

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. chapter 55.

■ 2. Section 199.4 is amended by revising paragraph (e)(19)(v) to read as follows:

§ 199.4 Basic program benefits.

* * * * *

(e) * * *

(19) * * *

(v) *Periods of care.* Hospice care is divided into distinct periods of care. The periods of care that may be elected by the terminally ill CHAMPUS beneficiary shall be as the Director, TRICARE determines to be appropriate, but shall not be less than those offered under Medicare's Hospice Program.

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■ 3. Section 199.14 is amended by revising paragraphs (a)(1)(ii)(C)(3), (a)(1)(iii)(A)(2), and (j)(1)(ix) to read as follows:

§ 199.14 Provider reimbursement methods.

* * * * *

(a) * * *

(1) * * *

(ii) * * *

(C) * * *

(3) All services related to heart and liver transplantation for admissions prior to October 1, 1998, which would otherwise be paid under the respective DRG.

* * * * *

(iii) * * *

(A) * * *

(2) Remove DRGs. Those DRGs that represent discharges with invalid data or diagnoses insufficient for DRG assignment purposes are removed from the database.

* * * * *

(j) * * *

(1) * * *

(ix) The allowable charge for physician assistant services other than assistant-at-surgery shall be at the same percentage, used by Medicare, of the allowable charge for a comparable service rendered by a physician performing the service in a similar location. For cases in which the physician assistant and the physician perform component services of a procedure other than assistant-at-surgery (e.g., home, office, or hospital visit), the combined allowable charge for the procedure may not exceed the allowable charge for the procedure rendered by a physician alone. The allowable charge for physician assistant

services performed as an assistant-at-surgery shall be at the same percentage, used by Medicare, of the allowable charge for a physician serving as an assistant surgeon when authorized as CHAMPUS benefits in accordance with the provisions of § 199.4(c)(3)(iii). Physician assistant services must be billed through the employing physician who must be an authorized CHAMPUS provider.

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Dated: June 20, 2012.

Patricia L. Toppings,
OSD Federal Register Liaison Officer,
Department of Defense.

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

[DOD-2011-HA-0058]

RIN 0720-AB51

TRICARE; Constructive Eligibility for TRICARE Benefits of Certain Persons Otherwise Ineligible Under Retroactive Determination of Entitlement to Medicare Part A Hospital Insurance Benefits

AGENCY: Office of the Secretary, Department of Defense.

ACTION: Final rule.

SUMMARY: The Department is publishing this final rule to implement section 706 of the National Defense Authorization Act (NDAA) for Fiscal Year 2010, Public Law 111-84. Specifically, section 706 exempts TRICARE beneficiaries under the age of 65 who become disabled from the requirement to enroll in Medicare Part B for the retroactive months of entitlement to Medicare Part A in order to maintain TRICARE coverage. This statutory amendment and final rule only impact eligibility for the period in which the beneficiary's disability determination is pending before the Social Security Administration. Eligible beneficiaries are still required to enroll in Medicare Part B in order to maintain their TRICARE coverage for future months, but are considered to have coverage under the TRICARE program for the retroactive months of their entitlement to Medicare Part A. This final rule also amends the eligibility section of the TRICARE regulation to more clearly address reinstatement of TRICARE eligibility following a gap in coverage due to lack of enrollment in Medicare Part B.

DATES: *Effective Date:* This final rule is effective July 27, 2012.

FOR FURTHER INFORMATION CONTACT: Ms. Anne Breslin, TRICARE Operations Branch, TRICARE Management Activity (TMA), 5111 Leesburg Pike, Suite 810, Falls Church, VA 22041, telephone (703) 681-0039.

SUPPLEMENTARY INFORMATION:**I. Background**

Prior to the enactment of section 706 of the National Defense Authorization Act for Fiscal Year 2010 (Pub. L. 111-84), 10 U.S.C. 1086(d) provided that a person who would otherwise receive benefits under section 1086 who is entitled to Medicare Part A hospital insurance is not eligible for TRICARE unless the individual is enrolled in Medicare Part B. When a TRICARE beneficiary becomes eligible for Medicare, Medicare becomes the primary payer and TRICARE is the secondary payer. Retroactive Medicare eligibility determinations therefore caused DoD and Medicare to reprocess claims. Section 706 of the Fiscal Year 2010 National Defense Authorization Act amended 10 U.S.C. 1086(d) to exempt TRICARE beneficiaries under the age of 65 who became Medicare eligible due to a retroactive disability determination from the requirement to enroll in Medicare Part B for the retroactive months of entitlement to Medicare Part A in order to maintain TRICARE coverage. This statutory amendment became effective upon enactment of the Fiscal Year 2010 National Defense Authorization Act on October 28, 2009. Prior to this amendment, beneficiaries who did not purchase Medicare Part B to cover the retroactive period lost their TRICARE eligibility during that period of time. As a result, beneficiaries and providers were then subject to TRICARE recoupment action for care provided during the period of retroactive disability. Pursuant to this amendment, TRICARE remains first payer for any claims filed during the retroactive months and disabled TRICARE beneficiaries are relieved of the financial burden of making retroactive payments to avoid a gap in coverage. This final rule amends the Code of Federal Regulations to conform to current statutory authority regarding TRICARE eligibility.

Additionally, due to an earlier administrative omission, this final rule also amends 32 CFR 199.3 to more clearly address reinstatement of TRICARE eligibility following a gap in coverage due to lack of enrollment in Part B. While most TRICARE

beneficiaries who become eligible for Medicare Part A maintain TRICARE coverage through prompt acceptance of Part B coverage, there are a number of beneficiaries that for one reason or another decline Part B and lose their TRICARE eligibility. For those individuals, they can have that eligibility reinstated at a later date if they re-enroll in Part B. This final rule amends the section on reinstatement of TRICARE eligibility to include beneficiaries who elect to enroll in Medicare Part B following a gap in TRICARE coverage.

II. Public Comments

We provided a 60-day public comment period following publication of the Proposed Rule in the Federal Register (76 FR 58204–58206) on September 20, 2011. We received no public comments.

III. Regulatory Procedures

Executive Order 12866, "Regulatory Planning and Review"; Executive Order 13563, "Improving Regulation and Regulatory Review"; and Public Law 96-354, "Regulatory Flexibility Act" (5 U.S.C. 601)

Executive Orders 12866 and 13563 require that a 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. 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 rule is not an economically significant regulatory action and will not have a significant impact on a substantial number of small entities for purposes of the RFA, thus this final rule is not subject to any of these requirements.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3511)

This rule will not impose additional information collection requirements on the public. OMB previously cleared the collection requirements under OMB Control Number 0704–0364.

Executive Order 13132, "Federalism"

We have examined the impact(s) of the rule under Executive Order 13132, and it does not have policies that have federalism implications that would have substantial direct effects on the States, on the relationship between the national

government and the States, or on the distribution of power and responsibilities among the various levels of government, therefore, consultation with State and local officials is not required.

Sec. 202, Public Law 104–4, "Unfunded Mandates Reform Act"

This rule does not contain unfunded mandates. It does not contain a Federal mandate that may result in the expenditure by State, local, and tribal governments, in aggregate, or by the private sector, of \$100 million or more in any one year.

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. chapter 55.

■ 2. Section 199.3 is amended by:

- a. Adding paragraph (f)(2)(iii);
■ b. Revising paragraph (f)(3)(ix)(C); and
■ c. Adding paragraph (g)(3) to read as follows:

§ 199.3 Eligibility.

* * * * *

(f) * * *

(2) * * *

(iii) Attainment of entitlement to hospital insurance benefits (Part A) under Medicare except as provided in paragraphs (b)(3), (f)(3)(vii), (f)(3)(viii) and (f)(3)(ix) of this section.

(3) * * *

(ix) * * *

(C) The individual is enrolled in Part B of Medicare except that in the case of a retroactive determination of entitlement to Medicare Part A hospital insurance benefits for a person under 65 years of age there is no requirement to enroll in Medicare Part B from the Medicare Part A entitlement date until the issuance of such retroactive determination; and

* * * * *

(g) * * *

(3) Enrollment in Medicare Part B. For individuals whose CHAMPUS eligibility has terminated pursuant to paragraph (f)(2)(iii) or (f)(3)(vi) of this section due to beneficiary action to decline Part B of Medicare, CHAMPUS eligibility resumes, effective on the date Medicare Part B coverage begins, if the person subsequently enrolls in Medicare Part B and the person is otherwise still eligible.

■ 3. Section 199.8 is amended by:

- a. Revising paragraph (d)(1)(i);
■ b. Redesignating paragraphs (d)(1)(vi), (d)(1)(vii) and (d)(1)(viii) as (d)(1)(vii), (d)(1)(viii), and (d)(1)(ix) respectively; and
■ c. Adding new paragraph (d)(1)(vi) to read as follows.

§ 199.8 Double coverage.

* * * * *

(d) * * *

(1) * * *

(i) General rule. In any case in which a beneficiary is eligible for both Medicare and CHAMPUS received medical or dental care for which payment may be made under Medicare and CHAMPUS, Medicare is always the primary payer except in the case of retroactive determinations of disability as provided in paragraph (d)(1)(v) of this section. For dependents of active duty members, payment will be determined in accordance to paragraph (c) of this section. For all other beneficiaries eligible for Medicare, the amount payable under CHAMPUS shall be the amount of actual out-of-pocket costs incurred by the beneficiary for that care over the sum of the amount paid for that care under Medicare and the total of all amounts paid or payable by third party payers other than Medicare.

* * * * *

(vi) Retroactive determinations of disability. In circumstances involving determinations of retroactive Medicare Part A entitlement for persons under 65 years of age, Medicare becomes the primary payer effective as of the date of issuance of the retroactive determination by the Social Security Administration. For care and services rendered prior to issuance of the retroactive determination, the CHAMPUS payment will be determined consistent with paragraph (d)(1)(iii)(B) of this section notwithstanding the beneficiary's retroactive entitlement for Medicare Part A during that period.

* * * * *

■ 4. Section 199.11 is amended by revising paragraph (f)(3) to read as follows:

§ 199.11 Overpayments recovery.

* * * * *

(f) * * *

(3) Claims arising from erroneous TRICARE payments in situations where the beneficiary has entitlement to an insurance, medical service, health and medical plan, including any plan offered by a third party payer as defined in 10 U.S.C. 1095(h)(1) or other government program, except in the case of a plan administered under Title XIX

of the Social Security Act (42 U.S.C. 1396, *et seq.*) through employment, by law, through membership in an organization, or as a student, or through the purchase of a private insurance or health plan, shall be recouped following the procedures in paragraph (f) of this section. If the other plan has not made payment to the beneficiary or provider, the contractor shall first attempt to recover the overpayment from the other plan through the contractor's coordination of benefits procedures. If the overpayment cannot be recovered from the other plan, or if the other plan has made payment, the overpayment will be recovered from the party that received the erroneous payment from TRICARE. Nothing in this section shall be construed to require recoupment from any sponsor, beneficiary, provider, supplier and/or the Medicare Program under Title XVIII of the Social Security Act in the event of a retroactive determination of entitlement to SSDI and Medicare Part A coverage made by the Social Security Administration as discussed in § 199.8(d) of this part.

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Dated: June 20, 2012.

Patricia L. Toppings,
OSD Federal Register Liaison Officer,
Department of Defense.

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DOD-2008-HA-0090]

RIN 0720-AB23

TRICARE; Off-Label Uses of Devices; Partial List of Examples of Unproven Drugs, Devices, Medical Treatments, or Procedures

AGENCY: Office of the Secretary, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: The Department of Defense is publishing this final rule to revise the definition of “unlabeled or off-label drug” to “off-label use of a drug or device.” This provision codifies the coverage of those medically necessary indications for which there are demonstrations from medical literature, national organizations, or technology assessment bodies that the off-label use is safe and effective and in accordance with nationally accepted standards of practice in the medical community. Additionally, this rule removes the

partial list of examples of unproven drugs, devices, and medical treatments or procedures proscribed in TRICARE regulations. We are removing the partial list from the regulation but will maintain the partial list in the TRICARE Policy Manual at www.tricare.mil.

DATES: *Effective Date:* This rule is effective July 27, 2012.

FOR FURTHER INFORMATION CONTACT: Ms. Elan Green, TRICARE Management Activity, Medical Benefits and Reimbursement Branch, telephone (303) 676-3907.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 31, 2009 (74 FR 44797-44798), the Office of the Secretary of Defense published for public comment a proposed rule that revised the definition of “unlabeled or off-label drug” to “off-label use of a drug or device.” In addition this proposed rule removed the partial list of examples of unproven drugs, devices, and medical treatments or procedures proscribed under Section 199.4(g)(15).

Off-Label Uses of Devices

On January 6, 1997, the Office of the Secretary of Defense published a final rule in the **Federal Register** (62 FR 627-631) clarifying the TRICARE exclusion of unproven drugs, devices, and medical treatments or procedures and adding the TRICARE definition of unlabeled or off-label drugs. This rule also added the provision for coverage of unlabeled or off-label uses of drugs that are Food and Drug Administration (FDA) approved drugs that are prescribed or administered by a health care practitioner and are used for indications or treatments not included in the approved labeling. We are now modifying the definition of “unlabeled or off-label drug” to “off-label use of a drug or device,” which includes a drug, biologic or device under the regulatory authority of the FDA. However, this proposed rule does not present new agency policy. Rather, it corrects an error and omission from the current rule. Coverage is limited to those indications for which there are demonstrations from medical literature, national organizations, or technology assessment bodies that the off-label use is safe and effective and in accordance with nationally accepted standards of practice in the medical community. In addition, the off-label use must be reviewed for medical necessity.

In general, good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics, and devices, including

combination products, according to their best knowledge and judgment. When providers use a product for an indication not in the approved labeling, they have a responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence. Limiting CHAMPUS cost-sharing to those off-label uses for which there are demonstrations from medical literature, national organizations, or technology assessment bodies that the off-label use is safe, effective, and in accordance with nationally accepted standards of practice in the medical community will help to ensure there is sufficient scientific evidence supporting the off-label use, without being overly onerous, while still promoting innovations in medical practice that benefit patients.

In reviewing the proposed rule, we discovered that we had inadvertently incorporated the TRICARE reliable evidence standard (as defined in 32 CFR 199.2) as the threshold for reviewing coverage for off-label or unlabeled use. The intent was not to make the standard of review more onerous but rather to expand the application of the existing provision regarding the cost-sharing of off-label use of drugs to also include the off-label use of devices and biologics. As a result, we are withdrawing the changes to the third paragraph of the Note to paragraph (g)(15)(i)(A) in section 199.4 with the exception of replacing the term “unlabeled or off-label uses of drugs” with “off-label uses of drugs and devices,” with an appropriate reference back to the definition of the term in 199.2. “Off-label uses of drugs and devices” includes off-label uses of drugs, biologics, devices, and combination products.

Although most biological products meet the definition of “drugs” under the Federal Food, Drug and Cosmetic Act, and are also regulated under that law, biological products are approved for marketing under the Public Health Services Act by means of a biologics license application. Thus, the definition of “off-label use of a drug or device” has been revised to acknowledge both the Federal Food, Drug and Cosmetic Act and the Public Health Services Act as sources of the FDA's regulatory authority over the marketing of these products.

Partial List of Examples of Unproven Drugs, Devices, and Medical Treatments or Procedures

By law, TRICARE can cost-share only medically necessary supplies and services. Any drug, device, and medical treatment or procedure, the safety and efficacy of which have not been