

Regulatory Flexibility Act

The interim rule will not have a significant economic impact upon a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 605 (b), and is deemed by the Commission to be a rule of agency practice that does not substantially affect the rights or obligations of non-agency parties pursuant to Section 804 (3) (c) of the Congressional Review Act.

Unfunded Mandates Reform Act of 1995

This rule will not cause State, local, or tribal governments, or the private sector, to spend \$100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. No action under the Unfunded Mandates Reform Act of 1995 is necessary.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by Sec. 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on the ability of United States-based companies to compete with foreign-based companies.

List of Subjects in 28 CFR Part 2

Administrative practice and procedure, Prisoners, Probation and Parole.

The Interim Rule

Accordingly, the U.S. Parole Commission is adopting the following amendment to 28 CFR part 2.

PART 2—[AMENDED]

- 1. The authority citation for 28 CFR part 2 continues to read as follows:

Authority: 18 U.S.C. 4203 (a) (1) and 4204 (a) (6).

- 2. Revise § 2.25 to read as follows:

§ 2.25 Hearings by videoconference.

Parole determination hearings (including rescission hearings), and institutional revocation hearings, may be conducted by a videoconference between the hearing examiner and the prisoner or releasee.

Dated: April 5, 2005.

Edward F. Reilly, Jr.,

Chairman, U.S. Parole Commission.

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DEPARTMENT OF DEFENSE

Office of the Secretary of Defense

32 CFR Part 199

RIN 0720-AA79

TRICARE; Elimination of Non-Availability Statement and Referral Authorization Requirements and Elimination of Specialized Treatment Services Program

AGENCY: Office of the Secretary, DoD.

ACTION: Final rule.

SUMMARY: This rule implements Section 735 of the National Defense Authorization Act for Fiscal Year 2002 (NDAA-02) (Pub. L. 107-107). It also implements Section 728 of the Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001 (NDAA-01) (Pub. L. 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. Section 735 of NDAA-02, however, authorizes the Department of Defense to make exceptions to the elimination of the requirement for a NAS through the exercise of a waiver process under certain specified conditions. This section also 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.

DATES: Effective Date: December 28, 2003.

ADDRESSES: 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 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 were to be available after March 2004, the NAS requirements are 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 is 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. The TRICARE policy requires

MTFs, TRICARE Regions, and the contractors to publicize any NAS requirements to the affected beneficiaries with respect to any use of the waiver authority. In addition, outreach efforts will include posting Web site announcements on the TRICARE Web site directing affected beneficiaries to their local MTF Web sites with regard to any use of the waiver authority.

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 were those designated facilities with regional, multi-regional or national catchment areas which provided complex medical and surgical services pursuant to 32 CFR 199.4(a)(10). Since the Department decided to terminate the STS program no later than June 1, 2003, all regional, multi-regional, and national NAS requirements under TRICARE Standard and authorization requirements under TRICARE Prime for STSs were eliminated before that date. The rationale behind the termination of the STS program was 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 placed an unreasonable burden on our beneficiaries who had to travel extended distances to the STS facilities. This provided for enhanced continuity of care for TRICARE Standard beneficiaries who generally receive most medical and surgical services from civilian providers of their choice. The interim final rule gave 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 implements Section 728 of 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 required 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 based on a determination of best business practices.

III. Public Comments

We published the interim final rule on July 31, 2003, and provided a 60-day comment period. We received comments from one national association and two other commenters. These comments and the Department's responses are summarized below.

Comment: Essentially, the commenter raised concerns regarding the stated means of communicating to beneficiaries and providers the intent to exercise the waiver authority to require a nonavailability statement (NAS). The interim final rule stated that if the waiver authority is exercised, the Department will notify the affected beneficiaries by publishing a notice in the **Federal Register**.

Response: While these are used to announce the program changes and requirements to the public, the **Federal Register** notices are not the only means of communication upon which the Department relies. The Department is sensitive to streamlining administrative processes and recognizes the importance of communicating with the

beneficiaries and providers with regard to any use of the waiver authority and any new NAS requirements. It is for this reason that we have included a provision in the TRICARE Policy Manual that requires military treatment facilities (MTFs), TRICARE Regions, and the contractors to publicize any NAS requirements to the affected beneficiaries with respect to any use of the waiver authority. We have included this clarification in this final rule. Normally, the TRICARE policy changes and new requirements are announced in the routine provider bulletins and beneficiary newsletters by TRICARE contractors. In addition, outreach efforts will include posting Web site announcements on the TRICARE Web site directing affected beneficiaries to their local MTF Web sites; sharing information with military and civilian media and beneficiary association publications; and partnering with network and non-network providers through the contractors and local American Medical Association organizations.

Comment: One commenter argued that the DoD should totally eliminate the NAS for TRICARE Standard beneficiaries and made several comments. With regard to the legislative provision that requires elimination of NAS or preauthorization from an MTF, this commenter stated that the law has eliminated preauthorization for TRICARE Standard, yet DoD rules do not comply. With regard to the title of this rule, the commenter argued that to title this rule "Elimination of the nonavailability statement" is deceiving to TRICARE Standard beneficiaries, since it has not been eliminated except for maternity care, and DoD should reveal the facts. The commenter stated that the beneficiary could have no rights under this rule to use TRICARE Standard rather than the MTF, and the rule grants authority to DoD to continue use of the NAS. With reference to the regulatory language in the rule, the commenter requested clarification regarding the use and impact of the term MTFs. Regarding the structure of the rule, the commenter stated that the entire document is confusing in applicability to TRICARE Prime vs. TRICARE Standard and suggested that at the beginning of each paragraph it should be specified whether it applies to Standard or Prime, or both. The commenter also raised concerns that the notification by a **Federal Register** notice with regard to using the waiver authority to require an NAS is inadequate and stated that unless a reasonable mechanism can be

established to notify each beneficiary and provider of the need for the NAS, the rule cannot be fairly implemented. In all cases when the beneficiary is denied a request for NAS, the commenter suggested that the beneficiary should be notified in writing within 24 hours giving the specific reasons related to: (a) The significant costs that would be avoided, (b) a specific procedure that must be provided at the affected MTF to ensure the proficiency levels of the practitioners, or (c) the lack of NAS data that would significantly interfere with TRICARE contract administration. The commenter emphasized the importance of detailed explanation for NAS denial and specific cost data and stated that the waiver authority is so liberal that the practical effect is to grant carte blanche authority to deny NAS request when the MTF is underutilized. Finally, the commenter presented a detailed argument in favor of total elimination of NAS.

Response: The rule eliminated the NAS requirements as provided by the law. It is incorrect to say that the DoD rules do not comply with respect to the elimination of MTF preauthorization. The fact is that under TRICARE, no care is preauthorized by MTFs and it was NAS that was administered by MTFs. The TRICARE contractors were required to preauthorize those admissions that required an NAS and that preauthorization was eliminated with the elimination of NAS. The title of this rule is appropriate and it is not deceiving as the rule does eliminate maternity and inpatient NAS with the exception of NAS for mental health admissions, and all the relevant information is presented in the rule. The fact that the rule provides information with regard to the waiver authority to require an NAS does not mean that it does not eliminate the inpatient NAS. It is incorrect to say that the beneficiary could have no rights under this rule to use TRICARE Standard other than the MTF. Use of an MTF is not required for emergency care or when a beneficiary has other health insurance and an NAS can never be required in such situations. The use of the term MTFs in the regulatory language is consistent with the provisions in Section 735 of the National Defense Authorization Act for Fiscal Year 2002. It is a plural of the term military treatment facility (MTF) and will be applicable when more than one MTF are granted a waiver to require an NAS. Regarding the structure of the rule, section I of the rule is clear that the NAS requirements are eliminated for non-enrolled beneficiaries and it has

defined a non-enrolled beneficiaries as a beneficiary who is not enrolled in TRICARE Prime and has chosen to use TRICARE Standard and TRICARE Extra options. It should be noted that the NAS applies to non-enrolled beneficiaries and it does not apply under TRICARE Prime. With regard to termination of the specialized treatment service (STS) program, we have added language in Section I of the rule that clarifies that the STS program was terminated under both the TRICARE Standard and Prime. Section II. of the rule is clear that the elimination of prior authorization before referral to specialty care providers applies under TRICARE Prime. With regard to the notification concerning the waiver authority to require an NAS, see the response under the first comment, above. It should be noted that whenever an NAS is denied, the beneficiary is promptly notified and given the appeal rights. The specific information pertaining to the significant costs, procedures, etc., pertains to the waiver criteria for requiring an NAS and will be required by the Department for review and consideration from the MTF requesting the waiver. With the exception of maternity care, the law gives DoD the waiver authority to require an NAS under certain specified conditions. However, it should be noted that granting a waiver to an MTF to require an NAS is a complicated process and it involves notification to the Congress. Given the complexity of the process and its impact on beneficiaries and providers, the Department does not foresee any waivers at this time. However, should there be any exceptions, the Department anticipates any waivers granted would be implemented on a local basis, as needed, and the NAS requirements will be announced well in advance of their implementation. Essentially, this rule has followed the directions provided by the statute.

Comment: The commenter supported the rule and suggested that TRICARE remove the requirement for prior authorization of outpatient medical procedures under TRICARE Standard that are approved by the beneficiary's other health insurance (OHI).

Response: With the exception of adjunctive dental care, Program for Persons with Disabilities benefit, outpatient psychotherapy beyond the eighth visit, and psychoanalysis, an earlier policy change removed the preauthorization requirements for outpatient medical procedures for those TRICARE beneficiaries who have OHI.

Regulatory Procedure

The rule has been reviewed by the Office of Management and Budget. 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 an unfunded mandate under the Unfunded Mandate Reform Act and it is not a significant regulatory action under E.O. 12866 that could potentially add more than \$100 million in estimated annual costs for DoD, or state, local, tribal governments, and the private sector. 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).

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 199.7 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.* Appropriate policy guidance may be issued as necessary to prescribe the conditions for issuance and use of a Nonavailability Statement.

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■ 3. Section 199.15 is amended by revising paragraphs (b)(4)(i)(B) and (b)(4)(ii)(D) to read as follows:

§ 199.15 Quality and utilization review peer review organization program.

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(b) * * *

(4) * * *

(i) * * *

(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 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, the Director, TRICARE Management Activity, or designee, may continue to require or waive medical necessity prior (or pre) authorization for other categories of other health care services based on best business practice.

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

§ 199.17 TRICARE program.

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(n) * * *

(2) * * *

(ii) * * *

(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 (authorization 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 TRICARE Regional Directors, 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.

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Dated: April 7, 2005.

Jeannette Owings-Ballard,

OSD Federal Register Liaison Officer,

Department of Defense.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[OAR-2004-0411; AD-FRL-7899-1]

RIN 2060-AK80

National Emission Standards for Hazardous Air Pollutants for Source Categories: Generic Maximum Achievable Control Technology Standards; and National Emission Standards for Ethylene Manufacturing Process Units: Heat Exchange Systems and Waste Operations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rules; amendments.

SUMMARY: The EPA is taking direct final action on amendments to the National Emissions Standards for Hazardous Air

Pollutants for Source Categories: Generic Maximum Control Technology Standards which were promulgated in June 1999 (64 FR 34863), and the National Emission Standards for Ethylene Manufacturing Units: Heat Exchange Systems and Waste Operations which were promulgated in July 2002 (67 FR 46258). The direct final rule amendments clarify the compliance requirements for benzene waste streams, clarify the requirements for heat exchangers and heat exchanger systems, and stipulate the provisions for offsite waste transfer in the national emission standards for ethylene manufacturing process units. The direct final rule amendments also correct the regulatory language that make emissions from ethylene cracking furnaces during decoking operations an exception to the provisions and delineate overlapping requirements for storage vessels and transfer racks.

In addition, the direct final rule amendments also correct errors in the proposed rule for the Acrylic and Modacrylic Fiber Production source category which were not corrected as indicated in the preamble to the June 1999 final rule (64 FR 34863).

We are issuing the amendments as direct final rules, without prior proposal, because we view the revisions as noncontroversial and anticipate no adverse comments. However, in the Proposed Rules section of this **Federal Register**, we are publishing a separate document that will serve as the proposal to amend the National Emissions Standards for Hazardous Air Pollutants for Source Categories: Generic Maximum Control Technology Standards and the National Emission Standards for Ethylene Manufacturing Process Units: Heat Exchange Systems and Waste Operations.

DATES: The direct final rule amendments are effective on June 13, 2005 without further notice, unless EPA receives adverse written comment by May 31, 2005. If adverse comments are received, EPA will publish a timely withdrawal in the **Federal Register** indicating which of the amendments will become effective, and which are being withdrawn due to adverse comment.

ADDRESSES: Submit your comments, identified by Docket ID No. OAR-2004-0411, by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- Agency Web site: <http://www.epa.gov/edocket>. EDOCKET, EPA's electronic public docket and comment system, is EPA's preferred method for