Transactions between U.S. Financial Services Providers and Foreign Persons—2014, contained herein, whether or not they are contacted by BEA to ensure complete coverage of financial services transactions between U.S. financial services providers and foreign persons. Also, a person, or its agent, that is contacted by BEA about reporting in this survey, either by sending a report form or by written inquiry, must respond in writing pursuant to this section. This may be accomplished by:

(1) Completing and returning the BE–180 survey by the due date; or,

(2) If exempt, by completing pages one through five of the BE–180 survey and returning them to BEA.

(b) *Who must report.* (1) A BE–180 report is required of each U.S. person that is a financial services provider or intermediary, or whose consolidated U.S. enterprise includes a separately organized subsidiary, or part, that is a financial services provider or intermediary, and that had transactions (either sales or purchases) directly with foreign persons in all financial services combined in excess of $3,000,000 during its fiscal year covered by the survey on an accrual basis. The $3,000,000 threshold should be applied to financial services transactions with foreign persons by all parts of the consolidated U.S. enterprise combined that are financial services providers or intermediaries. Because the $3,000,000 threshold applies separately to sales and purchases, the mandatory reporting requirement may apply only to sales, only to purchases, or to both.

(i) The determination of whether a U.S. financial services provider or intermediary is subject to this mandatory reporting requirement may be based on the judgment of knowledgeable persons in a company who can identify reportable transactions on a recall basis, with a reasonable degree of certainty, without conducting a detailed manual records search.

(ii) Reporters that file pursuant to this mandatory reporting requirement must provide data on total sales and/or purchases of each of the covered types of financial services transactions and must disaggregate the totals by country and by relationship to the foreign transactor (foreign affiliate, foreign parent group, or unaffiliated).

(2) *Voluntary reporting.* If, during the fiscal year covered, sales or purchases of financial services by a firm that is a financial services provider or intermediary, or by a firm's subsidiaries, or parts, combined that are financial services providers or intermediaries, are $3,000,000 or less, the U.S. person is requested to provide an estimate of the total for each type of service. Provision of this information is voluntary. The estimates may be judgmental, that is, based on recall, without conducting a detailed records search. Because the $3,000,000 threshold applies separately to sales and purchases, this voluntary reporting option may apply only to sales, only to purchases, or to both.

(3) *Exemption claims.* Any U.S. person that receives the BE–180 survey form from BEA, but is not subject to the mandatory reporting requirements and chooses not to report voluntarily, must file an exemption claim by completing pages one through five of the BE–180 survey and returning it to BEA. This requirement is necessary to ensure compliance with reporting requirements and efficient administration of the Act by eliminating unnecessary follow-up contact.

(c) *BE–180 definition of financial services provider.* The definition of financial services provider used for this survey is identical to the definition of the term as used in the North American Industry Classification System, United States, 2012, Sector 52—Finance and Insurance, and holding companies that own or influence, and are principally engaged in making management decisions for these firms (part of Sector 55—Management of Companies and Enterprises). For example, companies and/or subsidiaries and other separable parts of companies in the following industries are defined as financial services providers: Depository credit intermediation and related activities (including commercial banking, savings institutions, credit unions, and other depository credit intermediation); non-depository credit intermediation (including credit card issuing, sales financing, and other non-depository credit intermediation); activities related to credit intermediation (including mortgage and nonmortgage loan brokers, financial transactions processing, reserve, and clearinghouse activities, and other activities related to credit intermediation); securities and commodity contracts intermediation and brokerage (including investment banking and securities dealing, securities brokerage, commodity contracts and dealing, and commodity contracts brokerage); securities and commodity exchanges; other financial investment activities (including miscellaneous intermediation, portfolio management, investment advice, and all other financial investment activities); insurance carriers; insurance agencies, brokerages, and other insurance related activities; insurance and employee benefit funds (including pension funds, health and welfare funds, and other insurance funds); other investment pools and finds (including open-end investment funds, trusts, estates, and agency accounts, real estate investment trusts, and other financial vehicles); and holding companies that own, or influence the management decisions of, firms principally engaged in the aforementioned activities.

(d) *Covered types of services.* The BE–180 survey covers the following types of financial services transactions (sales or purchases) between U.S. financial services companies and foreign persons: brokerage services related to equity transactions; other brokerage services; underwriting and private placement services; financial management service (including fees for mutual funds, pension funds, exchange-traded funds, private equity funds, corporate portfolio, individual portfolio, hedge funds, trusts, and other); credit related services, except credit card services; credit card services; financial advisory and custody services; securities lending services; electronic funds transfer services; and other financial services.

(e) *Due date.* A fully completed and certified BE–180 report, or qualifying exemption claim with pages one through five completed, is due to be filed with BEA not later than October 1, 2015.

[FR Doc. 2015–11996 Filed 5–19–15; 8:45 am]

BILLING CODE 3510–06–M

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Docket No. SSA–2011–0098]

RIN 0960–AH43

Revised Medical Criteria for Evaluating Cancer (Malignant Neoplastic Diseases)

AGENCY: Social Security Administration.

ACTION: Final rule.

SUMMARY: We are revising the criteria in parts A and B of the Listing of Impairments (listings) that we use to evaluate claims involving cancer (malignant neoplastic diseases) under titles II and XVI of the Social Security Act (Act). These revisions reflect our adjudicative experience, advances in medical knowledge, recommendations from medical experts we consulted, and public comments we received in response to a Notice of Proposed Rulemaking (NPRM).

DATES: This rule is effective July 20, 2015.

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

SUPPLEMENTARY INFORMATION:

Background

We are revising and making final the regulations for evaluating cancer (malignant neoplastic diseases) that we proposed in an NPRM published in the **Federal Register** on December 17, 2013, at 78 FR 76508. Even though this rule will not go into effect until 60 days after publication of this document, for clarity we refer to it in this preamble as the ''final'' rule. We refer to the rule in effect prior to that time as the ''prior'' rule.

In the preamble to the NPRM, we discussed our proposed changes and our reasons for making them. Since we are mostly adopting those revisions as we proposed them, we are not repeating that information here. Interested readers may refer to the preamble in the NPRM, available at *http://www.regulations.gov.*

We are making some changes in this final rule based on the public comments we received on the NPRM. We explain these changes in the ''Summary of Public Comments'' below.

Why are we revising the cancer listings?

We developed this final rule as part of our ongoing review of the cancer body system. When we last revised the listings for this body system in a final rule published on October 6, 2009, we indicated that we would monitor and update the listings as needed.[1]

How long will this final rule stay in effect?

We are extending the effective date of the cancer body system in parts A and B of the listings until 5 years after the effective date of this final rule. The rule will remain in effect only until that date unless we extend the expiration date. We will continue to monitor the rule and may revise it, as needed, before the end of the 5-year period.

Summary of Public Comments

In the NPRM, we gave the public a 60-day comment period that ended on February 18, 2014. We received 15 comments. The commenters included national cancer advocacy groups, State agencies, a national group representing disability examiners in State agencies that make disability determinations for us, medical professionals, and individual members of the public.

We carefully considered all of the significant comments relevant to this rulemaking. We have condensed and summarized the comments below. We believe we have presented the commenters' concerns and suggestions accurately and completely and responded to all significant issues that were within the scope of this rule. We provide our reasons for adopting or not adopting the recommendations in our responses below.

General Comments

Comment: Many commenters supported our proposal to change the name of this body system from ''Malignant Neoplastic Diseases'' to ''Cancer'' to make the name more recognizable to the lay public. However, some commenters believed this change was not necessary or appropriate. These commenters believed the lay public is sufficiently aware of the meaning of the term ''malignant neoplastic diseases'' and that we should continue using it as the body system's name. One commenter thought ''malignant neoplastic diseases'' is a more encompassing name for the body system than ''cancer.'' The commenter contended the term ''cancer'' has traditionally meant only carcinoma, and does not include sarcoma, leukemia, or malignancies in other cell types.

Response: We disagree with the commenters' view that the lay public is sufficiently aware of the term ''malignant neoplastic diseases,'' and have adopted our proposal to change the name of this body system to ''Cancer.'' We believe the lay public understands that the term ''cancer'' means not only carcinoma but also the wide array of malignancies. The National Cancer Institute (NCI), National Cancer Society (NCS), and other recognized experts use the term ''cancer'' when referring to carcinoma, sarcoma, leukemia, lymphoma, and malignancies of the central nervous system in their publications.[2]

Comment: A commenter, who supported the proposed name change, recommended that we use the term ''anticancer therapy'' instead of ''antineoplastic therapy'' in this final rule.

Response: We agree with the commenter and have modified the listings accordingly.

Comment: One commenter suggested we have only one listing for evaluating small-cell carcinomas rather than adopt our proposal to provide a criterion for small-cell carcinoma under several, specific listings.[3]

Response: We did not adopt the comment. Some small-cell carcinomas might be included under the single listing the commenter proposed, but may have favorable prognoses and not be of listing-level severity. These small-cell carcinomas have a favorable prognosis because physicians can detect them in their early stages when it is still possible to remove the cancer. The final listings cover small-cell carcinomas that occur in certain organs and tissues where physicians are unlikely to detect them in their early stages, and treatment is mainly palliative.

Comment: One commenter suggested that we include the stage of the cancer in the final listings for evaluating central nervous system and cervical cancers, and lymphomas.

Response: We did not adopt the comment for two reasons. First, the cancers mentioned by the commenter may have different staging systems that are inconsistent with each other. Second, staging systems could change, potentially resulting in an inability to find people with listing-level impairments disabled at the listing step of the sequential evaluation process.

Comment: A commenter proposed we provide more guidance in part B for evaluating conditions in children, resulting from cancer or its treatment, that do not meet the listings. The commenter said such conditions might include organ dysfunction resulting from small-cell carcinomas, or secondary lymphedema resulting from breast cancer treatment. The commenter believed the additional guidance would make the final listings more comprehensive.

Response: We did not adopt the comment because we believe final sections 113.00F and 113.00G already

[1] See 74 FR 51229.

[2] For example, see ''NCI Home'' at *http://www.cancer.gov,* and ''American Cancer Society Home'' at *http://www.cancer.org/index.*

[3] We retained prior listing 13.14B for evaluating small-cell carcinoma in the lungs and added a criterion for small-cell carcinoma under the following specific listings: 13.02D for soft tissue cancers of the head and neck; 13.10D for cancer of the breast; 13.15C for cancer of the pleura and mediastinum; 13.16C for cancer of the esophagus or stomach; 13.17C for cancer of the small intestine; 13.18D for cancer of the large intestine; 13.22E for cancer of the urinary bladder; 13.23F for cancers of the female genital tract; and 13.24C for cancer of the prostate gland. We include a listing for small-cell carcinoma of the small intestine, even though it is a very rare cancer, to maintain internal consistency among the regulations, and because of the cancer's unfavorable prognosis.

provide the type of guidance the commenter recommended. In these sections, we explain that if a child has a medically determinable impairment that does not meet the listings, we will determine whether the impairment medically equals the listings. This determination would include impairments caused by the cancer or treatment side effects. If the impairment does not medically equal a listing, section 113.00F further explains that we will also determine whether the impairment functionally equals the listings. Again, this determination would include impairments caused by the cancer or treatment side effects.

Comment: One commenter recommended we provide more guidance for evaluating treatment failure in bone marrow and stem cell transplantation, and proposed specific language for making this change.

Response: We believe the change, and the specific language the commenter proposed, is not necessary because listings for bone marrow and stem cell transplantation have a criterion for evaluating *any* residual impairments following treatment. These residual impairments would include the evaluation of those associated with treatment failure.

Section 13.00E—When do we need longitudinal evidence?

Comment: One commenter asked us to specify which sources can provide the evidence required in final section 13.00E3c to document that the treating source has started multimodal therapy under final listings 13.02E, 13.11D, and 13.14C. The commenter indicated that we should accept this evidence only from an acceptable medical source such as a medical or osteopathic doctor.

Response: We did not adopt the comment because it may limit our ability to obtain evidence to determine if multimodal therapy has started and, thus, establish listing-level severity. While an acceptable medical source may provide this evidence, our existing policy allows us to accept evidence from other medical sources to establish the impairment's severity.[4] For example, this evidence may come from sources we do not consider acceptable medical sources, such as oncology nurse practitioners who administer chemotherapy and radiation therapists who deliver radiation treatments.

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

Comment: One commenter expressed concern over proposed sections 13.00I6 and 113.00I5, in which we clarified that we consider a cancer to be ''progressive'' if it is still growing after the person has completed at least half of his or her planned initial anticancer therapy. The commenter believed this criterion might delay adjudication if the adjudicator must contact the treating source to ask how much of planned treatment the person has completed.

Response: We did not adopt this comment. We disagree with the commenter because we do not expect adjudicators to obtain more information than we required under the prior regulations. The proposed and final sections express our intent to decide as quickly as possible that a person is disabled.

Comment: The same commenter thought that the definition of the term ''progressive'' could result in a finding that the claimant has a condition medically equivalent to cancer listings that do not require the malignancy to be progressive.

Response: We do not share the commenter's concern because, as we explain in sections 13.00C and 113.00C, we will only apply the criteria in a specific listing to a cancer originating from that specific site.

Comment: One commenter recommended that we revise the definition of ''persistent'' cancer in final section 13.00I5. The commenter also provided language for the suggested revision.

Response: We did not adopt the comment for two reasons. First, the language the commenter proposed could be misinterpreted to require that all of a person's anticancer therapy must fail to achieve a complete remission, including any second- or third-line therapies after initial anticancer therapy.[5] This interpretation would be contrary to our intent in listings that require only the planned initial anticancer therapy to fail. Second, the language the commenter proposed would not explain the meaning of the phrase ''failed to achieve a complete remission.'' By defining this phrase, the final section clarifies that the cancer is ''persistent'' if any of it remains after treatment is completed, even if the cancer responded to the initial therapy and became smaller.

Comment: One commenter recommended that the definition of the term ''unresectable'' in final section 13.00I8 address the presence of micrometastases. The commenter contended that ''unresectable'' should not include situations in which the surgeon removed the tumor and then used adjuvant therapy to eliminate any micrometastases.

Response: We did not adopt the comment. We believe the commenter's proposed change is unnecessary. Final section 13.00I8 defines ''adjuvant therapy'' as anticancer therapy given after surgery ''to eliminate any remaining cancer cells or lessen the chance of recurrence.'' These ''remaining cancer cells'' include micrometastases.

Sections 13.00K and 113.00K—How do we evaluate specific cancers?

Comment: A commenter recommended that we add examples of common indolent lymphomas in final section 13.00K1a. The commenter also recommended that we add examples of common solid tumors in final section 113.00K3.

Response: We did not adopt the comment. These recommendations appear to be administrative concerns better handled through training and operating instructions for our adjudicators.

Comment: A commenter recommended that we create a listing for primary peritoneal carcinoma. The commenter argued that having a listing would be better than the guidance in section 13.00K7, in which we explained that we can evaluate this cancer in women under final 13.23E for ovarian cancer, and evaluate it in men under 13.15A for malignant mesothelioma.

Response: We did not adopt the commenter's recommendation that we create a listing for primary peritoneal carcinoma. Primary peritoneal carcinoma is very rare, and we do not usually provide listings for rare cancers. Instead, we believe the better practice is to clarify in the introductory text which listings to use to evaluate certain rare cancers, as we did in final section 13.00K7 for primary peritoneal carcinoma.

Comment: A few commenters expressed concern about the clarification in proposed section 13.00K8 that excludes ''biochemical recurrence'' for evaluating recurrent cancer of the prostate gland in listing 13.24A. In this section, we defined ''biochemical recurrence'' as an increase in the serum prostate-specific antigen (PSA) level following the completion of anticancer therapy. Section 13.24A requires corroborating evidence to document recurrence, such as radiological studies or findings on physical exam. Commenters believed this requirement might delay a finding

[4] See 20 CFR 404.1513(d) and 416.913(d).

[5] We may consider follow-up surgery to be a part of initial anticancer treatment if the intent of the follow-up surgery is to obtain clear margins and the complete eradication of any residual cancer left behind.

of disability and unfairly penalize people with prostate cancer. They noted that doctors frequently use PSA values to determine recurrence and may initiate anticancer treatment for recurrent cancer upon this evidence alone.

Response: We agree that in some cases, an isolated PSA reading may support a diagnosis of recurrent prostate cancer, especially if this diagnosis is from an acceptable medical source and is consistent with the prevailing state of medical knowledge and clinical practice. However, we did not adopt the comments because we believe it is reasonable to require corroborating evidence to confirm the diagnosis. A rising PSA level alone does not necessarily mean prostate cancer has returned. Additional factors, such as the cancer's TNM [6] characteristics, PSA kinetics, timing of the biochemical recurrence, treatment modality, and Gleason score, should be considered.[7] [8] The American Joint Committee on Cancer notes that the natural progression from biochemical recurrence to clinical disease recurrence is highly variable and may depend on these additional factors.[9] In light of this variability and the other factors that should be considered, we continue to believe that we should exclude ''biochemical recurrence'' in listing 13.24A.

Comment: One commenter recommended that we delete the parenthetical reference to ''benign melanocytic tumor'' in final sections 13.00K9 and 113.00K6. The commenter claimed that citing a benign disease in the cancer listings may be confusing for adjudicators.

Response: We did not adopt the comment because we believe the reference to benign melanocytic tumor can direct adjudicators to the appropriate body systems for evaluating this condition, Skin Disorders (8.00 and 108.00). This reference is similar to how final sections 13.00K6c and 113.00K4c direct adjudicators to the appropriate body systems for evaluating benign brain tumors.

Listing 13.02—Soft Tissue Cancers of the Head and Neck (Except Salivary Glands—13.08—and Thyroid Gland—13.09)

Comment: A commenter recommended revisions to 13.02E to condense the final listing significantly.

Response: We did not adopt the comment because the proposed change might be misinterpreted to include any metastases in the head or neck from cancers originating elsewhere under listing 13.02E. Our intent in this listing is to evaluate cancers that receive multimodal therapy and originate in the head and neck only.

Listing 113.05—Lymphoma (Excluding All Types of Lymphoblastic Lymphomas—113.06)

Comment: A commenter recommended that we include cerebrospinal fluid (CSF) findings as evidence for determining listing-level lymphoma under final listings 113.05A1 and 113.05B1.

Response: We did not adopt the comment. It is not a standard clinical practice in lymphoma to conduct cerebrospinal fluid examination for analysis; therefore, we do not believe it is appropriate to require this evidence to establish severity. However, we will inform adjudicators, through training and operating instructions, that they can accept CSF findings if this evidence is available.

Listing 13.10—Breast (Except Sarcoma—13.04)

Comment: One commenter asked how long adjudicators should defer adjudication of cases for evaluating breast cancer with secondary lymphedema resulting from anticancer therapy and treated by surgery to salvage or restore the functioning of an upper extremity under proposed listing 13.10E.

Response: We disagree with the commenter's premise that adjudicators need to defer adjudication of these cases. Adjudicators can adjudicate a case at the listing step if the surgery is performed. The need for this surgery to salvage or restore functioning of an upper extremity demonstrates listing-level severity of the secondary lymphedema without the need to make a determination about the effectiveness of the surgery.

Comment: A commenter recommended we add a listing that prescribes a period of disability of at least 18 months for people receiving multimodal therapy for breast cancer. The commenter noted that multimodal therapy could last 6 or more months and produce very serious adverse effects. The commenter also noted that it is common for us to find these people disabled after the listing step in the sequential evaluation process by taking into consideration the adverse effects of treatment and that the length of treatment nearly satisfies the 12-month duration requirement. The commenter believed it would be better for us to make the determination of disability at the listing step.

Similarly, a commenter recommended we add a listing that prescribes a period of disability of at least 18 months for people receiving multimodal therapy that includes surgery for low anal cancers and rectal cancers. The commenter noted that neoadjuvant chemotherapy or radiation followed by surgery to eliminate these anal or rectal cancers frequently takes at least 12 months to complete. The treatment may result in prolonged debilitation although the impairment may not meet or medically equal the listings.

Response: We believe the commenter's proposed listing for breast cancer would cover many cases of early cancer. Most people with early breast cancer complete multimodal therapy within 6 months and recover from any adverse effects relatively soon. In these cases, the impairment would not preclude the ability to work for the required 12 months.

However, we agree with the commenter that in some cases multimodal therapy may take substantially longer than 6 months to complete. For example, very serious adverse effects may interrupt and prolong therapy, resulting in an active impairment lasting almost 12 months. It is a long-standing principle that we may make a finding of disability at the listing step if there is the expectation that an impairment that has been active for almost 12 months will preclude a person from engaging in any gainful activity for the required 12 months. We base this finding on the nature of the impairment; prescribed treatment; therapeutic history, including adverse effects of treatment; and other relevant considerations. Therefore, we partially adopted the comment by providing language in final section 13.00G3 to clarify that we can apply this principle to multimodal anticancer therapy for breast cancer and other cancers. We also added the clarifying language in final section 113.00G3 for children.

We did not make changes to listing 13.18 for evaluating anal and rectal cancers. This listing and the commenter's recommendation for a new listing covering multimodal therapy with surgery for anal and rectal cancers

[6] The acronym ''TNM'' relates to the *T*umor size, lymph *N*ode involvement, and presence of *M*etastases.

[7] PSA kinetics involves assessing the PSA level over time, such as measuring of its rate of change (velocity) and how long it takes it to double.

[8] The National Cancer Institute defines ''Gleason score'' as a system of grading prostate cancer tissue based on how it looks under the microscope (available at: *http://www.cancer.gov/dictionary?CdrID=45696*).

[9] See Carolyn C. Compton *et al.* eds., *Cancer Staging Atlas: A Companion to the Seventh Editions of the AJCC Cancer Staging Manual and Handbook,* New York: Springer, 2012, page 535–545.

are outside the scope of this rulemaking. However, we believe the changes made in final section 13.00G3 partially address this commenter's concerns.

Listing 13.13—Nervous System

Comment: One commenter recommended that we clarify in the introductory text whether adjudicators should use listing 13.13 to evaluate pituitary gland cancer in adults.

Response: We adopted the commenter's recommendation by providing language in final section 13.00K6a and final section 113.00K4a in the introductory text clarifying that we evaluate cancerous pituitary gland tumors, for example, pituitary carcinoma,[10] under final listing 13.13A1 and final listing 113.13A, respectively.

Comment: The same commenter expressed concern about the statement, in proposed sections 13.00K6b and 113.00K4b, that we consider brain tumors malignant only if they are classified as grade II or higher under the World Health Organization (WHO), ''Classification of Tumours of the Central Nervous System, 2007.'' The commenter asked how an adjudicator should evaluate central nervous system tumors graded under different classification systems.

Response: We believe we have addressed the commenter's concerns in existing operating instructions that help adjudicators determine the WHO grade of specific brain cancers if a different grading system is used or if the medical evidence does not identify a particular grading system.[11] These instructions also help adjudicators determine which grade to use when there are inconsistencies in the medical record, such as some medical evidence describing the tumor as grade II while other medical evidence describes it as grade III or grade IV.

Listing 13.23—Cancers of the Female Genital Tract—Carcinoma or Sarcoma

Comment: A commenter recommended that we add criteria in final listing 13.23B3 to take into account a cancer's histologic diagnosis and the age of the claimant at onset.

Response: We did not adopt this comment. We do not believe it is necessary to include such considerations in the listing because the prognosis is already poor for cervical cancer that meets the specific criteria of the listing. Considering the histological diagnosis would only confirm this prognosis, and the prognosis would remain poor regardless of a person's age.

Comment: A national advocacy group for women with ovarian cancer recommended that we reinstate a listing we deleted in 2009. The listing covered ovarian cancer with ruptured ovarian capsule, tumor on the serosal surface of the ovary, ascites with malignant cells, or positive peritoneal washings. The commenter believed we find most women with this extent of disease disabled at later steps of the sequential evaluation process after the listing step or on appeal. The commenter also believed the adverse effects of cancer treatment might be disabling in themselves, especially for women whose jobs require significant exertion or do not allow time off for recovery from treatment.

Response: We agree we could find a woman with the findings in the prior listing disabled after the listing step of the sequential evaluation process. We realize that adverse effects of ovarian cancer treatment may preclude a woman from working. However, we did not adopt the commenter's recommendation because many women with ovarian cancer that meets the specific criteria in the deleted listing would not have an impairment that precludes *any* gainful activity, which is the standard of severity in the listings.[12]

Other Changes

We made a number of editorial changes and technical corrections in the final rule to increase the clarity and consistency of the listings. For example, we redesignated proposed listing 13.05A3 for evaluating mantle cell lymphoma in adults as final listing 13.05D to make it a stand-alone listing consistent with stand-alone final listing 113.05D for evaluating mantle cell lymphoma in children. We also changed the parenthetical examples in prior sections 13.00H1 and 113.00H1 from ''at least 18 months from the date of diagnosis'' and ''at least 12 months from the date of diagnosis,'' respectively, to ''until at least 12 months from the date of transplantation'' to make these adult and child sections consistent.

Additionally, we redesignated proposed listings 13.29A3 and 113.29A3 for evaluating mucosal melanoma as stand-alone listings 13.29C and 113.29C. We made this change because we determined, through our ongoing review of the scientific and medical literature, that mucosal melanoma carries a very poor prognosis and is of listing-level severity regardless of whether it is an initial disease or a recurrent disease. We also added examples of distant sites frequently affected by metastases from cutaneous and ocular melanomas in 13.29B3 and 113.29B3.

What is our authority to make regulations 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.[13]

Regulatory Procedures

Executive Order 12866, as Supplemented by Executive Order 13563

We have consulted with the Office of Management and Budget (OMB) and determined that this final rule meets the criteria for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563, and was reviewed by OMB.

Regulatory Flexibility Act

We certify that this final rule has no significant economic impact on a substantial number of small entities because it affects only individuals. Therefore, a regulatory flexibility analysis was not required under the Regulatory Flexibility Act, as amended.

Paperwork Reduction Act

This final rule does not create any new or affect any existing collections and, therefore, does not require OMB 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: May 11, 2015.

Carolyn W. Colvin,

Acting Commissioner of Social Security.

For the reasons set out in the preamble, we are amending 20 CFR part 404 subpart P as set forth below:

[10] Pituitary gland carcinoma is highly malignant. Treatment is mainly palliative. People who have pituitary gland carcinoma have a mean survival time of only about 2 years.

[11] Program Operations Manual System, available at: *http://policy.ssa.gov/poms.nsf/lnx/0424585001.*

[12] See sections 404.1525 and 416.925.

[13] Sections 205(a), 702(a)(5), and 1631(d)(1).

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

Subpart P—Determining Disability and Blindness

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

■ 2. Amend appendix 1 to subpart P of part 404 as follows:

■ a. Revise item 14 of the introductory text before part A.

■ b. Amend part A by revising the body system name for section 13.00 in the table of contents.

■ c. Revise section 13.00 of part A.

■ d. Amend listing 13.02 of part A by revising the heading, revising listing 13.02B, removing listing 13.02C, redesignating listing 13.02D as new 13.02C, adding new listing 13.02D and revising listing 13.02E.

■ e. Amend listing 13.03 of part A by revising listing 13.03B.

■ f. Amend listing 13.04 of part A by revising listing 13.04B.

■ g. Amend listing 13.05 of part A by revising listings 13.05A1, 13.05A2 and 13.05B, and adding listing 13.05D.

■ h. Amend listing 13.06 of part A by revising the first sentence of listing 13.06B1 and revising listing 13.06B2b.

■ i. Amend listing 13.07 of part A by revising listing 13.07A.

■ j. Amend listing 13.10 of part A by revising listings 13.10A and 13.10C, adding the word ''OR'' after listing 13.10C, adding listing 13.10D, adding the word ''OR'' after listing 13.10D, and adding listing 13.10E.

■ k. Amend listing 13.11 of part A by revising listings 13.11B and 13.11D.

■ l. Amend listing 13.12 of part A by revising listing 13.12C.

■ m. Revise listing 13.13 of part A.

■ n. Amend listing 13.14C of part A by revising the first sentence.

■ o. Amend listing 13.15 of part A by revising listing 13.15B2 and adding the word ''OR'' after listing 13.15B2, and adding listing 13.15C.

■ p. Amend listing 13.16 of part A by adding the word ''OR'' after listing 13.16B, and adding listing 13.16C.

■ q. Amend listing 13.17 of part A by adding the word ''OR'' after listing 13.17B, and adding listing 13.17C.

■ r. Amend listing 13.18 of part A by adding the word ''OR'' after listing 13.18C, and adding listing 13.18D.

■ s. Revise listing 13.19 of part A.

■ t. Amend listing 13.20 of part A by revising listing 13.20B.

■ u. Amend listing 13.22 of part A by adding the word ''OR'' after listing 13.22D, and adding listing 13.22E.

■ v. Amend listing 13.23 of part A by revising the heading, revising listings 13.23A3, 13.23B, 13.23C3, 13.23D2 and 13.23E, adding the word ''OR'' after listing 13.23E, and adding listing 13.23F.

■ w. Amend listing 13.24 of part A by revising listing 13.24A, adding the word ''OR'' after listing 13.24B, and adding listing 13.24C.

■ x. Revise listing 13.25 of part A.

■ y. Amend listing 13.28 of part A by revising the heading.

■ z. Add listing 13.29 after listing 13.28 of part A.

■ aa. Amend part B by revising the body system name for section 113.00 in the table of contents.

■ bb. Revise section 113.00 of part B.

■ cc. Revise listing 113.03 of part B.

■ dd. Amend listing 113.05 of part B by revising the heading and listings 113.05A and 113.05B, adding the word ''OR'' after listing 113.05C, and adding listing 113.05D.

■ ee. Amend listing 113.06 of part B by revising listings 113.06A and 113.06B1.

■ ff. Amend listing 113.12 of part B by revising listing 113.12B.

■ gg. Revise listing 113.13 of part B.

■ hh. Add listing 113.29 after listing 113.21 of part B.

The revised and added text is set forth as follows:

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

* * * * *

14. Cancer (Malignant Neoplastic Diseases) (13.00 and 113.00): July 20, 2020.

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Part A

* * * * *

13.00 Cancer (Malignant Neoplastic Diseases)

* * * * *

13.00 CANCER (MALIGNANT NEOPLASTIC DISEASES)

A. *What impairments do these listings cover?* We use these listings to evaluate all cancers (malignant neoplastic diseases), except certain cancers associated with human immunodeficiency virus (HIV) infection. If you have HIV infection, we use the criteria in 14.08E to evaluate carcinoma of the cervix, Kaposi sarcoma, lymphoma, and squamous cell carcinoma of the anal canal and anal margin.

B. *What do we consider when we evaluate cancer under these listings?* We will consider factors including:

1. Origin of the cancer.
2. Extent of involvement.
3. Duration, frequency, and response to anticancer therapy.
4. Effects of any post-therapeutic residuals.

C. *How do we apply these listings?* We apply the criteria in a specific listing to a cancer originating from that specific site.

D. *What evidence do we need?*

1. We need medical evidence that specifies the type, extent, and site of the primary, recurrent, or metastatic lesion. When the primary site cannot be identified, we will use evidence documenting the site(s) of metastasis to evaluate the impairment under 13.27.

2. For operative procedures, including a biopsy or a needle aspiration, we generally need a copy of both the:

a. Operative note, and

b. Pathology report.

3. When we cannot get these documents, we will accept the summary of hospitalization(s) or other medical reports. This evidence should include details of the findings at surgery and, whenever appropriate, the pathological findings.

4. In some situations, we may also need evidence about recurrence, persistence, or progression of the cancer, the response to therapy, and any significant residuals. (See 13.00G.)

E. *When do we need longitudinal evidence?*

1. *Cancer with distant metastases.* We generally do not need longitudinal evidence for cancer that has metastasized beyond the regional lymph nodes because this cancer usually meets the requirements of a listing. Exceptions are for cancer with distant metastases that we expect to respond to anticancer therapy. For these exceptions, we usually need a longitudinal record of 3 months after therapy starts to determine whether the therapy achieved its intended effect, and whether this effect is likely to persist.

2. *Other cancers.* When there are no distant metastases, many of the listings require that we consider your response to initial anticancer 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 13.00I4.)

3. *Types of treatment.*

a. Whenever the initial planned therapy is a single modality, enough time must pass to allow a determination about whether the therapy will achieve its intended effect. If the treatment fails, the failure often happens within 6 months after treatment starts, and there will often be a change in the treatment regimen.

b. Whenever the initial planned therapy is multimodal, we usually cannot make a determination about the effectiveness of the therapy until we can determine the effects of all the planned modalities. In some cases, we may need to defer adjudication until we can assess the effectiveness of therapy. However, we do not need to defer adjudication to determine whether the therapy will achieve its intended effect if we can make a fully favorable determination or decision based on the length and effects of therapy, or the residuals of the cancer or therapy (see 13.00G).

c. We need evidence under 13.02E, 13.11D, and 13.14C to establish that your treating

source initiated multimodal anticancer therapy. We do not need to make a determination about the length or effectiveness of your therapy. Multimodal therapy has been initiated, and satisfies the requirements in 13.02E, 13.11D, and 13.14C, when your treating source starts the first modality. We may defer adjudication if your treating source plans multimodal therapy and has not yet initiated it.

F. *How do we evaluate impairments that do not meet one of the cancer listings?*

1. These listings are only examples of cancer that we consider severe enough to prevent you from doing any gainful activity. If your severe impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that meets the criteria of a listing in another body system.

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. (See §§ 404.1526 and 416.926 of this chapter.) If your impairment(s) does not meet or medically equal a listing, you may or may not have the residual functional capacity to engage in substantial gainful activity. In that situation, we proceed to the fourth, and, if necessary, the fifth steps of the sequential evaluation process in §§ 404.1520 and 416.920 of this chapter. We use the rules in §§ 404.1594 and 416.994 of this chapter, as appropriate, when we decide whether you continue to be disabled.

G. *How do we consider the effects of anticancer therapy?*

1. *How we consider the effects of anticancer therapy under the listings.* In many cases, cancers meet listing criteria only if the therapy is not effective and the cancer persists, progresses, or recurs. However, as explained in the following paragraphs, we will not delay adjudication if we can make a fully favorable determination or decision based on the evidence in the case record.

2. *Effects can vary widely.*

a. We consider each case on an individual basis because the therapy and its toxicity may vary widely. We will request a specific description of the therapy, including these items:

i. Drugs given.

ii. Dosage.

iii. Frequency of drug administration.

iv. Plans for continued drug administration.

v. Extent of surgery.

vi. Schedule and fields of radiation therapy.

b. We will also request a description of the complications or adverse effects of therapy, such as the following:

i. Continuing gastrointestinal symptoms.

ii. Persistent weakness.

iii. Neurological complications.

iv. Cardiovascular complications.

v. Reactive mental disorders.

3. *Effects of therapy may change.* The severity of the adverse effects of anticancer therapy may change during treatment; therefore, enough time must pass to allow us to evaluate the therapy's effect. The residual effects of treatment are temporary in most instances; however, on occasion, the effects may be disabling for a consecutive period of at least 12 months. In some situations, very serious adverse effects may interrupt and prolong multimodal anticancer therapy for a continuous period of almost 12 months. In these situations, we may determine there is an expectation that your impairment will preclude you from engaging in any gainful activity for at least 12 months.

4. *When the initial anticancer therapy is effective.* We evaluate any post-therapeutic residual impairment(s) not included in these listings under the criteria for the affected body system. We must consider any complications of therapy. When the residual impairment(s) does not meet or medically equal a listing, we must consider its effect on your ability to do substantial gainful activity.

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

1. In some listings, we specify that we will consider your impairment to be disabling until a particular point in time (for example, until at least 12 months from the date of transplantation). We may consider your impairment to be disabling beyond this point when the medical and other evidence justifies it.

2. When a listing does not contain such a specification, we will consider an impairment(s) that meets or medically equals a listing in this body system to be disabling until at least 3 years after onset of complete remission. 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. Following the appropriate period, we will consider any residuals, including residuals of the cancer or therapy (see 13.00G), in determining whether you are disabled. If you have a recurrence or relapse of your cancer, 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. *Anticancer therapy* means surgery, radiation, chemotherapy, hormones, immunotherapy, or bone marrow or stem cell transplantation. When we refer to surgery as an anticancer treatment, we mean surgical excision for treatment, not for diagnostic purposes.

2. *Inoperable* means 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 cancer that is too large or that has invaded crucial structures. This term does not include situations in which your cancer could have been surgically removed but another method of treatment was chosen; for example, an attempt at organ preservation. Your physician may determine whether the cancer is inoperable before or after you receive neoadjuvant therapy. *Neoadjuvant therapy* is anticancer therapy, such as chemotherapy or radiation, given before surgery in order to reduce the size of the cancer.

3. *Metastases* means the spread of cancer cells by blood, lymph, or other body fluid. This term does not include the spread of cancer cells by direct extension of the cancer to other tissues or organs.

4. *Multimodal therapy* means anticancer therapy that is a combination of at least two types of treatment 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, hormone therapy, and immunotherapy or biological modifier therapy). Examples of multimodal therapy include:

a. Surgery followed by chemotherapy or radiation.

b. Chemotherapy followed by surgery.

c. Chemotherapy and concurrent radiation.

5. *Persistent* means the planned initial anticancer therapy failed to achieve a complete remission of your cancer; that is, your cancer is evident, even if smaller, after the therapy has ended.

6. *Progressive* means the cancer becomes more extensive after treatment; that is, there is evidence that your cancer is growing after you have completed at least half of your planned initial anticancer therapy.

7. *Recurrent or relapse* means the cancer that was in complete remission or entirely removed by surgery has returned.

8. *Unresectable* means surgery or surgeries did not completely remove the cancer. This term includes situations in which your cancer is incompletely resected or the surgical margins are positive. It does not include situations in which there is a finding of a positive margin(s) if additional surgery obtains a margin(s) that is clear. It also does not include situations in which the cancer is completely resected but you are receiving adjuvant therapy. *Adjuvant therapy* is anticancer therapy, such as chemotherapy or radiation, given after surgery in order to eliminate any remaining cancer cells or lessen the chance of recurrence.

J. *Can we establish the existence of a disabling impairment prior to the date of the evidence that shows the cancer satisfies the criteria of a listing?* Yes. We will consider factors such as:

1. The type of cancer and its location.

2. The extent of involvement when the cancer was first demonstrated.

3. Your symptoms.

K. *How do we evaluate specific cancers?*

1. *Lymphoma.*

a. Many indolent (non-aggressive) lymphomas are controlled by well-tolerated treatment modalities, although the lymphomas may produce intermittent symptoms and signs. 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.) Once your disease stabilizes, 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 chooses to change it and not because of a failure to achieve stability.

c. We consider Hodgkin lymphoma that recurs more than 12 months after completing initial anticancer therapy to be a new disease rather than a recurrence.

2. *Leukemia.*

a. *Acute leukemia.* The initial diagnosis of acute leukemia, including the accelerated or blast phase of chronic myelogenous (granulocytic) leukemia, is based on definitive bone marrow examination. Additional diagnostic information is based on chromosomal analysis, cytochemical and surface marker studies on the abnormal cells, or other methods consistent with the prevailing state of medical knowledge and clinical practice. Recurrent disease must be documented by peripheral blood, bone marrow, or cerebrospinal fluid examination, or by testicular biopsy. The initial and follow-up pathology reports should be included.

b. *Chronic myelogenous leukemia (CML).* We need a diagnosis of CML based on documented granulocytosis, including immature forms such as differentiated or undifferentiated myelocytes and myeloblasts, and a chromosomal analysis that demonstrates the Philadelphia chromosome. In the absence of a chromosomal analysis, or if the Philadelphia chromosome is not present, the diagnosis may be made by other methods consistent with the prevailing state of medical knowledge and clinical practice. The requirement for CML in the accelerated or blast phase is met in 13.06B if laboratory findings show the proportion of blast (immature) cells in the peripheral blood or bone marrow is 10 percent or greater.

c. *Chronic lymphocytic leukemia.*

i. We require the diagnosis of chronic lymphocytic leukemia (CLL) to be documented by evidence of a chronic lymphocytosis of at least 10,000 cells/mm^3 for 3 months or longer, or other acceptable diagnostic techniques consistent with the prevailing state of medical knowledge and clinical practice.

ii. We evaluate the complications and residual impairment(s) from CLL under the appropriate listings, such as 13.05A2 or the hematological listings (7.00).

d. *Elevated white cell count.* In cases of chronic leukemia (either myelogenous or lymphocytic), an elevated white cell count, in itself, is not a factor in determining the severity of the impairment.

3. *Macroglobulinemia or heavy chain disease.* We require the diagnosis of these diseases to be confirmed by protein electrophoresis or immunoelectrophoresis. We evaluate the resulting impairment(s) under the appropriate listings, such as 13.05A2 or the hematological listings (7.00).

4. *Primary breast cancer.*

a. We evaluate bilateral primary breast cancer (synchronous or metachronous) under 13.10A, which covers local primary disease, and not as a primary disease that has metastasized.

b. We evaluate secondary lymphedema that results from anticancer therapy for breast cancer under 13.10E if the lymphedema is treated by surgery to salvage or restore the functioning of an upper extremity. Secondary lymphedema is edema that results from obstruction or destruction of normal lymphatic channels. We may not restrict our determination of the onset of disability to the date of the surgery; we may establish an earlier onset date of disability if the evidence in your case record supports such a finding.

5. *Carcinoma-in-situ.* Carcinoma-in-situ, or preinvasive carcinoma, usually responds to treatment. When we use the term ''carcinoma'' in these listings, it does not include carcinoma-in-situ.

6. *Primary central nervous system (CNS) cancers.* We use the criteria in 13.13 to evaluate cancers that originate within the CNS (that is, brain and spinal cord cancers).

a. The CNS cancers listed in 13.13A1 are highly malignant and respond poorly to treatment, and therefore we do not require additional criteria to evaluate them. We do not list pituitary gland cancer (for example, pituitary gland carcinoma) in 13.13A1, although this CNS cancer is highly malignant and responds poorly to treatment. We evaluate pituitary gland cancer under 13.13A1 and do not require additional criteria to evaluate it.

b. We consider a CNS tumor to be malignant if it is classified as Grade II, Grade III, or Grade IV under the World Health Organization (WHO) classification of tumors of the CNS (*WHO Classification of Tumours of the Central Nervous System,* 2007).

c. We evaluate benign (for example, WHO Grade I) CNS tumors under 11.05. We evaluate metastasized CNS cancers from non-CNS sites under the primary cancers (see 13.00C). We evaluate any complications of CNS cancers, such as resultant neurological or psychological impairments, under the criteria for the affected body system.

7. *Primary peritoneal carcinoma.* We use the criteria in 13.23E to evaluate primary peritoneal carcinoma in women because this cancer is often indistinguishable from ovarian cancer and is generally treated the same way as ovarian cancer. We use the criteria in 13.15A to evaluate primary peritoneal carcinoma in men because many of these cases are similar to malignant mesothelioma.

8. *Prostate cancer.* We exclude ''biochemical recurrence'' in 13.24A, which is defined as an increase in the serum prostate-specific antigen (PSA) level following the completion of the hormonal intervention therapy. We need corroborating evidence to document recurrence, such as radiological studies or findings on physical examination.

9. *Melanoma.* We evaluate malignant melanoma that affects the skin (cutaneous melanoma), eye (ocular melanoma), or mucosal membranes (mucosal melanoma) under 13.29. We evaluate melanoma that is not malignant that affects the skin (benign melanocytic tumor) under the listings in 8.00 or other affected body systems.

L. *How do we evaluate cancer treated by bone marrow or stem cell transplantation, including transplantation using stem cells from umbilical cord blood?* Bone marrow or stem cell transplantation is performed for a variety of cancers. We require the transplantation to occur before we evaluate it under these listings. We do not need to restrict our determination of the onset of disability to the date of the transplantation (13.05, 13.06, or 13.07) or the date of first treatment under the treatment plan that includes transplantation (13.28). We may be able to establish an earlier onset date of disability due to your transplantation if the evidence in your case record supports such a finding.

1. *Acute leukemia (including T-cell lymphoblastic lymphoma) or accelerated or blast phase of CML.* If you undergo bone marrow or stem cell transplantation for any of these disorders, we will consider you to be disabled until at least 24 months from the date of diagnosis or relapse, or at least 12 months from the date of transplantation, whichever is later.

2. *Lymphoma, multiple myeloma, or chronic phase of CML.* If you undergo bone marrow or stem cell transplantation for any of these disorders, we will consider you to be disabled until at least 12 months from the date of transplantation.

3. *Other cancers.* We will evaluate any other cancer treated with bone marrow or stem cell transplantation under 13.28, regardless of whether there is another listing that addresses that impairment. The length of time we will consider you to be disabled depends on whether you undergo allogeneic or autologous transplantation.

a. *Allogeneic bone marrow or stem cell transplantation.* If you undergo allogeneic transplantation (transplantation from an unrelated donor or a related donor other than an identical twin), we will consider you to be disabled until at least 12 months from the date of transplantation.

b. *Autologous bone marrow or stem cell transplantation.* If you undergo autologous transplantation (transplantation of your own cells or cells from your identical twin (syngeneic transplantation)), we will consider you to be disabled until at least 12 months from the date of the first treatment under the treatment plan that includes transplantation. The first treatment usually refers to the initial therapy given to prepare you for transplantation.

4. *Evaluating disability after the appropriate time period has elapsed.* We consider any residual impairment(s), such as complications arising from:

a. Graft-versus-host (GVH) disease.

b. Immunosuppressant therapy, such as frequent infections.

c. Significant deterioration of other organ systems.

* * * * *

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

* * * * *

B. Persistent or recurrent disease following initial anticancer therapy, except persistence or recurrence in the true vocal cord.

* * * * *

D. Small-cell (oat cell) carcinoma.

OR

E. Soft tissue cancers originating in the head and neck treated with multimodal anticancer therapy (see 13.00E3c). 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.

13.03 *Skin (except malignant melanoma—13.29).*

* * * * *

B. Carcinoma invading deep extradermal structures (for example, skeletal muscle, cartilage, or bone).

13.04 Soft tissue sarcoma.

* * * * *

B. Persistent or recurrent following initial anticancer therapy.

13.05 *Lymphoma (including mycosis fungoides, but excluding T-cell lymphoblastic lymphoma—13.06).* (See 13.00K1 and 13.00K2c.)

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

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

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

OR

B. Hodgkin lymphoma with failure to achieve clinically complete remission, or recurrent lymphoma within 12 months of completing initial anticancer therapy.

* * * * *

OR

D. Mantle cell lymphoma.

13.06 *Leukemia.* (See 13.00K2.)

* * * * *

B. * * *

1. Accelerated or blast phase (see 13.00K2b). * * *

* * * * *

2. Chronic phase, as described in a or b:

* * * * *

b. Progressive disease following initial anticancer therapy.

13.07 *Multiple myeloma (confirmed by appropriate serum or urine protein electrophoresis and bone marrow findings).*

A. Failure to respond or progressive disease following initial anticancer therapy.

* * * * *

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

A. Locally advanced cancer (inflammatory carcinoma, cancer of any size with direct extension to the chest wall or skin, or cancer of any size with metastases to the ipsilateral internal mammary nodes).

* * * * *

C. Recurrent carcinoma, except local recurrence that remits with anticancer therapy.

OR

D. Small-cell (oat cell) carcinoma.

OR

E. With secondary lymphedema that is caused by anticancer therapy and treated by surgery to salvage or restore the functioning of an upper extremity. (See 13.00K4b.) Consider under a disability until at least 12 months from the date of the surgery that treated the secondary lymphedema. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

13.11 *Skeletal system*—sarcoma.

* * * * *

B. Recurrent cancer (except local recurrence) after initial anticancer therapy.

* * * * *

D. All other cancers originating in bone with multimodal anticancer therapy (see 13.00E3c). Consider under a disability for 12 months from the date of diagnosis. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

13.12 *Maxilla, orbit, or temporal fossa.*

* * * * *

C. Cancer with extension to the orbit, meninges, sinuses, or base of the skull.

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

A. Primary central nervous system (CNS; that is, brain and spinal cord) cancers, as described in 1, 2, or 3:

1. Glioblastoma multiforme, ependymoblastoma, and diffuse intrinsic brain stem gliomas (see 13.00K6a).

2. Any Grade III or Grade IV CNS cancer (see 13.00K6b), including astrocytomas, sarcomas, and medulloblastoma and other primitive neuroectodermal tumors (PNETs).

3. Any primary CNS cancer, as described in a or b:

a. Metastatic.

b. Progressive or recurrent following initial anticancer therapy.

OR

B. Primary peripheral nerve or spinal root cancers, as described in 1 or 2:

1. Metastatic.

2. Progressive or recurrent following initial anticancer therapy.

13.14 *Lungs.*

* * * * *

C. Carcinoma of the superior sulcus (including Pancoast tumors) with multimodal anticancer therapy (see 13.00E3c). * * *

* * * * *

13.15 *Pleura or mediastinum.*

* * * * *

B. * * *

2. Persistent or recurrent following initial anticancer therapy.

OR

C. Small-cell (oat cell) carcinoma.

13.16 *Esophagus or stomach.*

* * * * *

B. * * *

OR

C. Small-cell (oat cell) carcinoma.

13.17 *Small intestine*—carcinoma, sarcoma, or carcinoid.

* * * * *

B. * * *

OR

C. Small-cell (oat cell) carcinoma.

13.18 *Large intestine (from ileocecal valve to and including anal canal).*

* * * * *

C. * * *

OR

D. Small-cell (oat cell) carcinoma.

13.19 *Liver or gallbladder*—cancer of the liver, gallbladder, or bile ducts.

13.20 *Pancreas.*

* * * * *

B. Islet cell carcinoma that is physiologically active and is either inoperable or unresectable.

* * * * *

13.22 *Urinary bladder*—carcinoma.

* * * * *

D. * * *

OR

E. Small-cell (oat cell) carcinoma.

13.23 *Cancers of the female genital tract*—carcinoma or sarcoma (including primary peritoneal carcinoma).

A. * * *

3. Persistent or recurrent following initial anticancer therapy.

B. Uterine cervix, as described in 1, 2, or 3:

1. Extending to the pelvic wall, lower portion of the vagina, or adjacent or distant organs.

2. Persistent or recurrent following initial anticancer therapy.

3. With metastases to distant (for example, para-aortic or supraclavicular) lymph nodes.

C. * * *

3. Persistent or recurrent following initial anticancer therapy.

D. * * *

2. Persistent or recurrent following initial anticancer therapy.

E. Ovaries, as described in 1 or 2:

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

a. Extension beyond the pelvis; for example, implants on, or direct extension to, peritoneal, omental, or bowel surfaces.

b. Metastases to or beyond the regional lymph nodes.

c. Recurrent following initial anticancer therapy.

2. Germ-cell cancers—progressive or recurrent following initial anticancer therapy.

OR

F. Small-cell (oat cell) carcinoma.

13.24 *Prostate gland*—carcinoma.

A. Progressive or recurrent (not including biochemical recurrence) despite initial hormonal intervention. (See 13.00K8.)

OR

B. * * *

OR

C. Small-cell (oat cell) carcinoma.

13.25 *Testicles*—cancer with metastatic disease progressive or recurrent following initial chemotherapy.

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13.28 *Cancer treated by bone marrow or stem cell transplantation.* (See 13.00L.)

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13.29 *Malignant melanoma* (including skin, ocular, or mucosal melanomas), as described in either A, B, or C:

A. Recurrent (except an additional primary melanoma at a different site, which is not considered to be recurrent disease) following either 1 or 2:

1. Wide excision (skin melanoma).

2. Enucleation of the eye (ocular melanoma).

OR

B. With metastases as described in 1, 2, or 3:

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

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

3. Metastases to adjacent skin (satellite lesions) or distant sites (for example, liver, lung, or brain).

OR

C. Mucosal melanoma.

* * * * *

Part B

* * * * *

113.00 Cancer (Malignant Neoplastic Diseases)

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113.00 CANCER (MALIGNANT NEOPLASTIC DISEASES)

A. *What impairments do these listings cover?* We use these listings to evaluate all cancers (malignant neoplastic diseases), except certain cancers associated with human immunodeficiency virus (HIV) infection. If you have HIV infection, we use the criteria in 114.08E to evaluate carcinoma of the cervix, Kaposi sarcoma, lymphoma, and squamous cell carcinoma of the anal canal and anal margin.

B. *What do we consider when we evaluate cancer under these listings?* We will consider factors including:

1. Origin of the cancer.

2. Extent of involvement.

3. Duration, frequency, and response to anticancer therapy.

4. Effects of any post-therapeutic residuals.

C. *How do we apply these listings?* We apply the criteria in a specific listing to a cancer originating from that specific site.

D. *What evidence do we need?*

1. We need medical evidence that specifies the type, extent, and site of the primary, recurrent, or metastatic lesion. When the primary site cannot be identified, we will use evidence documenting the site(s) of metastasis to evaluate the impairment under 13.27 in part A.

2. For operative procedures, including a biopsy or a needle aspiration, we generally need a copy of both the:

a. Operative note, and

b. Pathology report.

3. When we cannot get these documents, we will accept the summary of hospitalization(s) or other medical reports. This evidence should include details of the findings at surgery and, whenever appropriate, the pathological findings.

4. In some situations, we may also need evidence about recurrence, persistence, or progression of the cancer, the response to therapy, and any significant residuals. (See 113.00G.)

E. *When do we need longitudinal evidence?*

1. *Cancer with distant metastases.* Most cancer of childhood consists of a local lesion with metastases to regional lymph nodes and, less often, distant metastases. We generally do not need longitudinal evidence for cancer that has metastasized beyond the regional lymph nodes because this cancer usually meets the requirements of a listing. Exceptions are for cancer with distant metastases that we expect to respond to anticancer therapy. For these exceptions, we usually need a longitudinal record of 3 months after therapy starts to determine whether the therapy achieved its intended effect, and whether this effect is likely to persist.

2. *Other cancers.* When there are no distant metastases, many of the listings require that we consider your response to initial anticancer 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 113.00I3).

3. *Types of treatment.*

a. Whenever the initial planned therapy is a single modality, enough time must pass to allow a determination about whether the therapy will achieve its intended effect. If the treatment fails, the failure often happens within 6 months after treatment starts, and there will often be a change in the treatment regimen.

b. Whenever the initial planned therapy is multimodal, we usually cannot make a determination about the effectiveness of the therapy until we can determine the effects of all the planned modalities. In some cases, we may need to defer adjudication until we can assess the effectiveness of therapy. However, we do not need to defer adjudication to determine whether the therapy will achieve its intended effect if we can make a fully favorable determination or decision based on the length and effects of therapy, or the residuals of the cancer or therapy (see 113.00G).

F. *How do we evaluate impairments that do not meet one of the cancer listings?*

1. These listings are only examples of cancers that we consider severe enough to result in marked and severe functional limitations. If your severe impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that meets the criteria of a listing in another body system.

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. (See §§ 404.1526 and 416.926 of this chapter.) If your impairment(s) does not meet or medically equal a listing, we will also consider whether you have an impairment(s) that functionally equals the listings. (See § 416.926a of this chapter.) We use the rules in § 416.994a of this chapter when we decide whether you continue to be disabled.

G. *How do we consider the effects of anticancer therapy?*

1. *How we consider the effects of anticancer therapy under the listings.* In many cases, cancers meet listing criteria only if the therapy is not effective and the cancer persists, progresses, or recurs. However, as explained in the following paragraphs, we will not delay adjudication if we can make a fully favorable determination or decision based on the evidence in the case record.

2. *Effects can vary widely.*

a. We consider each case on an individual basis because the therapy and its toxicity may vary widely. We will request a specific description of the therapy, including these items:

i. Drugs given.

ii. Dosage.

iii. Frequency of drug administration.

iv. Plans for continued drug administration.

v. Extent of surgery.

vi. Schedule and fields of radiation therapy.

b. We will also request a description of the complications or adverse effects of therapy, such as the following:

i. Continuing gastrointestinal symptoms.

ii. Persistent weakness.

iii. Neurological complications.

iv. Cardiovascular complications.

v. Reactive mental disorders.

3. *Effects of therapy may change.* The severity of the adverse effects of anticancer therapy may change during treatment; therefore, enough time must pass to allow us to evaluate the therapy's effect. The residual effects of treatment are temporary in most instances; however, on occasion, the effects may be disabling for a consecutive period of at least 12 months. In some situations, very serious adverse effects may interrupt and prolong multimodal anticancer therapy for a continuous period of almost 12 months. In these situations, we may determine there is an expectation that your impairment will preclude you from engaging in any age-appropriate activities for at least 12 months.

4. *When the initial anticancer therapy is effective.* We evaluate any post-therapeutic residual impairment(s) not included in these listings under the criteria for the affected body system. We must consider any complications of therapy. When the residual impairment(s) does not meet a listing, we must consider whether it medically equals a listing, or, as appropriate, functionally equals the listings.

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

1. In some listings, we specify that we will consider your impairment to be disabling until a particular point in time (for example, until at least 12 months from the date of transplantation). We may consider your impairment to be disabling beyond this point when the medical and other evidence justifies it.

2. When a listing does not contain such a specification, we will consider an impairment(s) that meets or medically equals a listing in this body system to be disabling until at least 3 years after onset of complete remission. 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. Following the appropriate period, we will consider any residuals, including residuals of the cancer or therapy (see 113.00G), in determining whether you are disabled. If you have a recurrence or relapse of your cancer, 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. *Anticancer therapy* means surgery, radiation, chemotherapy, hormones, immunotherapy, or bone marrow or stem cell transplantation. When we refer to surgery as an anticancer treatment, we mean surgical excision for treatment, not for diagnostic purposes.

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

3. *Multimodal therapy* means anticancer therapy that is a combination of at least two types of treatment 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, hormone therapy, and immunotherapy or biological modifier therapy). Examples of multimodal therapy include:

a. Surgery followed by chemotherapy or radiation.

b. Chemotherapy followed by surgery.

c. Chemotherapy and concurrent radiation.

4. *Persistent* means the planned initial anticancer therapy failed to achieve a complete remission of your cancer; that is, your cancer is evident, even if smaller, after the therapy has ended.

5. *Progressive* means the cancer becomes more extensive after treatment; that is, there is evidence that your cancer is growing after you have completed at least half of your planned initial anticancer therapy.

6. *Recurrent or relapse* means the cancer that was in complete remission or entirely removed by surgery has returned.

J. *Can we establish the existence of a disabling impairment prior to the date of the evidence that shows the cancer satisfies the criteria of a listing?* Yes. We will consider factors such as:

1. The type of cancer and its location.

2. The extent of involvement when the cancer was first demonstrated.

3. Your symptoms.

K. *How do we evaluate specific cancers?*

1. *Lymphoma.*

a. We provide criteria for evaluating lymphomas that are disseminated or have not responded to anticancer therapy in 113.05.

b. Lymphoblastic lymphoma is treated with leukemia-based protocols, so we evaluate this type of cancer under 113.06.

2. *Leukemia.*

a. *Acute leukemia.* The initial diagnosis of acute leukemia, including the accelerated or blast phase of chronic myelogenous (granulocytic) leukemia, is based on definitive bone marrow examination. Additional diagnostic information is based on chromosomal analysis, cytochemical and surface marker studies on the abnormal cells, or other methods consistent with the prevailing state of medical knowledge and clinical practice. Recurrent disease must be documented by peripheral blood, bone marrow, or cerebrospinal fluid examination, or by testicular biopsy. The initial and follow-up pathology reports should be included.

b. *Chronic myelogenous leukemia (CML).* We need a diagnosis of CML based on documented granulocytosis, including immature forms such as differentiated or undifferentiated myelocytes and myeloblasts, and a chromosomal analysis that demonstrates the Philadelphia chromosome. In the absence of a chromosomal analysis, or if the Philadelphia chromosome is not present, the diagnosis may be made by other methods consistent with the prevailing state of medical knowledge and clinical practice. The requirement for CML in the accelerated or blast phase is met in 113.06B if laboratory findings show the proportion of blast (immature) cells in the peripheral blood or bone marrow is 10 percent or greater.

c. *Juvenile chronic myelogenous leukemia (JCML).* JCML is a rare, Philadelphia-chromosome-negative childhood leukemia that is aggressive and clinically similar to acute myelogenous leukemia. We evaluate JCML under 113.06A.

d. *Elevated white cell count.* In cases of chronic leukemia (either myelogenous or lymphocytic), an elevated white cell count, in itself, is not a factor in determining the severity of the impairment.

3. *Malignant solid tumors.* The tumors we consider under 113.03 include the histiocytosis syndromes except for solitary eosinophilic granuloma. We do not evaluate thyroid cancer (see 113.09), retinoblastomas (see 113.12), primary central nervous system (CNS) cancers (see 113.13), neuroblastomas (see 113.21), or malignant melanoma (see 113.29) under this listing.

4. *Primary central nervous system (CNS) cancers.* We use the criteria in 113.13 to evaluate cancers that originate within the CNS (that is, brain and spinal cord cancers).

a. The CNS cancers listed in 113.13A are highly malignant and respond poorly to treatment, and therefore we do not require additional criteria to evaluate them. We do not list pituitary gland cancer (for example, pituitary gland carcinoma) in 113.13A, although this CNS cancer is highly malignant and responds poorly to treatment. We evaluate pituitary gland cancer under 113.13A and do not require additional criteria to evaluate it.

b. We consider a CNS tumor to be malignant if it is classified as Grade II, Grade III, or Grade IV under the World Health Organization (WHO) classification of tumors of the CNS (*WHO Classification of Tumours of the Central Nervous System,* 2007).

c. We evaluate benign (for example, WHO Grade I) CNS tumors under 111.05. We evaluate metastasized CNS cancers from non-CNS sites under the primary cancers (see 113.00C). We evaluate any complications of CNS cancers, such as resultant neurological or psychological impairments, under the criteria for the affected body system.

5. *Retinoblastoma.* The treatment for bilateral retinoblastoma usually results in a visual impairment. We will evaluate any resulting visual impairment under 102.02.

6. *Melanoma.* We evaluate malignant melanoma that affects the skin (cutaneous melanoma), eye (ocular melanoma), or mucosal membranes (mucosal melanoma) under 113.29. We evaluate melanoma that is not malignant that affects the skin (benign melanocytic tumor) under the listings in 108.00 or other affected body systems.

L. *How do we evaluate cancer treated by bone marrow or stem cell transplantation, including transplantation using stem cells from umbilical cord blood?* Bone marrow or stem cell transplantation is performed for a variety of cancers. We require the transplantation to occur before we evaluate it under these listings. We do not need to restrict our determination of the onset of disability to the date of transplantation (113.05 or 113.06). We may be able to establish an earlier onset date of disability due to your transplantation if the evidence in your case record supports such a finding.

1. *Acute leukemia (including all types of lymphoblastic lymphomas and JCML) or accelerated or blast phase of CML.* If you undergo bone marrow or stem cell transplantation for any of these disorders, we will consider you to be disabled until at least 24 months from the date of diagnosis or relapse, or at least 12 months from the date of transplantation, whichever is later.

2. *Lymphoma or chronic phase of CML.* If you undergo bone marrow or stem cell transplantation for any of these disorders, we will consider you to be disabled until at least 12 months from the date of transplantation.

3. *Evaluating disability after the appropriate time period has elapsed.* We consider any residual impairment(s), such as complications arising from:

a. Graft-versus-host (GVH) disease.

b. Immunosuppressant therapy, such as frequent infections.

c. Significant deterioration of other organ systems.

113.01 Category of Impairments, Cancer (Malignant Neoplastic Diseases)

113.03 *Malignant solid tumors.* Consider under a disability:

A. For 24 months from the date of initial diagnosis. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

OR

B. For 24 months from the date of recurrence of active disease. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

113.05 *Lymphoma (excluding all types of lymphoblastic lymphomas—113.06).* (See 113.00K1.)

A. Non-Hodgkin lymphoma (including Burkitt's and anaplastic large cell), with either 1 or 2:

1. Bone marrow, brain, spinal cord, liver, or lung involvement at initial diagnosis. Consider under a disability for 24 months from the date of diagnosis. Thereafter, evaluate under 113.05A2, or any residual impairments(s) under the criteria for the affected body system.

2. Persistent or recurrent following initial anticancer therapy.

OR

B. Hodgkin lymphoma, with either 1 or 2:

1. Bone marrow, brain, spinal cord, liver, or lung involvement at initial diagnosis. Consider under a disability for 24 months from the date of diagnosis. Thereafter, evaluate under 113.05B2, or any residual impairment(s) under the criteria for the affected body system.

2. Persistent or recurrent following initial anticancer therapy.

OR

* * * * *

OR

D. Mantle cell lymphoma.

113.06 *Leukemia.* (See 113.00K2.)

A. Acute leukemia (including all types of lymphoblastic lymphomas and juvenile chronic myelogenous leukemia (JCML)). Consider under a disability until at least 24 months from the date of diagnosis or relapse, or at least 12 months from the date of bone marrow or stem cell transplantation, whichever is later. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

OR

B. * * *

1. Accelerated or blast phase (see 113.00K2b). Consider under a disability until at least 24 months from the date of diagnosis or relapse, or at least 12 months from the date of bone marrow or stem cell transplantation, whichever is later. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

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113.12 Retinoblastoma.

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B. Persistent or recurrent following initial anticancer therapy.

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113.13 *Nervous system.* (See 113.00K4.) Primary central nervous system (CNS; that is, brain and spinal cord) cancers, as described in A, B, or C:

A. Glioblastoma multiforme, ependymoblastoma, and diffuse intrinsic brain stem gliomas (see 113.00K4a).

B. Any Grade III or Grade IV CNS cancer (see 113.00K4b), including astrocytomas, sarcomas, and medulloblastoma and other primitive neuroectodermal tumors (PNETs).

C. Any primary CNS cancer, as described in 1 or 2:

1. Metastatic.

2. Progressive or recurrent following initial anticancer therapy.

* * * * *

113.29 *Malignant melanoma* (including skin, ocular, or mucosal melanomas), as described in either A, B, or C:

A. Recurrent (except an additional primary melanoma at a different site, which is not considered to be recurrent disease) following either 1 or 2:

1. Wide excision (skin melanoma).

2. Enucleation of the eye (ocular melanoma).

OR

B. With metastases as described in 1, 2, or 3:

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

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

3. Metastases to adjacent skin (satellite lesions) or distant sites (for example, liver, lung, or brain).

OR

C. Mucosal melanoma.

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DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972

AGENCY: Department of the Navy, DoD.

ACTION: Final rule.

SUMMARY: The Department of the Navy (DoN) is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972, as amended (72 COLREGS), to reflect that the Deputy Assistant Judge Advocate General (DAJAG) (Admiralty and Maritime Law) has determined that USS PRINCETON (CG 59) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with certain provisions of the 72 COLREGS without interfering with its special function as a naval ship. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

DATES: This rule is effective May 20, 2015 and is applicable beginning May 11, 2015.

FOR FURTHER INFORMATION CONTACT: Commander Theron R. Korsak, (Admiralty and Maritime Law), Office of the Judge Advocate General, Department of the Navy, 1322 Patterson Ave. SE., Suite 3000, Washington Navy Yard, DC 20374–5066, telephone 202–685–5040.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the DoN amends 32 CFR part 706.

This amendment provides notice that the DAJAG (Admiralty and Maritime Law), under authority delegated by the Secretary of the Navy, has certified that USS PRINCETON (CG 59) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with the following specific provisions of 72 COLREGS without interfering with its special function as a naval ship: Annex I, paragraph 3(a), pertaining to the horizontal distance between the forward and after masthead lights. The DAJAG (Admiralty and Maritime Law) has also certified that the lights involved are located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine safety, Navigation (water), Vessels.

For the reasons set forth in the preamble, the DoN amends part 706 of title 32 of the Code of Federal Regulations as follows:

PART 706—CERTIFICATIONS AND EXEMPTIONS UNDER THE INTERNATIONAL REGULATIONS FOR PREVENTING COLLISIONS AT SEA, 1972

■ 1. The authority citation for part 706 continues to read as follows:

Authority: 33 U.S.C. 1605.

■ 2. Section 706.2 is amended in Table Five by revising the entry for USS PRINCETON (CG 59) to read as follows:

§ 706.2 Certifications of the Secretary of the Navy under Executive Order 11964 and 33 U.S.C. 1605.

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