

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13.23 *Cancers of the female genital tract*—carcinoma or sarcoma.

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C. Vulva or vagina, as described in 1, 2, or 3:

1. Invading adjoining organs.

2. With metastases to or beyond the regional lymph nodes.

3. Persistent or recurrent following initial antineoplastic therapy.

* * * * *

E. Ovaries, as described in 1 or 2:

1. All tumors except germ cell tumors, with at least one of the following:

a. Tumor extension beyond the pelvis; for example, tumor implants on peritoneal, omental, or bowel surfaces.

b. Metastases to or beyond the regional lymph nodes.

c. Recurrent following initial antineoplastic therapy.

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13.24 *Prostate gland*—carcinoma.

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B. With visceral metastases (metastases to internal organs).

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13.27 *Primary site unknown after appropriate search for primary*—metastatic carcinoma or sarcoma, except for squamous cell carcinoma confined to the neck nodes.

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Part B

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113.00 MALIGNANT NEOPLASTIC DISEASES

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E. *When do we need longitudinal evidence?*

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2. *Other malignancies.* When there are no distant metastases, many of the listings require that we consider your response to initial antineoplastic therapy; that is, the initial planned treatment regimen. This therapy may consist of a single modality or a combination of modalities; that is, multimodal therapy (see 113.00I2).

* * * * *

H. *How long do we consider your impairment to be disabling?*

* * * * *

2. * * * When the impairment(s) has been in complete remission for at least 3 years, that is, the original tumor or a recurrence (or relapse) and any metastases have not been evident for at least 3 years, the impairment(s)

will no longer meet or medically equal the criteria of a listing in this body system.

3. * * * If you have a recurrence or relapse of your malignancy, your impairment may meet or medically equal one of the listings in this body system again.

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I. *What do we mean by the following terms?*

1. *Metastases:* The spread of tumor cells by blood, lymph, or other body fluid. This term does not include the spread of tumor cells by direct extension of the tumor to other tissue or organs.

2. *Multimodal therapy:* A combination of at least two types of treatment modalities given in close proximity as a unified whole and usually planned before any treatment has begun. There are three types of treatment modalities: Surgery, radiation, and systemic drug therapy (chemotherapy, hormonal therapy, and immunotherapy). Examples of multimodal therapy include:

a. Surgery followed by chemotherapy or radiation.

b. Chemotherapy followed by surgery.

c. Chemotherapy and concurrent radiation.

3. *Persistent:* Failure to achieve a complete remission.

4. *Progressive:* The malignancy becomes more extensive despite treatment.

5. *Recurrent, relapse:* A malignancy that was in complete remission or entirely removed by surgery has returned.

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

1. *Lymphoma.*

a. We provide criteria for evaluating aggressive lymphomas that have not responded to antineoplastic therapy in 113.05. Indolent (non-aggressive) lymphomas are rare in children. We will evaluate indolent lymphomas in children under 13.05 in part A.

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2. *Leukemia.*

a. *Acute leukemia.* * * * Recurrent disease must be documented by peripheral blood, bone marrow, or cerebrospinal fluid examination, or by testicular biopsy. * * *

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4. *Brain tumors.* We use the criteria in 113.13 to evaluate malignant brain tumors. We consider a brain tumor to be malignant if it is classified as grade II or higher under the World Health Organization (WHO) classification of tumors of the central nervous system (*WHO Classification of Tumours of the Central Nervous System*, 2007). We evaluate any complications of malignant brain tumors, such as resultant neurological or psychological impairments, under the criteria for the affected body system. We evaluate benign brain tumors under 111.05.

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113.09 *Thyroid gland.*

B. * * *

OR

C. Medullary carcinoma with metastases beyond the regional lymph nodes.

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113.13 *Brain tumors.* (See 113.00K4.) Highly malignant tumors, such as medulloblastoma or other primitive neuroectodermal tumors (PNETs) with documented metastases, grades III and IV astrocytomas, glioblastoma multiforme, ependymoblastoma, diffuse intrinsic brain stem gliomas, or primary sarcomas.

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[FR Doc. E9–23896 Filed 10–5–09; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–327F]

Schedules of Controlled Substances; Placement of Fospropofol Into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance fospropofol, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, into schedule IV of the Controlled Substances Act (CSA). As a result of this rule, the regulatory controls and criminal sanctions of schedule IV will be applicable to the manufacture, distribution, dispensing, importation, and exportation of fospropofol and products containing fospropofol.

DATES: *Effective Date:* November 5, 2009.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152, *Telephone:* (202) 307–7183.

SUPPLEMENTARY INFORMATION:

Background

On December 12, 2008, the Food and Drug Administration (FDA) approved fospropofol for marketing under the trade name Lusedra® in the United States as a drug product indicated for monitored anesthesia care (MAC) sedation in adult patients undergoing diagnostic or therapeutic procedures.

Fospropofol, 2,6-diisopropopylphenoxymethyl phosphate disodium, is a water soluble, phosphono-O-methyl prodrug of propofol. It is metabolized in the body to propofol, the active metabolite. Propofol has been available for medical use in the United States since 1989 and is not currently a controlled substance. The pharmacological effects of fospropofol are attributed to the pharmacological actions of propofol. Propofol binds to γ-aminobutyric acid ($GABA_A$) receptor and acts as a modulator by potentiating the activity of GABA at this receptor.

Since propofol is the active metabolite of fospropofol, the abuse potential of fospropofol is comparable to that of propofol. Animal self-administration studies demonstrated that the reinforcing effects of propofol are relatively low and comparable to midazolam and other schedule IV benzodiazepines. Fospropofol elicits behavioral effects similar to methohexital and midazolam, schedule IV sedative-hypnotics.

Since fospropofol is a new molecular entity, there has been no evidence of diversion, abuse, or law enforcement encounters involving the drug.

On February 27, 2009, the Acting Assistant Secretary for Health, Department of Health and Human Services (DHHS), sent the Deputy Administrator of DEA a scientific and medical evaluation and a letter recommending that fospropofol be placed into schedule IV of the CSA. Enclosed with the February 27, 2009, letter was a document prepared by the FDA entitled, ''Basis for the Recommendation for Control of Fospropofol and Its Salts in Schedule IV of the Controlled Substances Act (CSA).'' The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b)).

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendation from DHHS, the Deputy Administrator of the DEA published a Notice of Proposed Rulemaking entitled ''Schedules of Controlled Substances: Placement of Fospropofol into Schedule IV'' on July 23, 2009 (74 FR 36424), which proposed placement of fospropofol into schedule IV of the CSA. The proposed rule provided an opportunity for all interested persons to submit their written comments on or before August 24, 2009.

Comments Received

The DEA received two comments in response to the Notice of Proposed Rulemaking. One comment received from a concerned citizen did not relate to fospropofol, the substance that is being controlled. Thus DEA did not consider this comment.