

41217

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; Elimination of Nonavailability Statement and Referral Authorization Requirements and Elimination of Specialized Treatment Services Program

4. Rule Identification Number (RIN) or Other Unique Identifier (if applicable) 0720-AA79

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

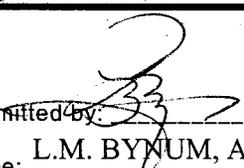
8. Priority of Regulation (fill in one)

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) December 28, 2003

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

Submitted by:  (signature)

Name: L.M. BYNUM, Alternate OSD Federal

Title: Register Liaison Officer, DoD 7/24/03

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

This interim final rule will implement Section 735 of the National Defense Authorization Act for Fiscal Year 2002 (NDAA-02) (Public Law 107-107). It will also implement Section 728 of the National Defense Authorization Act for Fiscal Year 2001 (NDAA-01) (Public Law 106-398). Section 735 of NDAA-02 eliminates the requirement for TRICARE Standard beneficiaries who live within a 40-mile radius of a military medical treatment facility (MTF) to obtain a nonavailability statement (NAS) or preauthorization from an MTF before receiving inpatient care (other than mental health services) or maternity care from a civilian provider in order that TRICARE will cost-share for such services. Further, this section eliminates the NAS requirement for specialized treatment services (STSs) for TRICARE Standard beneficiaries who live outside the 200-mile radius of a designated STS facility. This rule will portray the Department's decision to eliminate the STS program entirely. Finally, Section 728 of NDAA-01 requires that prior authorization before referral to a specialty care provider that is part of the contractor network be eliminated under any new TRICARE contract.

DEPARTMENT OF DEFENSE

Billing Code 5001-08

OFFICE OF THE SECRETARY

32 CFR Part 199

RIN 0720-AA79

TRICARE; Elimination of Nonavailability Statement and Referral Authorization Requirements and Elimination of Specialized Treatment Services Program

AGENCY: Office of the Secretary, DoD

ACTION: Interim Final Rule

SUMMARY: This rule implements Section 735 of the National Defense Authorization Act for Fiscal Year 2002 (NDAA-02) (Public Law 107-107). It also implements Section 728 of the National Defense Authorization Act for Fiscal Year 2001 (NDAA-01) (Public Law 106-398). Section 735 of NDAA-02 eliminates the requirement for TRICARE Standard beneficiaries who live within a 40-mile radius of a military medical treatment facility (MTF) to obtain a nonavailability statement (NAS) or preauthorization from an MTF before receiving inpatient care (other than mental health services) or maternity care from a civilian provider in order that TRICARE will cost-share for such services. Further, this section eliminates the NAS requirement for specialized treatment services (STSs) for TRICARE Standard beneficiaries who live outside the 200-mile radius of a designated STS facility. This rule portrays the Department's decision to eliminate the STS program entirely. Finally, Section 728 of NDAA-01 requires that prior authorization before referral to a specialty care provider that is part of the contractor network be eliminated under any new TRICARE contract. The Department is publishing this rule as an interim final rule with comment period as an exception to our standard practice of soliciting public comments prior to issuance in order to implement the statutory

requirements. Public comments, however, are invited and will be considered for possible revisions to this rule.

DATES: This rule is effective: December 28, 2003.

Comment Date: Written comments will be accepted until [insert date 60 days from the date of publication in the FEDERAL REGISTER].

ADDRESSES: Forward comments to Medical Benefits and Reimbursement Systems, TRICARE Management Activity, 16401 East Centretech Parkway, Aurora, CO 80011-9066.

FOR FURTHER INFORMATION CONTACT: Tariq Shahid, TRICARE Management Activity, telephone (303) 676-3801.

SUPPLEMENTARY INFORMATION:

I. Elimination of Nonavailability Statement Requirement and Specialized Treatment Service Program.

The National Defense Authorization Act for Fiscal Year 2002 (NDAA-02) was signed into law on December 28, 2001. Section 735 of NDAA-02 amends Section 721 of the NDAA-01 with respect to the nonavailability statement (NAS) elimination requirements and eliminates the requirement for non-enrolled TRICARE beneficiaries who live within a 40-mile radius of a military medical treatment facility (MTF) to obtain an NAS or preauthorization from an MTF before receiving nonemergent inpatient or obstetrical (inpatient or outpatient) services from a civilian provider in order that TRICARE will cost-share for such services. A non-enrolled TRICARE beneficiary is a beneficiary who has not enrolled in TRICARE Prime, but who has chosen to use the TRICARE Standard and TRICARE Extra options. Section 735 retains MTF NAS authority for inpatient mental health services within the usual 40-mile catchment area. The section establishes that the NAS elimination requirements are to take effect on the earlier of the date the health care services

are provided under new TRICARE contracts or the date that is two years after the date of the enactment of NDAA-02. As the health care services under new TRICARE contracts will not be available until after March 2004, the NAS requirements will be eliminated for admissions occurring on or after December 28, 2003, which is the date that is two years after the date of the enactment of NDAA-02. For obstetrical care, the NAS requirement will be eliminated for maternity episodes wherein the first prenatal visit occurs on or after December 28, 2003. An NAS is required when the first prenatal visit occurs before December 28, 2003, by 10 U.S.C. 1080(b). The NAS for inpatient mental health care will continue to be required.

With the exception of maternity care, Section 735 of NDAA-02 gives the Secretary of DoD the authority to waive the NAS elimination requirements if: (a) significant costs would be avoided by performing specific procedures at the affected military treatment facility (MTF); (b) a specific procedure must be provided at the affected MTF to ensure the proficiency levels of the practitioners at the facility; or (c) the lack of NAS data would significantly interfere with TRICARE contract administration. When this waiver authority will be exercised, the Department will notify the affected beneficiaries by publishing a notice in the Federal Register and notify the Congress.

Section 735 of NDAA-02 furthermore eliminates the multi-regional and national NAS requirement for specialized treatment services (STSs) for TRICARE Standard beneficiaries who live outside the 200-mile radius of a STS facility. STS facilities are those designated facilities with regional, multi-regional or national catchment areas which provide complex medical and surgical services as currently provided in 32 CFR 199.4(a)(10). Since the Department has decided to terminate the STS program no later than June 1, 2003, all regional, multi-regional, and national NAS requirements for STSs will be eliminated before that date. The rationale behind the termination of the STS program is that this program was not based upon nationally developed consensus or

evidenced-based criteria for clinical quality (there were none at the inception of this program) and had not consistently demonstrated cost-benefit to the government. In addition, the NAS requirement for STSs has placed an unreasonable burden on our beneficiaries who have had to travel extended distances to the STS facilities. This would provide for enhanced continuity of care for TRICARE Standard beneficiaries who generally receive most medical and surgical services from civilian providers of their choice. This rule gives notice of the Department's decision to terminate the STS program entirely no later than June 1, 2003.

II. Elimination of Prior Authorization before Referrals to Specialty Care Providers.

This rule will implement Section 728 of the National Defense Authorization Act for Fiscal Year 2001 (NDAA-01) (Pub. L. 106-398) which was enacted on October 30, 2000. Section 728 requires that prior authorization (or more precisely, preauthorization as defined in 32 CFR 199.2(b)) before referral to a specialty care provider that is part of the network be eliminated as part of any new TRICARE contracts entered into by the Department of Defense after the date of the enactment of the Act. This means that medical necessity preauthorization will not be required when primary care or specialty care providers refer TRICARE Prime patients for consultation appointment services, which are provided within the contractors' network of providers. Only TRICARE Prime patients require preauthorization for obtaining consultation appointment services. TRICARE Prime beneficiaries are required to use network providers if available. This rule removes the requirement to obtain a medical necessity determination when the consultation services are provided within the contractor's network. Section 728 of NDAA-01 does not eliminate the requirement for medical necessity preauthorizations for specific procedures or other health care services which specialty providers may recommend for beneficiaries as a result of the original consultation appointment or the need for preauthorization referral to non-network providers. For example, a consultation might result in a recommendation for

a high cost surgical procedure on a nonemergent basis. The specialist's intent to perform this procedure may still be subjected to medical necessity preauthorization based upon utilization review criteria as has been TRICARE policy for years in conformance with the peer review organization program in section 199.15.

In summary, under new TRICARE contracts, requests for consultation appointment services will not be subjected to medical necessity preauthorization though other health care services may continue to require preauthorizations. TRICARE contractors may determine which other categories of health care services (procedures, nonemergent admissions) will require medical necessity preauthorization in accordance with their best business practices.

REGULATORY PROCEDURE

Executive order 12866 requires certain regulatory assessments for any significant regulatory action, defined as one which would result in an annual effect on the economy of \$100 million or more, or 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 significant impact on a substantial number of small entities.

This rule is not a significant regulatory action under E.O. 12866 that could potentially add more than \$100 million in estimated annual costs for DoD. This rule does not require a regulatory flexibility analysis as the policy action was taken by Congress and the rule merely puts it into effect. The policy of the Regulatory Flexibility Act that agencies adequately evaluate all potential options for an action does not apply when Congress has already dictated the action.

This rule will not impose significant additional information collection requirements on the public under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3511).

This rule is being issued as an interim final rule, with comment period, as an exception to our standard practice of soliciting public comments prior to issuance. This is because there is no discretion being exercised. The NDAA-02 (Public Law 107-107) mandated elimination of the NAS for maternity care entirely, and for inpatient care unless it met very restrictive criteria, and there is no discretion on the effective date. The Assistant Secretary of Defense (Health Affairs) has determined that following the standard practice in this case would be unnecessary, impractical, and contrary to the public interest.

Public comments are invited. All comments will be carefully considered. A discussion of the major issues received by public comments will be included with the issuance of the final rule.

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; and 10 U.S.C. Chapter 55.

2. Section 199.2(b) is amended by revising the definition for "Preauthorization," by removing the definition for "Specialized Treatment Service Facility," and by adding the definitions for "Consultation appointment" and "Medically or psychologically necessary preauthorization" and placing them in alphabetical order to read as follows:

§199.2 Definitions.

* * * * *

(b) * * *

* * * * *

Consultation appointment. An appointment for evaluation of medical symptoms resulting in a plan for management which may include elements of further evaluation, treatment and follow-up evaluation. Such an appointment does not include surgical intervention or other invasive diagnostic or therapeutic procedures beyond the level of very simple office procedures, or basic laboratory work but rather provides the beneficiary with an authoritative opinion.

* * * * *

Medically or psychologically necessary preauthorization: A pre (or prior) authorization for payment for medical/surgical or psychological services based upon criteria that are generally accepted by qualified professionals to be reasonable and adequate for diagnosis and treatment of an illness, injury, pregnancy, and mental disorder.

* * * * *

Preauthorization. A decision issued in writing, or electronically by the Director, TRICARE Management Activity, or a designee, that TRICARE benefits are payable for certain services that a beneficiary has not yet received. The term prior authorization is commonly substituted for preauthorization and has the same meaning.

* * * * *

3. Section 199.4 is amended by revising paragraphs (a)(9) and (a)(9)(i)(B), by removing paragraph (a)(9)(i)(C), by revising paragraph (a)(9)(iv), by adding a new paragraph (a)(9)(vii), by removing and reserving paragraph (a)(10), and by revising paragraphs (e)(16)(i) and (e)(16)(ii) to read as follows:

§199.4 Basic program benefits

(a) * * *

(9) Nonavailability Statements within a 40-mile catchment area. In some geographic locations, it is necessary for CHAMPUS beneficiaries not enrolled in TRICARE Prime to determine whether the required inpatient mental health care can be provided through a Uniformed Service facility. If the required care cannot be provided, the hospital commander, or a designee, will issue a Nonavailability Statement (NAS) (DD Form 1251). Except for emergencies, an NAS should be issued before inpatient mental health care is obtained from a civilian source. Failure to secure such a statement may waive the beneficiary's rights to benefits under CHAMPUS/TRICARE.

(i) * * *

(B) For CHAMPUS beneficiaries who are not enrolled in TRICARE Prime, an NAS is required for services in connection with nonemergency hospital inpatient mental health care if such services are available at a military treatment facility (MTF) located within a 40-mile radius of the residence of the beneficiary, except that a NAS is not required for services otherwise available at an MTF located within a 40-mile radius of the beneficiary's residence when another insurance plan or program provides the beneficiary's primary coverage for the services. This requirement for an NAS does not apply to beneficiaries enrolled in TRICARE Prime, even when those beneficiaries use the point-of-service option under §199.17(n)(3).

* * * * *

(iv) Nonavailability Statement (DD Form 1251) must be filed with applicable claim. When a claim is submitted for TRICARE benefits that includes services for which an NAS was issued, a valid NAS authorization must be on the DoD required system.

* * * * *

(vii) With the exception of maternity services, the Assistant Secretary of Defense for Health Affairs (ASD(HA)) may require an NAS prior to TRICARE cost-sharing for additional services from

civilian sources if such services are to be provided to a beneficiary who lives within a 40-mile catchment area of an MTF where such services are available and the ASD(HA):

(A) demonstrates that significant costs would be avoided by performing specific procedures at the affected MTF or MTFs; or

(B) determines that a specific procedure must be provided at the affected MTF or MTFs to ensure the proficiency levels of the practitioners at the MTF or MTFs; or

(C) determines that the lack of NAS data would significantly interfere with TRICARE contract administration; and

(D) provides notification of the ASD(HA)'s intent to require an NAS under this authority to covered beneficiaries who receive care at the MTF or MTFs that will be affected by the decision to require an NAS under this authority; and

(E) provides at least 60-day notification to the Committees on Armed Services of the House of Representatives and the Senate of the ASD(HA)'s intent to require an NAS under this authority, the reason for the NAS requirement, and the date that an NAS will be required.

(10) [Reserved].

* * * * *

(e) * * *

(16) * * *

(i) Benefit. The CHAMPUS Basic Program may share the cost of medically necessary services and supplies associated with maternity care which are not otherwise excluded by this part.

(ii) Cost-share. Maternity care cost-share shall be determined as follows:

* * * * *

4. Section 199.7 is amended by revising paragraph (a)(7)(i) to read as follows:

§199.7 Claims Submission, Review, and Payment

(a) * * *

(7) * * *

(i) Rules applicable to issuance of Nonavailability Statement. The ASD(HA) may issue a DoD Instruction to prescribe rules for the issuance of Nonavailability Statement.

* * * * *

5. Section 199.15 is amended by revising paragraph (b)(4)(i) and by adding a new paragraph (b)(4)(ii)(D) to read as follows:

§199.15 Quality and Utilization Review Peer Review Organization Program

* * * * *

(b) * * *

(4) * * *

(i) In general. All health care services for which payment is sought under TRICARE are subject to review for appropriateness of utilization as determined by the Director, TRICARE Management Activity, or a designee.

(A) The procedures for this review may be prospective (before the care is provided), concurrent (while the care is in process), or retrospective (after the care has been provided). Regardless of the procedures of this utilization review, the same generally accepted standards, norms and criteria for evaluating the medical necessity, appropriateness and reasonableness of the care involved shall apply. The Director, TRICARE Management Activity, or a designee, shall establish procedures for conducting reviews, including types of health care services for which preauthorization or concurrent review shall be required. Preauthorization or concurrent review may be required for categories of health care services. Except where required by law, the categories of health care

services for which preauthorization or concurrent review is required may vary in different geographical locations or for different types of providers.

(B) For healthcare services provided under TRICARE contracts entered into by the Department of Defense after October 30, 2000, medical necessity preauthorization will not be required for referrals for specialty consultation appointment services requested by primary care providers or specialty providers when referring TRICARE Prime beneficiaries for specialty consultation appointment services within the TRICARE contractor's network. However, the lack of medical necessity preauthorization requirements for consultative appointment services does not mean that non-emergent admissions or invasive diagnostic or therapeutic procedures which in and of themselves constitute categories of health care services related to, but beyond the level of the consultation appointment service, are also not subject to medical necessity prior authorization. In fact many such health care services may continue to require medical necessity prior authorization as determined by the Director, TRICARE Management Activity, or a designee. TRICARE Prime beneficiaries are also required to obtain preauthorization before seeking health care services from a non-network provider.

(ii) * * *

(D) For healthcare services provided under TRICARE contracts entered into by the Department of Defense after October 30, 2000, medical necessity preauthorization for specialty consultation appointment services within the TRICARE contractor's network will not be required. However TRICARE contractors shall determine, based upon best-business practice, utility and cost-savings, the categories of other health care services which are best served by medical necessity prior (or pre) authorization and may request a waiver from the Director, TRICARE Management Activity,

or designee, from compliance with previously established requirements for medical necessity prior (or pre) authorization.

* * * * *

6. Section 199.17 is amended by revising paragraph (n)(2)(ii) to read as follows:

§199.17 TRICARE Program

* * * * *

(n) * * *

(2) * * *

(ii) For any necessary specialty care and nonemergent inpatient care, the primary care manager or the Health Care Finder will assist in making an appropriate referral.

(A) For healthcare services provided under managed care support contracts entered into by the Department of Defense before October 30, 2000, all such nonemergency specialty care and inpatient care must be preauthorized by the primary care manager or the Health Care Finder.

(B) For healthcare services provided under TRICARE contracts entered into by the Department of Defense on or after October 30, 2000, referral requests (consultation requests) for specialty care consultation appointment services for TRICARE Prime beneficiaries must be submitted by primary care managers. Such referrals will be authorized by Health Care Finders (authorizations numbers will be assigned so as to facilitate claims processing) but medical necessity preauthorization will not be required for referral consultation appointment services within the TRICARE contractor's network. Some health care services subsequent to consultation appointments (invasive procedures, nonemergent admissions and other health care services as determined by the Director, TRICARE Management Activity, or a designee) will require medical necessity preauthorization. Though referrals for specialty care are generally the responsibility of the primary

care managers, subject to discretion exercised by the regional Lead Agents, and established in regional policy or memoranda of understanding, specialist providers may be permitted to refer patients for additional specialty consultation appointment services within the TRICARE contractor's network without prior authorization by primary care managers or subject to medical necessity preauthorization.

* * * * *

L. M. Bynum
Alternate OSD Federal Register Liaison Officer
Department of Defense
July 24, 2003