

(7) A "veterinary feed directive" is a written statement issued by a licensed veterinarian in the course of the veterinarian's professional practice that orders the use of a veterinary feed directive (VFD) drug in or on an animal feed. This written statement authorizes the client (the owner of the animal or animals or other caretaker) to obtain and use the VFD drug in or on an animal feed to treat the client's animals only in accordance with the directions for use approved or indexed by the Food and Drug Administration (FDA). A veterinarian may issue a VFD only if a valid veterinarian-client-patient relationship exists, as defined in § 530.3(i) of this chapter.

35. Amend § 558.5 by revising paragraphs (c) and (d) to read as follows:

§ 558.5 Requirements for liquid medicated feed.

(c) *What is required for new animal drugs intended for use in liquid feed?* Any new animal drug intended for use in liquid feed must be approved for such use under section 512 of the act or index listed under section 572 of the act. Such approvals under section 512 of the act must be:

- (1) An original NADA,
(2) A supplemental NADA, or
(3) An abbreviated NADA.

(d) *What are the approval requirements under section 512 of the act for new animal drugs intended for use in liquid feed?* An approval under section 512 of the act for a new animal drug intended for use in liquid feed must contain the following information:

- (1) Data, or a reference to data in a master file (MF), that shows the relevant ranges of conditions under which the drug will be chemically stable in liquid feed under field use conditions; and
(2) Data, or a reference to data in an MF, that shows that the drug is physically stable in liquid feed under field conditions; or
(3) Feed labeling with recirculation or agitation directions as follows:
(i) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of

the tank that is visible at the top. Agitate daily as described even when not used.

36. Amend § 558.6 by revising paragraphs (a)(4)(iv) and (a)(6) to read as follows:

§ 558.6 Veterinary feed directive drugs.

- (a) * * *
(4) * * *
(iv) Approved or index listed indications for use.

(6) You must issue a VFD only for the approved or indexed conditions and indications for use of the VFD drug.

PART 589—SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED

37. The authority citation for 21 CFR part 589 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 371.

38. Revise § 589.1000 to read as follows:

§ 589.1000 Gentian violet.

The Food and Drug Administration has determined that gentian violet has not been shown by adequate scientific data to be safe for use in animal feed. Use of gentian violet in animal feed causes the feed to be adulterated and in violation of the Federal Food, Drug, and Cosmetic Act (the act), in the absence of a regulation providing for its safe use as a food additive under section 409 of the act, unless it is subject to an effective notice of claimed investigational exemption for a food additive under § 570.17 of this chapter, or unless the substance is intended for use as a new animal drug and is subject to an approved application under section 512 of the act, or an index listing under section 572 of the act, or an effective notice of claimed investigational exemption for a new animal drug under part 511 of this chapter or § 516.125 of this chapter.

Dated: June 15, 2006.
Jeffrey Shuren,
Assistant Commissioner for Policy.
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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DOD-2006-OS-0091]

RIN 0720-AB00

TRICARE; Reserve and Guard Family Member Benefits

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement sections 704 and 705 of the Ronald W. Reagan National Defense Authorization Act for Fiscal Year 2005. These provisions would apply to eligible family members who become eligible for TRICARE as a result of their Reserve Component (RC) sponsor (including those with delayed effective date orders up to 90 days) being called or ordered to active duty for more than 30 days in support of a federal/contingency operation and choose to participate in TRICARE Standard or Extra, rather than enroll in TRICARE Prime. The first provision would provide the Secretary the authority to waive the annual TRICARE Standard (or Extra) deductible, which is set by law (10 U.S.C. 1079(b)) at \$150 per individual and \$300 per family (\$50/\$150 for families of members in pay grades E-4 and below). The second provision would provide the Secretary the authority to increase TRICARE payments up to 115 percent of the TRICARE maximum allowable charge, less the applicable patient cost share if not previously waived under the first provision, for covered outpatient health services received from a provider that does not participate (accept assignment) with TRICARE. These provisions would help ensure timely access to health care and maintain clinically appropriate continuity of health care to family members of Reservists and Guardsmen activated in support of a federal/contingency operation; limit the out-of-pocket health care expenses for those family members; and remove potential barriers to health care access by Guard and Reserve families.

DATES: Written comments received at the address indicated below by October 23, 2006.

ADDRESSES: You may submit comments, identified by docket number and or RIN number and title, by any of the following methods:

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

• Mail: Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301-1160.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at <http://regulations.gov> as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: LT COL James Whitton, Strategic Initiatives Division, TRICARE Operations, TRICARE Management Activity, telephone (703) 681-0039.

SUPPLEMENTARY INFORMATION:

I. Introduction and Background

On November 5, 2001, the Department of Defense (DoD) published notice of a nationwide TRICARE Demonstration Project (66 FR 55928-55930). This demonstration was conducted under the authority of 10 U.S.C. 1092. In this demonstration project, DoD addressed unreasonable impediments to the continuity of health care encountered by certain family members of Reservists and National Guard called to active duty in support of a federal contingency operation for more than 30 days. On November 12, 2003, DoD published a notice (68 FR 64087) to extend through October 31, 2004, the demonstration project which was scheduled to end on November 1, 2003. On October 1, 2004, the DoD published another notice (69 FR 58895) extending the demonstration project, previously scheduled to end on October 31, 2004, to October 31, 2005. On October 12, 2005, DoD published a notice (70 FR 59320) to extend the demonstration project, previously scheduled to end on October 31, 2005, to October 31, 2007. The continued deployment of RC members in support of Operation Noble Eagle/Operation Enduring Freedom and Operation Iraqi Freedom warrants making permanent the Secretary's authority to exercise certain components of this demonstration project. Sections 704 and 705 of the Ronald W. Reagan National Defense Authorization Act for Fiscal Year 2005 provide DoD authority to make two components of the demonstration project permanent and amend section 1095d(a) and section 1079(h) of Title 10, United States Code, as appropriate. In accordance with these two statutory provisions, DoD proposes

to implement this discretionary authority.

II. Permanent Benefits Offered to Reserve Component Families

A. *Waiver of deductible* (paragraph 199.4(f)(2)(i)(H)). Eligible family members of RC sponsors called or ordered to active duty for more than 30 days in support of a federal contingency operation, who choose to participate in TRICARE Standard, may not be responsible for paying the annual TRICARE Standard deductible. By law, the TRICARE Standard deductible for active duty family members is \$150 per individual, \$300 per family (\$50/\$150 for E-4s and below) each fiscal year. Exercise of the authority to waive this annual deductible would appropriately limit out-of-pocket expenses for many Reserve and Guard family members, in consideration of the fact that many may have already paid annual deductibles under their civilian health plan.

B. *Increased payment to providers* (paragraph 199.14(j)). Executive of the authority contained in this program would allow an increase in TRICARE payments up to 115 percent of the TRICARE maximum allowable charge, less the applicable patient cost share if not previously waived under the first provision, for outpatient care received from a provider that does not participate (accept assignment) under TRICARE. This would help Reserve and Guard family members be able to continue to see civilian providers with whom they would have established relations and would promote access and clinically appropriate continuity of care.

III. Regulatory Procedures

Executive Order 12866 requires certain regulatory assessments for any significant regulatory action that would result in an annual effect on the economy of \$100 million or more. The Congressional Review Act establishes certain procedures for major rules, defined as those with similar major 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 that would have significant impact on a substantial number of small entities. This proposed rule would not have an annual effect on the economy of \$100 million or more. An IGCE estimates the annual cost for both of these provisions at less than \$30 million.

This rule, however, does address a novel policy issues relating to waiving the deductibles for one category of family member beneficiaries and not

others, as well as allowing providers who treat this same group of beneficiaries to receive reimbursement at a higher rate than providers who treat similar beneficiaries. Thus this rule has been reviewed by the Office of Management and Budget under E.O. 12866.

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

We have examined the impact(s) of the proposed 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.

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 proposed to be 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 proposed to be amended by revising paragraph (f)(2)(i)(H) to read as follows:

§ 199.4 Basic program benefits.

* * * * *

(f) * * *

(2) * * *

(i) * * *

(H) The Director, TRICARE Management Activity, may waive the annual individual or family fiscal year deductible for dependents of a Reserve Component member who is called or ordered to active duty for a period of more than 30 days or a National Guard member who is called or ordered to full-time federal National Guard duty for a period of more than 30 days in support of a contingency operation (as defined in 10 U.S.C. 101(a)(13)). For purposes of this paragraph, a dependent is a lawful husband or wife of the member and a child as defined in paragraphs (b)(2)(ii)(A) through (F) and (b)(2)(ii)(H)(1), (2), and (4) of § 199.3.

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3. Section 199.14 is proposed to be amended by adding paragraph (j)(1)(i)(E) to read as follows:

§ 199.14 Provider reimbursement methods.

* * * * *

- (j) * * *
- (1) * * *
- (i) * * *

(E) *Special rule for certain TRICARE Standard Beneficiaries.* In the case of a dependent spouse or child, as defined in paragraphs (b)(2)(ii)(A) through (F) and (b)(2)(ii)(H)(1), (2), and (4) of § 199.3, of a Reserve component member serving on active duty pursuant to a call or order to active duty for a period of more than 30 days in support of a contingency operation under a provision of law referred to in section 101(a)(13)(B) of title 10, United States Code, the Director, TRICARE Management Activity, may authorize for non-participating providers the allowable charge to be the lower of the billed amount or 115% of the applicable balance billing limit under paragraph (j)(1)(i)(C) of this section, less the applicable beneficiary cost share.

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August 15, 2006.

L.M. Bynum,

*OSD Federal Register Liaison Officer,
Department of Defense.*

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BILLING CODE 5001-06-P

DEPARTMENT OF EDUCATION

34 CFR Part 280

Magnet Schools Assistance Program

AGENCY: Office of Innovation and Improvement, Department of Education.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Secretary proposes to amend the regulations governing the Magnet Schools Assistance Program (MSAP) in 34 CFR part 280. These proposed amendments would allow the MSAP to use an approach similar to that in 34 CFR 75.200 for establishing selection criteria in grant competitions. Under this approach the MSAP would have the flexibility to use selection criteria from its program regulations, from the menu of general selection criteria in the Education Department General Administrative Regulations (EDGAR) in 34 CFR 75.210, based on statutory provisions in accordance with 34 CFR 75.209, or from any combination of these.

DATES: We must receive your comments on or before September 21, 2006.

ADDRESSES: Address all comments about these proposed regulations to Steven L. Brockhouse, U.S. Department of Education, 400 Maryland Avenue, SW., room 4W229, Washington, DC 20202-5970. If you prefer to send your comments through the Internet, you may address them to us at the U.S. Government Web site: <http://www.regulations.gov>.

Or you may send your Internet comments to us at the following address: steve.brockhouse@ed.gov.

You must include the term "MSAP NPRM" in the subject line of your electronic message.

FOR FURTHER INFORMATION CONTACT: Steven L. Brockhouse. Telephone: (202) 260-2476 or via Internet: steve.brockhouse@ed.gov.

If you use a telecommunications device for the deaf (TDD), you may call the Federal Relay Service (FRS) at 1-800-877-8339.

Individuals with disabilities may obtain this document in an alternative format (e.g., Braille, large print, audiotape, or computer diskette) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

SUPPLEMENTARY INFORMATION:

Invitation To Comment

We invite you to submit comments regarding these proposed regulations. To ensure that your comments have maximum effect in developing the final regulations, we urge you to identify clearly the specific section or sections of the proposed regulations that each of your comments addresses and to arrange your comments in the same order as the proposed regulations.

We invite you to assist us in complying with the specific requirements of Executive Order 12866 and its overall requirement of reducing regulatory burden that might result from these proposed regulations. Please let us know of any further opportunities we should take to reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about these proposed regulations in room 4W229, 400 Maryland Avenue, SW., Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Eastern time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record

On request, we will supply an appropriate aid to an individual with a

disability who needs assistance to review the comments or other documents in the public rulemaking record for these proposed regulations. If you want to schedule an appointment for this type of aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Background

On March 6, 1997, the Secretary published final regulations (62 FR 10398) amending the provisions of EDGAR governing discretionary grant programs administered directly by us. These amendments established an approach by which the Secretary could use different types of selection criteria when evaluating a grant application. Specifically, § 75.200 was amended to permit the Secretary to use selection criteria based on statutory provisions in accordance with 34 CFR 75.209, selection criteria in program-specific regulations, selection criteria established under 34 CFR 75.210, or any combination of these. Section 75.210 provides a menu of selection criteria. For a competition, the Secretary selects from the menu one or more criteria that best enable us to identify the highest-quality applications consistent with the program purpose, statutory requirements, and any priorities established. Within each criterion, the Secretary may further define the criterion by selecting one or more specific factors.

At the time that these final regulations were published, we also amended, through notice and comment rulemaking, the regulations for a number of Department programs that contained program-specific selection criteria, so that these programs could use the criteria in 34 CFR 75.210, criteria based on statutory provisions, or the criteria in their program regulations for grant competitions. The MSAP regulations were not amended at that time.

This notice of proposed rulemaking would conform the MSAP regulations to those of the majority of other discretionary grant programs in the Department. We believe that by expanding the range of selection criteria that could be used in a specific grant competition, we will be able to administer the MSAP more effectively to best meet the program's statutory purposes and requirements and to better ensure that MSAP projects are effectively integrated with State and local reform activities.

We intend that the MSAP will use the selection criteria in 34 CFR 75.210 in conjunction with criteria based on the statute and in the program-specific