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# Submission of Federal Rules Under the Congressional Review Act

President of the Senate  Speaker of the House of Representatives  GAO

Please fill the circles electronically or with black pen or #2 pencil.

1. Name of Department or Agency

2. Subdivision or Office

Department of Defense

Office of the Secretary

3. Rule Title

TRICARE Program; Inclusion of Anesthesiologist Assistants as Authorized Providers; Coverage of Cardiac Rehabilitation in Freestanding Cardiac Rehabilitation Facilities.

4. Rule Identification Number (RIN) or Other Unique Identifier (if applicable) 0720-AA76

5. Major Rule  Non-major Rule

6. Final Rule  Other

7. With respect to this rule, did your agency solicit public comments? Yes  No  N/A

8. Priority of Regulation (fill in one)

Economically Significant; or Significant; or Substantive, Nonsignificant

Routine and Frequent or Informational/Administrative/Other  
(Do not complete the other side of this form if filled in above.)

9. Effective Date (if applicable) 30 days from date of publication

10. Is a concise Summary of the Rule provided? Yes  No

Submitted by: [Signature] (signature)

Name: L.M. BYNUM, Alternate OSD Federal

Title: Register Liaison Officer, DoD 5/12/04

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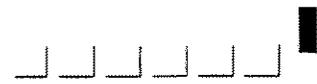
For Congressional Use Only:

Date Received: \_\_\_\_\_

Committee of Jurisdiction: \_\_\_\_\_



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Yes No N/A

- A. With respect to this rule, did your agency prepare an analysis of costs and benefits?  Yes  No  N/A
- B. With respect to this rule, at the final rulemaking stage, did your agency
  - 1. certify that the rule would not have a significant economic impact on a substantial number of small entities under 5 U.S.C. § 605(b)?  Yes  No  N/A
  - 2. prepare a final Regulatory Flexibility Analysis under 5 U.S.C. § 604(a)?  Yes  No  N/A
- C. With respect to this rule, did your agency prepare a written statement under § 202 of the Unfunded Mandates Reform Act of 1995?  Yes  No  N/A
- D. With respect to this rule, did your agency prepare an Environmental Assessment or an Environmental Impact Statement under the National Environmental Policy Act (NEPA)?  Yes  No  N/A
- E. Does this rule contain a collection of information requiring OMB approval under the Paperwork Reduction Act of 1995?  Yes  No  N/A
- F. Did you discuss any of the following in the preamble to the rule?
  - E.O. 13132, Federalism  Yes  No  N/A
  - E.O. 12630, Government Actions and Interference with Constitutionally Protected Property Rights  Yes  No  N/A
  - E.O. 12866, Regulatory Planning and Review  Yes  No  N/A
  - E.O. 12988, Civil Justice Reform  Yes  No  N/A
  - E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks  Yes  No  N/A
  - Other statutes or executive orders discussed in the preamble concerning the rulemaking process (please specify)

CONCISE GENERAL STATEMENT  
IN ACCORDANCE WITH  
SECTION 801 OF PUBLIC LAW 104-121  
0720-AA76

This final rule establishes a new category of provider as an authorized TRICARE provider, and it increases the settings where cardiac rehabilitation can be covered as a TRICARE benefit. It recognizes anesthesiologist assistants as authorized providers under certain circumstances. It also authorizes cardiac rehabilitation services, which are already a covered TRICARE benefit when provided by hospitals, to be provided in freestanding cardiac rehabilitation facilities.

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DEPARTMENT OF DEFENSE

Billing Code 5001-06

Office of the Secretary

32 CFR Part 199

RIN 0720-AA76

TRICARE Program; Inclusion of Anesthesiologist Assistants as Authorized Providers; Coverage of Cardiac Rehabilitation in Freestanding Cardiac Rehabilitation Facilities.

**AGENCY:** Office of the Secretary, DoD.

**ACTION:** Final rule.

**SUMMARY:** This final rule establishes a new category of provider as an authorized TRICARE provider and it increases the settings where cardiac rehabilitation can be covered as a TRICARE benefit. It recognizes anesthesiologist assistants (AAs) as authorized providers under certain circumstances. It also authorizes cardiac rehabilitation services, which are already a covered TRICARE benefit when provided by hospitals, to be provided in freestanding cardiac rehabilitation facilities.

**DATES:** This rule is effective [insert date of publication]. Comments on the addition of §199.6 (e)(3)(iii)(J) will be accepted until [insert 30 days after publication]. The chart below identifies start Healthcare Delivery dates of this rule in various areas.

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T-NEX Region/Contractor	States	Start Healthcare Delivery
North (Health Net Federal Services, Inc.)	Illinois, Indiana, Kentucky, Michigan, Ohio, Wisconsin, West Virginia, Virginia (except the Northern Virginia/National Capital Area), North Carolina, Eastern Iowa, Rock Island, IL, Fort Campbell catchment area of Tennessee	July 1, 2004
	Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Northern Virginia, West Virginia (portion)	September 1, 2004
South (Humana Military Healthcare Services)	Oklahoma, Arkansas and major portions of Texas and Louisiana	November 1, 2004
	Alabama, Florida, Georgia, Mississippi, Eastern Louisiana, South Carolina, Tennessee, small area of Arkansas, New Orleans area	August 1, 2004
West (TriWest Healthcare Alliance Corp.)	Washington, Oregon, Northern Idaho	June 1, 2004
	California, Hawaii, Alaska	July 1, 2004
	Arizona, Colorado, Idaho, Iowa, Kansas, Minnesota, Missouri, Montana, Nebraska, Nevada, New Mexico, North Dakota, South Dakota, western portion of Texas, Wyoming	October 1, 2004

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**ADDRESSES:** TRICARE Management Activity (TMA), Medical Benefits and Reimbursement Systems, 16401 East Centretch Parkway, Aurora, CO 80011-9043.

**FOR FURTHER INFORMATION CONTACT:** Stan Regensberg, Medical Benefits and Reimbursement Systems, TMA, (303) 676-3742.

**SUPPLEMENTARY INFORMATION:**

**I. Summary of Final Rule Provisions**

**A. Inclusion of Anesthesiologist Assistants as Authorized Providers:**

At present only two types of anesthesia providers may provide services to TRICARE beneficiaries—anesthesiologists and certified registered nurse anesthetists (CRNAs). In some areas of the country, anesthesiologist assistants, after completing the specified training, being accredited, and, where required, being licensed by the state also provide anesthesia services. The Centers for Medicare and Medicaid Services (CMS) already recognizes anesthesiologist assistants as authorized providers (42 CFR 410.69). This final rule establishes anesthesiologist assistants as authorized providers under the same conditions applied by CMS.

The reader should refer to the proposed rule that was published on April 3, 2003, (68 FR 16247) for detailed information regarding this action.

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**B. Coverage of Cardiac Rehabilitation in Freestanding Cardiac Rehabilitation**

**Centers**

Currently TRICARE provides coverage/payment for inpatient or outpatient services and/or supplies provided in connection with a cardiac rehabilitation program when provided by a TRICARE authorized hospital. Since hospital based cardiac rehabilitation is already an established benefit under TRICARE, this final rule simply applies that benefit and reimbursement structure to freestanding cardiac rehabilitation programs.

The reader should refer to the proposed rule that was published on April 3, 2003, (68 FR 16247) for detailed information regarding this benefit and reimbursement for it.

**C. Clarification Regarding the Status of Certified Registered Nurse Anesthetists**

TRICARE is issuing a provision for certified registered nurse anesthetists (CRNAs). It provides a separate designation for CRNAs by clarifying their existing status in the TRICARE program as an independent provider operating under their state licensure and meeting the requirements for a certified registered nurse anesthetist.

**II. Public Comments**

We received no comments regarding the coverage of cardiac rehabilitation services in freestanding cardiac rehabilitation facilities.

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We received a large number of comments, both in support of and opposed to, our proposal to authorize AAs as TRICARE providers. The comments were from individuals as well as national organizations representing groups of providers. The following comments were in support of our proposal.

*Comment:* A number of anesthesiologists commented that they employ AAs and are very satisfied with their services.

*Comment:* A number of commenters noted that AAs are recognized by many commercial insurances and managed care plans.

*Comment:* Many commenters, both individuals and national provider organizations, described the extensive training that AAs receive. They noted that the training lasts for 24 – 27 months and includes master's level coursework after a bachelor's degree that must include pre-medical courses such as biology, chemistry, physics, and calculus. The training also includes 2,500 hours of direct patient contact of clinical rotations in every area of anesthesia (i.e., trauma, cardiac, thoracic, obstetrical, pediatric, etc.). They also noted that the AA training programs are nationally accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP) which accredits training programs for 2,100 other allied health educational programs at 1,300 institutions.

Presently, there are two AA training programs (Case Western Medical School and Emory

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University Medical School) with another to begin shortly (South University Medical School). Graduates of the programs must pass a national certification examination administered by the National Board of Medical Examiners for the National Commission for Certification of Anesthesiologist Assistants. This examination is administered the first Saturday in June and has a six hour duration. The exam may occur prior to graduation; however, all course work and instruction has been completed by the date of the exam. Additional clinical experience finishes out the time from exam to graduation. Upon graduation, the AA will be told whether he or she has passed the exam. The AA can not practice without official notification that he or she has passed the exam.

*Comment:* Many commenters noted that in order to practice their profession, AAs must pass a national certification examination administered by the National Board of Medical Examiners for the National Commission for Certification of Anesthesiologist Assistants. In addition, AAs must have 40 hours of continuing medical education every two years and complete a recertification every six years.

As stated above, we also received a number of comments that were opposed to our proposal to authorize AAs as TRICARE providers. Since these comments disagree with our final decision, we provide a response to each comment to explain why we have elected to authorize AAs as TRICARE providers.

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*Comment:* A number of commenters stated that only five states license AAs and questioned why TRICARE should recognize AAs “if most of the country does not recognize the AA practice”.

*Response:* As stated in the proposed rule, we will require that AAs comply with all applicable requirements of state law and be licensed, where applicable, by the state in which they practice. As described in section 199.6(c)(2) of this part describing conditions of authorization for individual providers, in jurisdictions that do not license a specific category of individual professional, certification by a Qualified Accreditation Organization is required. As described in section 199.6(c)(3) of this part, in jurisdictions that do not provide for licensure or certification, the provider must be certified by or eligible for full clinical membership in the appropriate national professional association that sets standards for the specific profession. The fact that AAs are required to be licensed in six states and not all is not pertinent. Many other states recognize them, but do not require them to be licensed and we believe that their qualifications justify TRICARE recognition.

*Comment:* A national provider organization noted that AAs have been recognized by Medicare since 1983, and that CMS considers AAs and CRNAs to be equivalent providers and uses the term “anesthetist” for both professions.

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*Response:* However, TRICARE recognizes the increased training required by certified registered nurse anesthetists compared to AAs, and as a result, authorizes CRNAs to practice independent of physician supervision in those states where the licensure permits. TRICARE is publishing a provision in this rule to clarify CRNAs' authority to practice independently.

*Comment:* Many commenters stated that AAs may not be the solution to correct the current national anesthesia provider shortage, since they must be supervised by an anesthesiologist.

*Response:* We did not propose authorizing AAs in order to alleviate any provider shortage or to solve any other problem. Our proposal was based on the fact that they are certified by a nationally recognized organization, are a recognized provider in many states and by many third-party payers, are licensed by several states, and are authorized under Medicare.

*Comment:* One national provider organization questioned if recognizing AAs will increase TRICARE costs.

*Response:* It will not. As we stated in the proposed rule, payment for anesthesia services provided by an anesthesiologist and an AA under the anesthesiologist's direct supervision

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will never exceed what would have been paid if the services were provided only by the anesthesiologist.

*Comment:* A number of commenters noted that the military system requires healthcare providers who can be mobilized at a moment's notice to provide quick response in military conflicts. It is not effective to deploy AAs who would have to be accompanied by an anesthesiologist.

*Response:* We want to stress that this final rule affects only services provided in civilian facilities and is wholly separate from services provided within the military's direct care system. AAs will not practice in MTFs; they will not be commissioned, nor will they deploy to support our troops.

*Comment:* Many commenters suggested that TRICARE should conduct a study on the safety record and cost effectiveness of AAs before recognizing them.

*Response:* We believe the issue of cost effectiveness is moot, as explained above. With regard to a study of the safety record of AAs, we don't believe this is necessary for several reasons. First, CMS has recognized AAs for 20 years and there have been no issues of safety. Second, a national provider organization stated that the professional liability insurance rates charged to AAs and nurse anesthetists are the same, and there is no evidence to indicate there is any difference between AAs and nurse anesthetists with

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respect to claims filed. Perhaps most importantly, two national organizations representing physicians have strongly endorsed our proposal, and the physician is ultimately the person most responsible for patient safety. Third, AAs will not be recognized as individual professional providers with the ability to bill independently, but rather as extenders of the anesthesiologist who is responsible for direct supervision of the AA or AAs.

*Comment:* One commenter noted that when CMS proposed allowing CRNAs to practice without physician supervision in 1997 this was opposed, and the final rule called for a patient safety study to be conducted. The commenter believes AAs should be included in this study.

*Response:* As stated above, we do not believe a study of the safety of AAs is necessary. In addition, a study of whether an allied health professional can safely practice without physician supervision is an entirely different issue from what we have proposed, since we will require AAs to be under the direct supervision of a physician. TRICARE defines direct supervision of an AA by an anesthesiologist as follows: the anesthesiologist performs a pre-anesthetic examination and evaluation; the anesthesiologist prescribes the anesthesia plan; the anesthesiologist personally participates in the most demanding aspects of the anesthesia plan including, if applicable, induction and emergence; the anesthesiologist ensures that any procedures in the anesthesia plan that he or she does not

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perform are performed by a qualified AA; the anesthesiologist monitors the course of anesthesia administration at frequent intervals; the anesthesiologist remains physically present and available for immediate personal diagnosis and treatment of emergencies; the anesthesiologist provides indicated post-anesthesia care; the anesthesiologist performs no other services while he or she supervises no more than four anesthesiologist assistants concurrently or a lesser number if so limited by the state in which the procedure is performed. The Director, TMA, or a designee, shall issue TRICARE policies, instructions, procedures, guidelines, standards, and criteria as may be necessary to implement the intent of this section. TRICARE has modeled its definition of direct supervision on the current Medicare definition of “medically directed anesthesia services,” with three notable variations. First, Medicare uses the terminology “medically directed anesthesia services;” whereas, TRICARE uses “direct supervision.” For purposes of definition, such terminology is interchangeable. Second, Medicare refers to a qualified individual who performs anesthesia procedures not rendered by a physician as defined in Medicare operating instructions. For TRICARE, a qualified individual who performs anesthesia procedures under 32 CFR 199.6 (I), established by this final rule, is an AA. The final difference pertains to the number of AAs an anesthesiologist may concurrently supervise. TRICARE and MEDICARE both require that “the

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anesthesiologist performs no other services while he or she supervises no more than four anesthesiologist assistants concurrently” however TRICARE includes additional language to indicate that in cases where state law further restricts the number of AAs an Anesthesiologists can concurrently supervise TRICARE will defer to state law. The relevant phrase states “or a lesser number if so limited by the state in which the procedure is performed.”

*Comment:* One commenter noted that our proposed rule stated that AAs will be authorized under the same conditions applied by CMS and questioned if that means that all CMS rules relating to anesthesia apply to AAs or just some. Also, will the CMS medical direction rules apply, and what does direct supervision mean?

*Response:* We intend to apply all the CMS rules to AAs who provide services to TRICARE beneficiaries. However, we are adding one additional condition regarding the medical direction of AAs. CMS allows physicians to provide concurrent medical direction of up to four AAs or CRNAs. We will use that standard in general, but we will also require that if a state has a more stringent requirement, the state’s requirement must be followed. Direct supervision means the same as medical direction under CMS, and we have expanded the regulatory section to include those requirements.

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*Comment:* One commenter asked if AAs must be licensed or can they practice under a form of delegated medicine?

*Response:* As stated in the proposed rule, AAs must comply with all applicable requirements of state law and be licensed, where applicable. Therefore, they must be licensed only where a state requires them to be licensed. In other states, they may practice as unlicensed providers under the delegated authority of a physician as permitted by state law.

*Comment:* One commenter noted that the proposed rule states that an AA program must build on a premedical undergraduate science background but stated that neither currently existing AA educational program requires a premedical major. The commenter asked if this means the programs will have to change their requirements.

*Response:* The AA programs will not have to change their requirements. The proposed rule and the final rule require only that the AA program must build on a premedical science background. It does not require that the participant have a premedical science major. It is important to note that both programs require extensive undergraduate science coursework. In addition, the accreditation standard for AA programs as required by the Commission on Accreditation of Allied Health Education Programs requires undergraduate coursework that includes “studies in biology, chemistry, mathematics, and

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physics which are usually required for graduate study or its equivalent in the basic medical sciences.”

### **III. Changes in the Final Rule**

We have made no changes to the provisions on coverage of cardiac rehabilitation in freestanding cardiac rehabilitation centers. However, based on comments we received on the proposed rule, we have made several changes to the final rule language regarding the inclusion of anesthesiologist assistants as authorized providers.

The profession’s name is singular and not singular possessive as we used it in the proposed rule. Accordingly, the final rule uses “anesthesiologist assistant”.

It was suggested that we delete the term “Master’s level medical school-based” in describing the required AA programs in order to reflect changes in CAAHEP accreditation standards that permit a shared program between a medical school and a university program outside the medical school. We reviewed the accreditation standards and, based on that, we have changed the wording to require that the program be established under the auspices of a medical school rather than be “medical school-based”. However, we are retaining the language regarding Master’s level for clarity.

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It was also suggested that when we refer to the Committee on Allied Health Education and Accreditation we include the words “or its successor organization”. We have done this in the final rule.

As stated in our response to the public comments, we have added language to the regulatory provisions to ensure clarity of what is required for direct supervision.

Lastly, we have within this final rule included a provision to provide a separate designation for certified registered nurse anesthetists (CRNAs) by clarifying their existing status in the TRICARE program as an independent provider operating under their state licensure and meeting the requirements for a certified registered nurse anesthetist.

### **IV. Regulatory Procedures.**

Executive Order (EO) 12866 requires that a comprehensive regulatory impact analysis be performed on any economically significant regulatory action, defined as one which 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

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

This is not a significant regulatory action under EO 12866 and has been reviewed by the Office of Management and Budget. In addition, we certify that this final rule will not significantly affect a substantial number of small entities.

**Paperwork Reduction Act**

This rule imposes no burden as defined by the Paperwork Reduction Act of 1995.

List of Subjects in 32 CFR Part 199

Claims, handicapped, health insurance, and 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 199.4 is amended by revising paragraph (e)(18)(iv) to read as follows.

§199.4 Basic program benefits.

\* \* \* \* \*

(e) \* \* \*

(18) \* \* \*

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(iv) Providers. A provider of cardiac rehabilitation services must be a TRICARE authorized hospital (see §199.6 (b)(4)(i)) or a freestanding cardiac rehabilitation facility that meets the requirements of §199.6 (f). All cardiac rehabilitation services must be ordered by a physician.

\* \* \* \* \*

3. Section 199.6 is amended by redesignating paragraph (c)(3)(iii)(I) as paragraph (c)(3)(iii)(K) and adding new paragraphs (c)(3)(iii)(I) and (c)(3)(iii)(J) to read as follows:

§199.6 Authorized providers.

\* \* \* \* \*

(c) \* \* \*

(3) \* \* \*

(iii) \* \* \*

(I) Anesthesiologist Assistant. An anesthesiologist assistant may provide covered anesthesia services, if the anesthesiologist assistant:

(1) Works under the direct supervision of an anesthesiologist who bills for the services and for each patient;

(i) The anesthesiologist performs a pre-anesthetic examination and evaluation;

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- (ii) The anesthesiologist prescribes the anesthesia plan;
  - (iii) The anesthesiologist personally participates in the most demanding aspects of the anesthesia plan including, if applicable, induction and emergence;
  - (iv) The anesthesiologist ensures that any procedures in the anesthesia plan that he or she does not perform are performed by a qualified anesthesiologist assistant;
  - (v) The anesthesiologist monitors the course of anesthesia administration at frequent intervals;
  - (vi) The anesthesiologist remains physically present and available for immediate personal diagnosis and treatment of emergencies;
  - (vii) The anesthesiologist provides indicated post-anesthesia care; and
  - (viii) The anesthesiologist performs no other services while he or she supervises no more than four anesthesiologist assistants concurrently or a lesser number if so limited by the state in which the procedure is performed.
- (2) Is in compliance with all applicable requirements of state law, including any licensure requirements the state imposes on nonphysician anesthetists; and
- (3) Is a graduate of a Master's level anesthesiologist assistant educational program that is established under the auspices of an accredited medical school and that:

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(i) Is accredited by the Committee on Allied Health Education and Accreditation, or its successor organization; and

(ii) Includes approximately two years of specialized basic science and clinical education in anesthesia at a level that builds on a premedical undergraduate science background.

(4) The Director, TMA, or a designee, shall issue TRICARE policies, instructions, procedures, guidelines, standards, and criteria as may be necessary to implement the intent of this section.

(J) Certified Registered Nurse Anesthetist (CRNA). A certified registered nurse anesthetist may provide covered care independent of physician referral and supervision as specified by state licensure. For purposes of CHAMPUS, a certified registered nurse anesthetist is an individual who:

(1) Is a licensed, registered nurse; and

(2) Is certified by the Council on Certification of Nurse Anesthetists, or its successor organization.

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L.M. Bynum  
Alternate OSD Federal Register  
Liaison Officer,  
Department of Defense  
May 17, 2004