

§ 890.3500 External assembled lower limb prosthesis.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 890.9.

68. Section 890.3710 is amended by revising paragraph (b) to read as follows:

§ 890.3710 Powered communication system.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 890.9.

69. Section 890.3725 is amended by revising paragraph (b) to read as follows:

§ 890.3725 Powered environmental control system.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 890.9.

70. Section 890.5160 is amended by revising paragraph (b) to read as follows:

§ 890.5160 Air-fluidized bed.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 890.9.

71. Section 890.5170 is amended by revising paragraph (b) to read as follows:

§ 890.5170 Powered flotation therapy bed.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 890.9.

72. Section 890.5225 is amended by revising paragraph (b) to read as follows:

§ 890.5225 Powered patient rotation bed.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 890.9.

73. Section 890.5720 is amended by revising paragraph (b) to read as follows:

§ 890.5720 Water circulating hot or cold pack.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 890.9.

74. Section 890.5740 is amended by revising paragraph (b) to read as follows:

§ 890.5740 Powered heating pad.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E part 807 of this chapter subject to § 890.9.

PART 892—RADIOLOGY DEVICES

75. The authority citation for 21 CFR part 892 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

76. Section 892.9 is amended by designating the introductory text as paragraph (a), by redesignating paragraphs (a) and (b) as paragraphs (a)(1) and (a)(2), respectively, and by adding new paragraph (b) to read as follows:

§ 892.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

* * * * *

(b) The exemption from the requirement of premarket notification for a generic type of class II device applies only to those class II devices that have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type, or, in the case of in vitro diagnostic devices, for which a misdiagnosis, as a result of using the device, would not be associated with high morbidity or mortality. A class II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification when:

(1) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(2) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(3) The device is an in vitro device that is intended:

(i) For use in the diagnosis, monitoring, or screening of neoplastic

diseases with the exception of immunohistochemical devices;

(ii) For use in screening or diagnosis of familial and acquired genetic disorders, including inborn errors of metabolism;

(iii) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

(iv) For assessing the risk of cardiovascular diseases;

(v) For use in diabetes management;

(vi) For identifying or inferring the identity of a microorganism directly from clinical material;

(vii) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) and IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(viii) For noninvasive testing; and

(ix) For near patient testing (point of care).

77. Section 892.1980 is amended by revising paragraph (b) to read as follows:

§ 892.1980 Radiologic table.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 892.9.

Dated: October 22, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98-29189 Filed 11-2-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF DEFENSE**Office of the Secretary****32 CFR Part 199**

RIN 0720-AA42

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); State Victims of Crime Compensation Programs; Voice Prosthesis

AGENCY: Office of the Secretary, DoD.

ACTION: Final rule.

SUMMARY: This final rule establishes CHAMPUS as primary payer to State Victims of Crime Compensation Programs; and voice prostheses as a CHAMPUS benefit.

EFFECTIVE DATES: Amendments to §§ 199.2 and 199.8 are effective

September 13, 1994 and § 199.4(g)(48) is effective October 5, 1994.

FOR FURTHER INFORMATION CONTACT: Connie Kiese, TRICARE Management Activity, Office of Medical Benefits and Reimbursement Systems (303) 676-3578.

SUPPLEMENTARY INFORMATION: On October 20, 1997, DoD published an interim rule with a public comment period; however, no comments were received. Therefore, the interim final rule is being adopted as the final rule.

Under 10 U.S.C. 1079(j)(1), no CHAMPUS benefits shall be available for the payment for any service or supply for persons enrolled in any other insurance, medical service, or health plan to the extent that the service or supply is a benefit under the other plan, except in the case of those plans administered under title XIX of the Social Security Act (Medicaid), (51 FR 24008). Therefore, in all double coverage situations, and for all classes of beneficiaries, CHAMPUS shall be secondary payer except when the other medical coverage is provided through Medicaid.

However, on September 13, 1994, Public Law 103-322 was signed into law. Section 230202 of that law states that notwithstanding any other law, if the compensation paid by an eligible crime victim compensation plan would cover costs that a Federal program or a federally financed State or local program would otherwise pay, the crime compensation program shall not pay that compensation; and the other program shall make its payments without regard to the existence of the crime victim compensation program.

This provision mandates, as an exception to 10 U.S.C. 1079(j)(1), that CHAMPUS assume primary payer status to State Victims of Crime Compensation Programs. Benefits will be granted retroactively effective September 13, 1994.

Public Law 103-337, Section 705, October 5, 1994, added voice prostheses to the benefits available under CHAMPUS. Benefits will be granted retroactively effective October 5, 1994.

Regulatory Procedures

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 a regulation which would have a significant impact on a substantial number of small entities.

This is not such a regulation. Nor is this final rule a significant regulatory action under Executive Order 12866.

The changes set forth in this final rule are minor revisions to the existing regulation. In addition, this final rule does not impose new information collection requirements for purposes of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3511).

List of Subjects in 32 CFR Part 199

Claims, Handicapped, Health Insurance, Military personnel.

PART 199—[AMENDED]

Accordingly, 32 CFR part 199 is amended as follows:

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

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

2. Section 199.2(b) is amended by revising the definition "State Victims of Crime Compensation Programs" to read as follows:

§ 199.2 Definitions

* * * * *

(b) * * *

State victims of crime compensation programs. Benefits available to victims of crime under the Violent Crime Control and Law Enforcement Act.

* * * * *

3. Section 199.4 is amended by revising paragraph (g)(48) to read as follows:

§ 199.4 Basic program benefits

* * * * *

(g) * * *

(48) *Prosthetic devices.* Prostheses, except artificial limbs, voice prostheses, eyes, or if an item is inserted surgically in the body as an integral part of a surgical procedure. All dental prostheses are excluded, except for those specially required in connection with otherwise covered orthodontia directly related to the surgical correction of a cleft palate anomaly.

* * * * *

4. Section 199.8 is amended by revising paragraphs (b)(3)(iii), (b) (3)(iv) and (b)(3)(v) to read as follows:

§ 199.8 Double coverage.

* * * * *

(b) * * *

(3) * * *

(iii) Entitlement to receive care from Uniformed Services medical care facilities;

(iv) Certain Federal Government programs, as prescribed by the Director, OCHAMPUS, that are designed to provide benefits to a distinct beneficiary population and for which entitlement does not derive from either premium payment of monetary contribution (for example, the Indian Health Service); or

(v) State Victims of Crime Compensation Programs.

* * * * *

Dated: October 19, 1998.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 98-28414 Filed 11-2-98; 8:45 am]

BILLING CODE 5000-04-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD 05-98-093]

RIN 2115-AE46

Special Local Regulations for Marine Events; Blackbeard's Bounty Festival Pirate Attack, Bogue Sound, Morehead City, North Carolina

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: Temporary special local regulations are being adopted for the Blackbeard's Bounty Festival Pirate Attack to be held in the waters of Bogue Sound, between the Morehead City waterfront and Sugar Loaf Island, North Carolina. These special local regulations are necessary to control vessel traffic in the immediate vicinity of this event. The effect will be to restrict general navigation in the regulated area for the safety of spectators, event participants, and transiting vessels.

EFFECTIVE DATE: This regulation is effective from 1:30 p.m. to 6 p.m. on November 7, 1998.

FOR FURTHER INFORMATION CONTACT: Petty Officer Matheny, Marine Events Coordinator, Commander, Coast Guard Group Fort Macon, P.O. Box 237, Atlantic Beach, North Carolina 28512-0237, telephone number (252) 247-4570.

SUPPLEMENTARY INFORMATION:

Regulatory History

In accordance with 5 U.S.C. 553, a notice of proposed rulemaking was not published for this regulation and good cause exists for making it effective in less than 30 days from the date of publication. Following normal rulemaking procedures would have been impractical. The request to hold the event was not received until October 9, 1998. Publishing a notice of proposed rulemaking and delaying its effective date would be contrary to safety interests, since immediate action is needed to minimize potential danger to the participants in this event.