Directorate of Defense Trade Controls (DDTC). The office at the Department of State, formerly known as the Office of Defense Trade Controls and before that as the Office of Munitions Control, responsible for reviewing applications to export and reexport items on the U.S. Munitions List. (See 22 CFR parts 120 through 130.)

* * * * *

PART 774—[AMENDED]

■ 11. The authority citation for part 774 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 18 U.S.C. 2510 *et seq.*; 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.*, 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 46 U.S.C. app. 466c; 50 U.S.C. app. 5; Sec. 901–911, Pub. L. 106–387; Sec. 221, Pub. L. 107–56; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 6, 2004, 69 FR 48763 (August 10, 2004).

■ 12. In Supplement No. 1 to Part 774, revise all references to the ''Office of Defense Trade Controls'' to read ''Directorate of Defense Trade Controls''; revise all references to ''Directorate of Defense Trade Control'' to read ''Directorate of Defense Trade Controls''; and revise all references to ''DTC'' to read ''DDTC''.

Dated: October 4, 2004.

Peter Lichtenbaum,

Assistant Secretary for Export Administration.

[FR Doc. 04–22861 Filed 10–8–04; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 558

New Animal Drugs; Change of Sponsor; Sulfaquinoxaline

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for an approved new animal drug application (NADA) from Hess & Clark, Inc., to Phoenix Scientific, Inc.

DATES: This rule is effective October 12, 2004.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6967, e-mail: *david.newkirk@fda.gov*.

SUPPLEMENTARY INFORMATION: Hess & Clark, Inc., 944 Nandino Blvd., Lexington, KY 40511, has informed FDA that it has transferred ownership of , and all rights and interest in, the following three approved NADAs, to Phoenix Scientific, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503:

NADA Number	Trade Name
6–391	S.Q. (sulfaquinoxaline) 40% Medicated Feed
6–677	S.Q. (sulfaquinoxaline) 20% Solution
7–087	Sulfaquinoxaline Solubilized

Accordingly, the agency is amending the regulations in 21 CFR 520.2325a and 558.586 to reflect the transfer of ownership and a current format.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 520

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 520 and 558 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.2325a [Amended]

■ 2. Section 520.2325a is amended in paragraph (a)(1) by removing ''050749'' and by adding in its place ''059130''.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

■ 4. Section 558.586 is amended by revising the section heading; by removing paragraphs (c) and (d); by redesignating paragraphs (e) and (f) as paragraphs (c) and (d); and by revising paragraph (a) and adding paragraph (b) to read as follows:

§ 558.586 Sulfaquinoxaline.

(a) *Specifications.* Type A medicated articles containing 40 percent sulfaquinoxaline.

(b) *Approvals.* See No. 059130 in § 510.600(c) of this chapter.

* * * * *

Dated: September 27, 2004.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 04–22760 Filed 10–8–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

RIN 0720–AA89

TRICARE; Changes Included in the National Defense Authorization Act for Fiscal Year 2002, (NDAA–02), and a Technical Correction Included in the NDAA–03

AGENCY: Office of the Secretary, DoD.

ACTION: Final rule.

SUMMARY: This rule makes several changes to the TRICARE program authorized by Congress in the NDAA–02. Specifically, revisions to the definition of durable medical equipment (DME); adoption of the same pricing methods for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) as are in effect for the Centers for Medicare & Medicaid Services (CMS); clarification that rehabilitative therapy is a TRICARE benefit; addition of augmentative communication devices (ACD)/speech generating devices (SGDs) as a TRICARE benefit; addition of hearing aids for family members of active duty members as a TRICARE Basic Program benefit; revisions to the definition of prosthetics; permanent authority for transitional health care for certain members separated from active duty; and revisions to the time period of eligibility for transitional health care.

This final rule also addresses a technical correction found in section 706 of the Bob Stump NDAA–03, relating to transitional health care for dependents of certain members separated from active duty.

DATES: This rule is effective December 13, 2004. Actual implementation will coincide with the transition in each TRICARE Region to the next generation

TRICARE Managed Care Support Contracts, which are scheduled to take effect over a period of months ending on November 1, 2004.

ADDRESSES: TRICARE Management Activity, Medical Benefits and Reimbursement Systems, 16401 East Centretech Parkway, Aurora, Colorado 80011–9066.

FOR FURTHER INFORMATION CONTACT: Ann N. Fazzini, Medical Benefits and Reimbursement Systems, TRICARE Management Activity, telephone, (303) 676–3803. Questions regarding payment of specific claims should be addressed to the appropriate TRICARE contractor.

SUPPLEMENTARY INFORMATION:

Background

In the **Federal Register** of April 16, 2003, (68 FR 18575), the Office of the Secretary of Defense published for public comment a proposed rule regarding a number of changes included in the NDAA–02 (Pub. L. 107–107, December 28, 2001). These changes include revisions to the definition of durable medical equipment (DME); adoption of the same pricing methods for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) as are in effect for the Centers for Medicare & Medicaid Services (CMS); clarification that rehabilitative therapy is a TRICARE benefit; addition of augmentative communication devices (ACD)/speech generating devices (SGDs) as a TRICARE benefit; addition of hearing aids for family members of active duty members as a TRICARE Basic Program benefit; and revisions to the definition of prosthetics.

In addition to the above benefit changes, the NDAA 02 gave permanent authority for transitional health care for certain members separated from active duty. Prior to the NDAA 02, the Transitional Assistance Management Program (TAMP)—the program through which certain separating members and their dependents receive transitional health care—was scheduled to cease as of December 30, 2001. The NDAA 02, deleted the expiration date and made the TAMP program a permanent program.

Another change was made to transitional health care by the NDAA 02. Prior to the NDAA 02, certain separating members and their dependents received transitional health care until the earlier of: (1) 30 days after the date of the release of the member from active duty; or (2) the date on which the member and the dependents of the member are covered by a health plan sponsored by an employer. The groups who received transitional health care within the above parameters included: (1) A member of a reserve component called or ordered to active duty in support of a contingency operation; (2) a member involuntarily retained on active duty under section 12305 in support of a contingency operation; or (3) a member who voluntarily agrees to remain on active duty for a period of less than one year in support of a contingency operation.

The changes made in the NDAA 02 deleted the 30 day limit and changed the coverage period to 60 days of coverage for those separated with less than six years of active service or 120 days of coverage for those separated with six or more years of active service.

This final rule also provides for a technical correction found in the Bob Stump NDAA 03.

The NDAA 04, Pub. L. 108–136, contains additional changes to the transitional health care coverage period. These changes expire on December 31, 2004. If these changes are extended or made permanent they will be addressed in a separate rule.

As a result of the publication of the proposed rule, the following comments were received from interested parties, associations and the government agencies that by law TRICARE is required to consult during the rule making process.

Review of Comments

We noticed the comments that we received could be classified into four major areas. The first is that there is a perception that the NDAA 02 language somehow eliminates or diminishes the ''medical necessity'' provision and other provisions found in TRICARE law. The second is a lack of understanding or awareness that the Program for Persons with Disabilities (PWPWD) and the TRICARE Basic Program are separate and distinct programs. The third is disagreement with our statement in the proposed rule that TRICARE's current policies in place at the time provide coverage within the NDAA 02 criteria. The fourth and final area is a concern with our proposed definition of rehabilitative therapy.

We address each of these major areas separately and then address the general comments that we received on the proposed rule.

I. Medical Necessity and Other Provision

Several of the changes authorized by Congress permit therapy for the purpose of either improving, restoring, maintaining, or preventing deterioration of function, or an accessory or item of supply that is used in conjunction with a device for the purpose of achieving therapeutic benefit and proper functioning. We received comments from several entities stating that they believe the statutory reference to the ''functional status'' of a beneficiary is to be used as the sole basis for determining coverage, rather than using the requirement that a service or supply must be medically or psychologically necessary as required by 10 U.S.C. 1079(a)(13). This belief is incorrect. One is to keep in mind that the provisions found in the NDAA 02 must be read in conjunction with the all other statutory provisions and parameters that govern the TRICARE program under title 10, United States Code, chapter 55. The most significant parameter for the TRICARE program is found at 1079(a)(13) and excludes:

> Any service or supply which is not medically or psychologically necessary to prevent, diagnose, or treat a mental or physical illness, injury, or bodily malfunction as assessed or diagnosed by a physician, dentist, clinical psychologist, certified marriage and family therapist, optometrist, podiatrist, certified nurse-midwife, certified nurse practitioner, or certified clinical social worker, as appropriate, may not be provided, except as authorized elsewhere * * *.

The types of health care services authorized by Congress in the NDAA–02 that this rule implements provide for the types of health care that ''may be'' provided by the TRICARE program. This must be read in conjunction with the medical necessity requirement. Consequently, any therapy for the purpose of either improving, restoring, maintaining, or preventing deterioration of function, or an accessory or item off supply that is used in conjunction with a device for the purpose of achieving therapeutic benefit and proper functioning must be medically necessary before it can be cost shared by TRICARE.

Another provision/parameter of the TRICARE program that must be considered when interpreting the NDAA 02 legislation is the prohibition against providing custodial care. Custodial care is excluded from TRICARE coverage under section 1077(b)(1) and is defined in section 1072(a) as:

> Custodial care means treatment or services, regardless of who recommends such treatment or services or where such treatment or services are provided that—(A) can be rendered safely and reasonably by a person who is not medically skilled; or (B) is or are designed mainly to help the patient with activities of daily living.

In summary, we do not concur with the interpretation that the NDAA 02

language reduces the significance of or eliminates the use of the medical necessity provision and other provisions found in TRICARE law. TRICARE considers the functional status of an individual as a factor, but that factor does not usurp the requirement of medical necessity or custodial care. The medical necessity and custodial care provisions, as well as all other parameters and provisions that govern the TRICARE program, must be considered concurrently with the provisions added in the NDAA 02, consistent with the rules of statutory construction defined in title 10, Untied States Code.

II. PFPWD in Relation to the Basic Program

The PFPWD and the TRICARE Basic Program are separate and distinct programs with their own statutory basis, to include separate/different eligibility provisions, cost-sharing provisions, and benefit provisions. The PFPWD, based upon 10 U.S.C. 1079(d)–(f), is implemented in 32 CFR 199.5, and describes eligibility provisions, cost-sharing provisions, and benefit provisions under the PFPWD. The changes to the PFPWD authorized by section 701(d) of the NDAA 02 are being implemented under a separate rule. The TRICARE Basic Program Benefits are implemented in 32 CFR 199.4. While the programs are separate and distinct, the PFPWD is available for use in conjunction with the TRICARE Basic Program. The PFPWD was congressionally established approximately 35 years ago to help defray the costs of services not available either through the TRICARE Basic Program or through other public agencies. This includes, but is not limited to, services such as training, special education and adjunct services (*e.g.,* equipment adaptation).

This rule makes no changes to the PFPWD program found at 32 CFR 199.5. There are some services and supplies that are currently covered under the PFPWD but are not covered under the TRICARE Basic Program. This will continue. For example, training, special education, and eyeglasses may be covered under the PFPWD but they are excluded from the TRICARE Basic Program.

Hearing aids are currently allowed exclusively as a benefit under the PFPWD; however, upon implementation of this final rule, hearing aids will be considered a benefit under the TRICARE Basic Program, although still statutorily limited to dependents of active duty members.

Additionally, upon implementation of this rule, those ACDs/SGDs defined in this rule and that otherwise meet the policies and provisions of the TRICARE Basic Program will be covered as a benefit under the Basic Program. There will be some communicative devices, that do not meet the definition of ACD/SGD, but that are considered communication devices, that have been allowed for coverage under the PFPWD. This will not change and those devices will continue to be provided.

Again, this rule makes no change to the regulatory section that governs the PFPWD.

III. TRICARE's Current Policies

We received comments stating that the NDAA 02 provisions ''Congress intended that this new law would stimulate TRICARE to provide greater access to appropriate assistive devices, technologies and related services.'' The comments subsequently expressed concerns with our position that TRICARE's policies in place at this time provide coverage within these criteria. When we made the ''current policies'' statement, we were referring to the policies found in the TRICARE Policy Manual and the TRICARE Reimbursement Manual. These manuals contain detailed policies on a variety of topics, to include DME and prosthetics. They may be accessed through the TRICARE Web site at *http://www.tma.osd.mil.* The policies expressed in these manuals are TRICARE's interpretation of its governing statutes (primarily title 10, United States Code, chapter 55) and our regulation implementing these statutes (32 CFR part 199).

We reviewed the proposed rule and found that we made the statement regarding our current policies in the **SUPPLEMENTARY INFORMATION** Section of the rule in two places: the durable medical equipment section and the prosthetics section. Regarding DME, we received comments stressing that TRICARE needs to be aware of the necessity to customize DME to meet an individual's needs. We are. The Durable Medical Equipment policy is found at chapter 7, section 3.1 in the TRICARE Policy Manual. This policy defines DME and provides guidance on when DME may be repaired, replaced, modified, and/or customized. The policy currently reflects the provisions added in the NDAA–02. This final rule incorporates the new statutory authorization into 32 CFR part 199. In the Supplementary Information we were simply saying that our interpretation of previous statutory authorizations and implementing regulations in the TRICARE Policy Manual were consistent with how we interpret the new authorizations. Hence, TRICARE's current policies in place provide coverage within the NDAA 02 criteria.

With regard to prosthetics, section 702 of NDAA–02, gives the Department the authority to provide a prosthetic device that includes the following: (1) Any accessory or item of supply that is used in conjunction with the device for the purpose of achieving therapeutic benefit and proper functioning. (2) Services necessary to train the recipient of the device in the use of the device. (3) Repair of the device for normal wear and tear or damage. (4) Replacement of the device if the device is lost or irreparably damaged or the cost of repair would exceed 60 percent of the cost of replacement. (5) A prosthetic device customized for a patient may be provided under this section only by a prosthetic practitioner who is qualified to customize the device, as determined under regulations prescribed by the Secretary of Defense in consultation with the other Secretaries.

As stated in the proposed rule, TRICARE's current policies do offer benefits for the above criteria 1, 2, 3, and 5. Regarding criterion (4), TRICARE currently allows for replacement when required due to growth or change in the patient's condition. Nonetheless, our policies will be revised to ensure consistency with the language found in section 702 and will reflect a greater opportunity to acquire replacement prosthesis.

Regarding criterion 5, TRICARE has no specific provider requirements for a prosthetic practitioner to be qualified to customize the device. Rather, otherwise authorized TRICARE providers currently provide prostheses and customization of prostheses, such as medical equipment firms, medical supply firms, and Durable Medical Equipment, Prosthetic, Orthotic supplies providers/suppliers. As stated in the proposed rule, we are aware that CMS has established a Negotiated Rulemaking Committee on Special Payment Provisions and Requirements for Prosthetics and Certain Custom-Fabricated Orthotics. The purpose of this committee is to advise CMS on developing a proposed rule that would establish payment provisions and requirements for providers of prostheses and custom-fabricated orthotics under the CMS. Once the Committee provides its findings, we will review them for consideration under the TRICARE program. After our review, we will use the rulemaking process and the public will have an opportunity to comment on our proposed provisions regarding these

types of providers. In the meantime, we will continue to allow prostheses customization by otherwise authorized TRICARE providers.

The proposed rule states that where our current policies deviate from the new statutory language, we are adopting the new statutory language and will amend our policies to reflect that language.

IV. Rehabilitative Therapy

We received numerous comments from entities who expressed concern with our definition of rehabilitative therapy. The commenters stated that defining rehabilitative therapy to include only physical therapy (PT), speech therapy (ST), and occupational therapy (OT) violates that intent of the statute. The commenters listed numerous additional therapies that they believe should be available for coverage under the statutory language.

Again, parameters and provisions that govern the TRICARE program must be read in their entirety. By defining rehabilitative therapy as PT, OT, and ST, we did not mean to imply that all other therapies are excluded and are not eligible for TRICARE coverage. Other therapies that are medically necessary and appropriate, that are proven medical treatment, that are not considered as custodial care, that are provided by an authorized TRICARE provider and that are not otherwise excluded as a TRICARE benefit may be considered for TRICARE coverage.

However, in order to avoid any misunderstanding, we have revised the definition of rehabilitative therapy to reflect the statutory language rather than define it as PT, OT, and ST only.

V. Additional Comments

In addition to the four major areas in which we received comments, we received general comments regarding most of the proposed provisions. Those comments are responded to as follows:

ACD/SGD

Comment 1: One commenter questioned whether including the highly specific definition of an ACD/SGD in the TRICARE regulation is appropriate. The commenter proposed that TRICARE adopt a more general definition of ACD/SGD devices in its regulations, leaving the specific distinctions of the TRICARE Policy Manual.

Response: We concur with this recommendation. The purpose of the CFR is to provide broad guidelines and policies. The publishing of detailed criteria for a speech generating device in section 32 CFR 199.2 may prove difficult to maintain and update, if necessary. To assist our beneficiaries in obtaining benefit coverage in a timely manner, the detailed ACD/SGD definition included in the proposed rule has been replaced with the statutory language. We will, place the specific ACD/SGD criteria that were included in the proposed rule into the TRICARE Policy Manual (TPM). That is, we will be adopting CMS's augmentative communication device guidelines as we indicated in the proposed rule and we will incorporate CMS's guidelines into the TPM. The TPM contains policies to implement 32 CFR Part 199 and must be used in conjunction with the CFR for complete policy information. The TPM can be accessed through the TRICARE Web site at *http://www.tricare.osd.mil.*

Comment 2: We received comments regarding the specific ACD/SGD criteria. For example, it was pointed out to us that we failed to include one of CMS's criteria in our definition.

Response: The omission of the criterion was an oversight and will be corrected. We have decided to include only the NDAA 02 statutory requirements in the regulation rather than listing the specific ACD/SGD criteria. We plan to include the specifics regarding ACD/SGD coverage (*i.e.,* criteria similar to CMS's coverage criteria) in the TRICARE Policy Manual.

Comment 3: We received comments regarding our decision to adopt CMS's coverage of SGDs for ACDs. Some of the commenters applauded our decision to adopt CMS's policy. Others expressed dissatisfaction.

Response: The NDAA 02 amended title 10, United States Code, by adding a new subsection 1077(e)(2), which says, ''An augmentative communication device may be provided under subsection (a)(15).'' Subsection (a)(15) states that the Department may provide, ''Prosthetic devices, as determined by the Secretary of Defense to be necessary because of significant conditions resulting from trauma, congenital anomalies, or disease.'' The Department, in developing its guidelines, policies, and coverage criteria of ACDs/SGDs, is required to classify them as voice prosthesis, while CMS may classify ACDs/SGDs as durable medical equipment. Although we are required to classify them as voice prosthesis, our decision to adopt CMS's coverage of SGDs for ACDs is consistent with TRICARE seeking consistency with CMS. CMS, like TRICARE, is a federal program, and where appropriate, adoption of their national standard helps ensure delivery of a uniform benefit.

Comment 4: A commenter asked whether argumentative communication devices/or speech generating devices were covered previously only under the PFPWD. They also asked whether tracheostomy valves and cochlear implants were purchased under TRICARE and whether these provisions will remain unchanged.

Response: ACDs/SGDs are currently allowed under the PFPWD when there is a serious physical disability and the individual qualifies for the PFPWD. Since certain ACDs/SGDs will now be a benefit under the Basic Program, the individual will no longer have to qualify for PFPWD. Also, unlike hearing aids, this benefit is not limited to dependents of active duty members. The PFPWD is a program statutorily limited to only active duty dependents, so this is an expansion of benefits.

Tracheostomy valves and cochlear implants have been TRICARE benefits and this remains unchanged.

Comment 5: A commenter recommended that ACDs/SGDs also include non-speech generating devices which also help an individual to maximize communication skills for functional and effective communication.

Response: The statutory language states that ACDs may be provided as a voice prosthesis. We interpret this as speech generating devices only. There will be some communicative devices that do not meet the definition of ACD/SGD, but that are considered communication devices, that have been allowed for coverage under the PFPWD. This will not change and those devices will continue to be provided.

Comment 6: The narrative introduction to the proposed ACD/SGD regulations states that ''In proposing this policy, we have also taken into consideration recommendations provided to us by the American Speech Language Hearing Association (ASHA) in defining this benefit.'' ASHA's recommendations, submitted in March 22, 2002, did not infer that covered ACDs should be limited to SGDs as currently proposed.

Response: We apologize for inferring that the ASHA recommended that ACDs should be limited to those SGDs outlined in the proposed rule.

Comment 7: A commenter recommended that the services of speech-language pathologists be required as related to ACD/SGD evaluation and establishment of a treatment plan. Such is the requirement specified in the DMERC Supplier Manual reference above. If it is not appropriate to include this requirement in the regulation, then it should appear in the policy manual.

Response: TRICARE will allow otherwise covered medically necessary and appropriate services required and prescribed by a physician that are associated with the ACD/SGD.

Prosthetics

Comment 8: One commenter restated the changes regarding prosthetics and expressed concern that the same coverage policies are not being applied to TRICARE's orthotic benefit.

Response: The NDAA 02 statutory language refers only to prosthetic devices and makes no mention of orthotic care. Therefore, orthotic care is not addressed in this regulation.

Comment 9: We have concerns about the future findings of the CMS established Negotiated Rulemaking Committee on Special Payment Provisions and Requirements for Prosthetics and Orthotics.

Response: If TRICARE decides to make any changes based on CMS's negotiated rulemaking, we will publish a proposed rule with a comment period giving the public an opportunity to voice their concerns.

Hearing Aids

Comment 10: Two commenters stated that they agree that there is not industry standard or industry definition of ''profound'' hearing loss and they proposed changing the dB level of profound hearing loss for children. The dB level in the proposed rule was 26 dB. The commenter asked us to change it to 15dB.

Response: The statutory language provides coverage for a hearing aid when a ''profound hearing loss'' is present. There is no industry standard or industry definition of ''profound'', we consulted with TRICARE, Veterans Affairs, and Service physicians and Audiology Consultants who informed us a 26dB level falls within a mild hearing loss range. Consequently, we believe 26dB is a reasonable and generous interpretation of profound hearing loss. Under PFPWD, the dB level was 45dB or greater in one ear or 30dB in both ears. By lowering the dB level to 26 we are making this benefit much more generous than what was previously available under the PFPWD.

Comment 11: We were asked to include a statement that testing areas should be in compliance with ANSI standard S3.1–1999, Maximum Permissible Ambient Noise Levels for Audiometric Test Rooms, or any future revision thereof.

Response: We have taken this under advisement. If necessary and appropriate, we will include such a statement in the TRICARE Policy Manual hearing aid issuance.

Comment 12: A commenter urged TRICARE to require that any hearing aid fitting services for a TRICARE beneficiary be provided by an ASHA-certified, and where applicable, licensed audiologist. We believe that audiologists holding the Certificate of Clinical Competence in Audiology (CCC–A) as granted by ASHA will help assure a high level of quality in the delivery of this important benefit.

Response: TRICARE has established the regulatory criteria for being an authorized TRICARE provider based upon the broad statutory guidelines contained in title 10, United States Code, chapter 55, and primarily 10 U.S.C. 1079(a)(13) and 1079(a)(8). For individual paramedical providers under TRICARE, 32 CFR 199.6(c)(3)(iii)(I)(*4*) lists audiologists. Paramedical providers may be reimbursed for services provided on a fee-for-service basis only if the beneficiary is referred by a physician for the treatment of a medically diagnosed condition and a physician must also provide continuing and ongoing oversight and supervision of the program or episode of treatment provided by the audiologists. All paramedical providers must be licensed if required in that state, and where a state does not license a specific category or paramedical, certification by a Qualified Accreditation Organization as defined in § 199.2 is required. Certification must be at full clinical practice level.

Comment 13. One commenter stated that they prefer that the limitation exists that anyone with hearing loss ''that interferes with communication'' would be eligible for coverage.

Response: The term ''profound'' hearing loss appears in the statute and TRICARE has used its discretion in interpreting that term. Prior to the implementation of this rule, and when the benefit was available under PFPWD, the dB level was 45dB or greater in one ear or 30dB in both ears. By lowering the dB level to 26 we are making this benefit much more generous than what was previously available under the PFPWD.

Comment 14: One commenter stated that the proposed criteria for adults and children listed in this new rule will appropriately allow patients with vocational, social, psychological and environmental needs to receive benefits from hearing amplification. However, they also stated that the evaluation and treatment process would be greatly enhanced by the development of a comprehensive protocol utilizing non-audiometric data. They state that a comprehensive protocol for determining hearing aid candidacy and treatment strategies would include data such as the client's physical status (dexterity, visual status), psychological status (attitude, motivation, cognitive and mental status), and communication status (auditory-visual speech perception abilities, auditory speech perception abilities) and the unique communication environments in which the client must function.

Response: In addition to now paying for a hearing aid for a dependent of an active duty member who has a profound hearing loss, TRICARE will also cover all medically necessary and appropriate services and supplies associated with the hearing aid.

Comment 15: A commenter advised us that we may receive some comments which dispute the proposed rule's proposed definition of what constitutes a ''profound'' hearing loss, since typical clinical categorizations (using pure tone hearing thresholds alone) would not typically associate ''profound'' with the range of hearing thresholds listed in section 199.2. They stated that they are aware of, and agree with, the intentions of the audiologist consultants from the Department of Defense and the Department of Veterans Affairs who provided guidance in the drafting of this rule. They also agree that there is no universal standard for ''profound'' loss. The comment continued by stating that if hearing aids were only made available to individuals with audiometric thresholds exceeding 90dBHL (considered by many physicians to represent a profound loss, using only pure tone audiometry results), most hearing impaired patients would be inappropriately excluded.

Response: We thank the commenter for their support and acknowledgement of the sufficiency and appropriateness of our criteria of 40dB and 26db when defining a profound hearing loss.

Comment 16: A comment was received recommending that the Supplementary Information portion of Section V. Hearing Aids include the requirements for a qualified audiologist.

Response: Audiologists are currently authorized providers under TRICARE. See 32 CFR 199.6 (c)(3)(iii)(I). Now that hearing aids are a Basic Program benefit for active duty family members, otherwise covered services and supplies associated with audiologists and speech therapists may be covered. Consequently, we have deleted the Basic Program exclusion found at 32 CFR 199.4 (g)(45) regarding audiologists and speech therapists. While we are deleting the exclusion, it is necessary to point out that otherwise covered

services and supplies from these types of providers may be provided only if the beneficiary is referred by a physician for the treatment of a medically diagnosed condition and a physician must also provide continuing and ongoing oversight and supervision of these providers.

Comment 17: We find no reference in the rule to how TRICARE payment methods would apply. We anticipate that TRICARE payments for hearing aids will remain consistent with what the standard had been under the PFPWD. Under this program, the active duty sponsor was responsible for a co-payment based on their rank (*e.g.* ranging from $25 to $250 per $1000, per device).

Response: Under the TRICARE Basic Program, the beneficiary's cost share (and deductible, if any) will be based upon which program they are participating in (TRICARE Prime, Standard, or Extra), and their status as the dependent of an active duty member (statutorily hearing aids are available to only the dependent of an active duty family member). Cost shares and deductibles are also statutorily based upon these two factors. The copayments and cost-shares for the TRICARE Basic Program have a different statutory basis than the PFPWD. Because hearing aids will now be obtained by dependents of an active duty family member under the Basic Program, the Basic Program cost-sharing provisions must apply. These copayments are as follows: TRICARE Prime active duty beneficiaries will have no copayment (i.e., a $0.00 copayment); those who use TRICARE Standard will have a 20% cost share after meeting their statutory fiscal year deductible ($150 for an individual/$300 for a family; $50/$100 for dependents of E—4 or below); those who use TRICARE Extra will have 15% cost-sharing after meeting their statutory deductible.

Comment 18: Is this really an expansion of hearing aid benefits to AD dependents since it is already being provided under the PFPWD guidelines and all who need an aid qualify for PFPWD?

Response: Hearing aids will be offered under the Basic Program only and will not be offered as a benefit under the PFPWD once this rule is implemented. It is an enhancement of benefits because we have relaxed the hearing levels necessary to qualify for a hearing aid and have offered hearing aids to all active duty family members who meet the criteria. Additionally, those enrolled in TRICARE Prime will have no cost share, as opposed to the statutory cost share based on rank that they pay today when they access the benefit under the PFPWD.

Comment 19: Does the change mean that the military treatment facility (MTFs) will be fitting and purchasing the aids through our VA contract, rather than in the civilian sector, thus saving tax dollars and that is the reason for the change?

Response: The reason for the change is that the NDAA–02 authorized hearing aids as a TRICARE benefit under the Basic program. The use of a VA contract to fit and purchase hearing aids is a decision that needs to be made by the MTF.

Comment 20: Currently assistive listening devices are purchased via the PFPWD. The exclusion of auditory sensory enhancing devices in the proposed rule will not affect what we currently purchase through the PFPWD correct?

Response: Correct. The exclusion found in the proposed rule applies to the TRICARE Basic program, not the PFPWD.

DME

Comment 21: Under the new statute, we would anticipate, assuming that other conditions of coverage are met, that TRICARE would cover certain sensory or communication aids such as screen readers, Closed Circuit TVs, or other optical scanners for people with vision impairments. Similarly we would expect that TRICARE would potentially cover certain home modifications such as grab bars and raised toilet seats that facilitate better functioning with self care, safety, and may prevent conditions such as hip fractures and other injuries from falls.

Response: As previously discussed, under 10 U.S.C. 1079(a)(13), TRICARE may not provide any service or supply which is not medically or psychologically necessary to prevent, diagnose, or treat a mental or physical illness, injury, or bodily malfunction as assessed or diagnosed by a physician or other authorized provider. Those items of DME as defined in section 199.2 that are also medically necessary and appropriate are covered. There are some items that may serve a preventive purpose, but TRICARE has a very limited preventive benefit that is based on statute. Consequently, some of those items listed by the commenter do not meet coverage provisions.

Comment 22: A commenter stated that the Medicaid program makes no express reference to DME in contrast to the CMS. They continued to express that for the Medicaid program, the operative term is equipment. In their opinion, the TRICARE program continues to require covered DME to be ''primarily and customarily designed and intended to serve a medical purpose rather than primarily for transportation, comfort or convenience. The regulations also continue to prohibit coverage for ''luxury'' or ''deluxe'' items. These requirements appear out of step with the new statute's standard of maximizing function and preventing deterioration of function.

Response: Medicaid and TRICARE are separate programs each with their own governing statutes and provisions. Medical necessity is a requirement for the TRICARE program and the NDAA 02 statutory language must be read in conjunction with the existing medical necessity requirement. DME with deluxe, luxury, or immaterial features which increase the cost of the item to the government relative to a similar item without those features is excluded. *See* 32 CFR 199.4(d)(3)(ii)((D)(*3*).

Comment 23: A commenter opined that technology has blurred the line between what can legitimately be called a convenience or luxury and what improves the functionality of quality of life of the person, thereby improving his or her health status.

Response: We will allow DME that meets the definition described in this final rule, is medically or psychologically necessary, and meets all parameters of TRICARE coverage.

Comment 24: One commenter indicated that in the final rule, TRICARE should specifically address the issue of accessing power mobility before a long term manual wheelchair user is no longer able to propel him or herself due to secondary injury as a result of such wheelchair use.

Response: Current regulatory provisions (32 CFR 199.4(d)(3)(iv)(C)) cover a wheelchair, or a CHAMPUS approved alternative, which is medically necessary to provide basic mobility, including additional cost for medically necessary modifications to accommodate a particular disability. These may be covered as durable medical equipment. Additionally, the Policy Manual allows for electric-powered, cart-type transports as an alternative to an electric wheelchair. DME with deluxe, luxury, or immaterial features which increase the cost of the term to the government relative to a similar item without those features remains a TRICARE exclusion.

Comment 25: A commenter suggested that we change the current definition of DME to conform to CMS's definition of DME. CMS defines DME as equipment furnished by a supplier or a home health agency that—(1) Can withstand repeated use; (2) is primarily and

customarily used to serve a medical use; (3) generally is not useful to an individual in the absence of an illness or injury; (4) is appropriate for use in the home. Alternatively, the commenter suggested that TRICARE revise its definition of DME by deleting the wording ''* * * rather than primarily for transportation, comfort or convenience * * *'' and adding a separate criterion that DME ''generally is not useful to an individual in the absence of an illness or injury''.

Response: The proposed rule stated that we intended to modify the DME definition to incorporate the NDAA 02 language into the DME definition. The revised DME definition was proposed to read as follows: Equipment for which the allowable charge is over $100 and which:

(1) Is medically necessary for the treatment of a covered illness or injury;

(2) Improves, restores, or maintains the function of a malformed, diseased, or injured body part, or can otherwise minimize or prevent the deterioration of the patient's function or condition;

(3) Can maximize the patient's function consistent with the patient's physiological or medical needs.

(4) Is primarily and customarily designed and intended to serve a medical purpose rather than primarily for transportation, comfort, or convenience

(5) Can withstand repeated use;

(6) Provides the medically appropriate level of performance and quality for the medical condition present (that is, nonluxury or nondeluxe);

(7) Is other than spectacles, eyeglasses, contact lenses, or other optical devices, hearing aids (unless otherwise provided as a covered TRICARE benefit), or other communication devices (unless otherwise provided as a covered TRICARE benefit); and

(8) Is other than exercise equipment, spas, whirlpools, hot tubs, swimming pools or other such items.

When we received this comment, we reviewed both our current and proposed DME definition. It became clear to us that some of the criteria included in the definition were actually coverage criteria rather than criteria that identify DME. We then compared the current and proposed TRICARE definitions for DME to the definition used by CMS. Based on that side-by-side comparison, we decided to update our DME definition by adopting the same first three criteria listed in CMS's definition for use in TRICARE's definition as that these criteria have a crosswalk to criteria found in our current DME definition. We did not adopt the fourth criteria in the CMS definition regarding in-home use because it provides a restriction not currently found under the TRICARE program. Additionally, we moved the coverage criteria currently found in the DME definition at 32 CFR 199.2, to 32 CFR 199.4(d)(3)(ii)(A) which outlines the scope of the DME benefit. This final rule has been revised accordingly.

Misc. Comments/Admin Comments

Comment 26: A commenter expressed concern with the statement in the ''Regulatory Procedures'' section of the proposed rule stating that this regulation is ''not economically significant.'' They interpreted this to mean that the TRICARE program ''does not anticipate spending any more resources on this benefit category than the program did before this new law was adopted.''

Response: The language does not mean that the TRICARE program does not anticipate spending any more resources on this benefit category than the program did before the new law. The statement is a requirement in rulemaking under the Regulatory Flexibility Act (RFA). There are three specific RFA requirements applicable to rulemaking:

1. Analysis of the impact of each rulemaking on small entities and evaluation of alternatives that would accomplish regulatory objectives without unduly burdening small entities or erecting barriers to competition.

2. The periodic review of existing agency rules which have a significant economic impact on a substantial number of small entities.

3. Preparation and publication of a semiannual agenda listing rules under development that may have a significant economic impact on a substantial number of small entities.

Additionally, Executive Order 12866 requires that comprehensive regulatory impact analysis be performed on any economically significant regulatory action, defined as one that would result in an annual effect of $100 million or more on the national economy or which would have other substantial impacts.

Neither the RFA or Executive Order 12866 provide spending limits for these additional benefits and our statement in the proposed rule shall have no impact on the resources provided for this new benefit. TRICARE shall provide the benefits within the provisions outlined in this final rule.

Comment 27: Add ''Bob Stump'' in front of NDAA–03.

Response: Done.

Summary of Regulatory Modifications

The following modifications were made as a result of suggestions received during the public comment period:

(1) We revised the definition of ACD/SGD to comply with the statutory language. Additionally, we eliminated the specific criteria for an ACD/SGD and will be placing that into the TRICARE Policy Manual.

(2) We adopted a modified version of CMS's definition of DME and moved criteria found in the current DME definition to 32 CFR 199.4.

(3) We revised the definition of prosthetics to comply with the statutory language.

(4) We revised the definition of rehabilitative therapy to comply with the statutory language.

(5) We clarified that rehabilitative therapy are therapies that are medically necessary and appropriate, that are proven medical treatment, that are not considered custodial care, that are provided by an authorized TRICARE provider and that are not otherwise excluded as a TRICARE benefit may be considered for TRICARE coverage.

Regulatory Procedures

Executive Order 12866 requires that a regulatory impact analysis be performed on any economically significant rule. An economically significant rule is defined as one that would result in the annual effect on the national economy of $100 million or more, or have other substantial impact. The Regulatory Flexibility Act (RFA) requires that each Federal Agency prepare, and make available for public comment, a regulatory flexibility analysis when the agency issues regulations which would have a significant impact on a substantial number of small entities.

As previously mentioned this final rule is not a major rule under the Congressional Review Act, because its economic impact will be less than $100 million. The changes set forth in this final rule are revisions to existing regulation. The changes made in this final rule involve an expansion of TRICARE benefits. In addition, this final rule will have minor impact and will not significantly affect a substantial number of small entities. In light of the above, no regulatory impact analysis is required.

This final rule will not impose additional information collection requirements on the public under the Paperwork Reduction Act of 1995 (44 U.S.C. 55).

List of Subjects in 32 CFR Part 199

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, Military personnel.

■ Accordingly, 32 CFR part 199 is amended as follows:

PART 199—[AMENDED]

■ 1. The authority citation for Part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. 55.

■ 2. Section 199.2(b) is amended by revising the definitions of ''Durable medical eqiupment'', and ''Prosthetic devices (prosthesis)'', by adding definitions of ''Augmentative communication device'', ''Profound hearing loss'', ''Prosthetic'', ''Prosthetic supplies'', ''Rehabilitative therapy'', and ''Speech generating device'' in alphabetical order to read as follows:

§ 199.2 Definitions.

* * * * *

(b) * * *

Augmentative communication device (ACD). A voice prosthesis as determined by the Secretary of Defense to be necessary because of significant conditions resulting from trauma, congenital anomalies, or disease. Also referred to as Speech Generating Device.

* * * * *

Durable medical equipment. Equipment that—

(1) Can withstand repeated use;

(2) Is primarily and customarily used to serve a medical purpose; and

(3) Generally is not useful to an individual in the absence of an illness or injury.

Profound hearing loss (adults). An ''adult'' (a spouse as defined in section 32 CFR 199.3(b) of this part of a member of the Uniformed Services on active duty for more than 30 days) with a hearing threshold of:

(1) 40 dB HL or greater in one or both ears when tested at 500, 1,000, 1,500, 2,000, 3,000, or 4,000Hz; or

(2) 26 dB HL or greater in one or both ears at any three or more of those frequencies; or

(3) A speech recognition score less than 94 percent.

Profound hearing loss (children). A ''child'' (an unmarried child of an active duty member who otherwise meets the criteria (including age requirements) in 32 CFR 199.3 of this part) with a 26dB HL or greater hearing threshold level in one or both ears when tested in the frequency range at 500, 1,000, 2,000, 3,000 or 4,000 Hz.

* * * * *

Prosthetic or Prosthetic Device (prosthesis). A prosthetic or prosthetic device (prosthesis) determined by the Secretary of Defense to be necessary because of significant conditions resulting from trauma, congenital anomalies, or diseases.

Prosthetic supplies. Supplies that are necessary for the effective use of a prosthetic or prosthetic device.

* * * * *

Rehabilitative therapy. Any rehabilitative therapy that is necessary to improve, restore, or maintain function, or to minimize or prevent deterioration of function, of a patient and prescribed by a physician.

* * * * *

Speech generating device (SGD). See Augmentative Communication Device.

* * * * *

■ 3. Section 199.3 is amended by revising paragraph (e) to read as follows:

§ 199.3 Eligibility.

* * * * *

(e) Eligibility Under the Transitional Assistance Management Program (TAMP). (1) Transitional health care benefits under TRICARE are authorized for the following eligibles:

(i) A member who is involuntarily separated from active duty and the dependents of the member.

(ii) A member of a reserve component who is separated from active duty to which called or ordered in support of a contingency operation if the active duty is active duty for a period of more than 30 days and the dependents of the member.

(iii) A member who is separated from active duty for which the member is involuntarily retained under 10 U.S.C. 12305, is support of a contingency operation and the dependents of the member.

(iv) A member who is separated from active duty pursuant to a voluntary agreement of the member to remain on active duty for a period of less than one year in support of a contingency operation and the dependents of the member.

(2) Time period of eligibility. Transitional health care shall be available for a specified period of time for members and dependents beginning on the date which the member is separated as follows:

(i) For members separated with less than 6 years of active service, 60 days.

(ii) For members separated with 6 or more years of active service, 120 days.

* * * * *

■ 4. Section 199.4 is amended by revising paragraph (d)(3)(ii)(A), paragraph (d)(3)(vii), the text of paragraph (g)(41) preceding the note, paragraph (g)(47), paragraph (g)(51), by adding new paragraphs (e)(23), (e)(24), (e)(25), and by removing and reserving (g)(45) to read as follows:

§ 199.4 Basic program benefits.

* * * * *

(d) * * *

(3) * * *

(ii) * * *

(A) Scope of benefit. (*1*) Subject to the exceptions in paragraphs (d)(3)(ii)(B) and (d)(3)(ii)(C) of this section, only durable medical equipment (DME) which is ordered by a physician for the specific use of the beneficiary shall be covered.

(*2*) In addition, any customization of durable medical equipment owned by the patient is authorized to be provided to the patient and any accessory or item of supply for any such authorized durable medical equipment, may be provided to the patient if the customization, accessory, or item of supply is essential for—

(*i*) Achieving therapeutic benefit for the patient

(*ii*) Making the equipment serviceable; or

(*iii*) Otherwise assuring the proper functioning of the equipment.

(*3*) Further, equipment as defined in § 199.2 of this part and which:

(*i*) Is medically necessary for the treatment of a covered illness or injury;

(*ii*) Improves, restores, or maintains the function of a malformed, diseased, or injured body part, or can otherwise minimize or prevent the deterioration of the patient's function or condition;

(*iii*) Can maximize the patient's function consistent with the patient's physiological or medical needs;

(*iv*) Provides the medically appropriate level of performance and quality for the medical condition present (that is, nonluxury or nondeluxe);

(*v*) Is not otherwise excluded by this Regulation.

* * * * *

(vii) Prosthetics, prosthetic devices, and prosthetic supplies, as determined by the Secretary of Defense to be necessary because of significant conditions resulting from trauma, congenital anomalies, or disease. Additionally, the following are covered:

(A) Any accessory or item of supply that is used in conjunction with the device for the purpose of achieving therapeutic benefit and proper functioning;

(B) Services necessary to train the recipient of the device in the use of the device;

(C) Repair of the device for normal wear and tear or damage;

(D) Replacement of the device if the device is lost or irreparably damaged or

the cost of repair would exceed 60 percent of the cost of replacement.

* * * * *

(e) * * *

(23) A speech generating device (SGD) as defined in § 199.2 of this part is covered as a voice prosthesis. The prosthesis provisions found in paragraph (d)(3)(vii) of this section apply.

(24) A hearing aid, but only for a dependent of a member of the uniformed services on active duty and only if the dependent has a profound hearing loss as defined in § 199.2 of this part. Medically necessary and appropriate services and supplies, including hearing examinations, required in connection with this hearing aid benefit are covered.

(25) Rehabilitation therapy as defined in § 199.2 of this part to improve, restore, or maintain function, or to minimize or prevent deterioration of function, of a patient when prescribed by a physician. The rehabilitation therapy must be medically necessary and appropriate medical care, rendered by an authorized provider, necessary to the establishment of a safe and effective maintenance program in connecti9n with a specific medical condition, and must not be custodial care or otherwise excluded from coverage.

* * * * *

(g) * * *

(41) *Hair transplants, wigs/hair pieces/cranial prosthesis.*

Note: * * *

* * * * *

(45) [Reserved]

* * * * *

(47) *Eye and hearing examinations.* Eye and hearing examinations except as specifically provided in paragraphs (c)(2)(xvi), (c)(3)(xi), and (e)(24) of this section, or except when rendered in connection with medical or surgical treatment of a covered illness or injury.

* * * * *

(51) *Hearing aids.* Hearing aids or other auditory sensory enhancing devices, except those allowed in paragraph (e)(24) of this section.

* * * * *

■ 4. Section 199.14 is amended by redesignating paragraphs (k) through (n) as (l) through (o) and by adding a new paragraph (k) to read as follows:

§ 199.14 Provider reimbursement methods.

* * * * *

(k) *Reimbursement of Durable Medical Equipment, Prosthetics, orthotics and Supplies 9DMEPOS).* Reimbursement of DMEPOS may be based on the same amounts established under the Centers for Medicare and Medicaid Services (CMS) DMEPOS fee schedule under 42 CFR part 414, subpart D.

* * * * *

Dated: September 28, 2004

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD08–04–034]

RIN 1625–AA09

Drawbridge Operation Regulation; Tensas River, Clayton, LA

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is removing the existing drawbridge operation regulation for the draw of the Union Pacific Railroad bridge across the Tensas River, mile 27.2, at Clayton, Louisiana. The movable span of the bridge has been removed and the remains of the bridge are still in place. Since the movable span of the bridge has been removed, the regulation controlling the opening and closing of the bridge is no longer necessary.

DATES: This rule is effective October 12, 2004.

ADDRESSES: Documents referred to in this rule are available for inspection or copying at the office of the Eighth Coast Guard District, Bridge Administration Branch, 500 Poydras Street, New Orleans, Louisiana 70130–3310, between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (504) 589–2965. The Eighth District Bridge Administration Branch maintains the public docket for this rulemaking.

FOR FURTHER INFORMATION CONTACT: David Frank, Bridge Administration Branch, at (504) 589–2965.

SUPPLEMENTARY INFORMATION:

Good Cause for Not Publishing an NPRM

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds good cause exists for not publishing an NPRM. Public comment is not necessary since the bridge that the regulation governed is out of service and mariners are no longer required to request an opening to transit through the bridge.

Good Cause for Making Rule Effective in Less Than 30 Days

Under 5 U.S.C. 553(d)(3), the Coast Guard finds good cause exists for making this rule effective in less than 30 days after publication in the **Federal Register**. There is no need to delay the implementation of this rule because the bridge it governs is already out of service and mariners are no longer required to request an opening.

Background and Purpose

The movable span of the railroad bridge across the Tensas River, mile 27.2, which had previously serviced the area has been removed and the remaining portions of the bridge presently remain in place. These remaining portions of the bridge will be removed in the near future or permitted to remain in place by the U.S. Army Corps of Engineers. Since the movable span has been removed, mariners are no longer required to request openings for the bridge. The regulation governing the operation of the bridge is found in 33 CFR 117.503(a). The purpose of this rule is to remove 33 CFR 117.503(a) from the Code of Federal Regulations since it governs a bridge that is no longer in service and the movable span has been removed.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS).

We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary.

This rule removes the special regulation for a bridge that is already out of service.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises