the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect 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.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The Federal Aviation Administration (FAA) amends § 39.13 by adding the following new airworthiness directive (AD):

Airbus: Docket No. FAA–2006–25079; Directorate Identifier 2006–NM–065–AD.

Comments Due Date

(a) The FAA must receive comments on this AD action by July 20, 2006.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Airbus Model A310–304, –308, –324, and –325 airplanes, certificated in any category; equipped with auxiliary center tanks (ACTs); except those on which Airbus Modification 8928 has been done in production.

Unsafe Condition

(d) This AD results from a report that it was not possible to transfer fuel from ACTs 1 and 2 during flight, and no electronic centralized aircraft monitor warnings were triggered. Investigation revealed a faulty static inverter and blown fuse, resulting in failure of certain fueling bus bars and subsequent failure of the automatic ACT fuel transfer. We are issuing this AD to prevent these failures, combined with failure of the non-return valve (NRV) to close. If the NRV is open during flight, the fuel supply to the engines may be reduced during cross-feed operation to the extent that fuel starvation could occur and result in engine flameout.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Replacement

(f) Within 15,000 flight hours after the effective date of this AD: Replace the existing NRV with a new, improved NRV by doing all the actions in accordance with the Accomplishment Instructions of Airbus Service Bulletin A310–28–2158, dated September 1, 2005.

Note 1: The Airbus service bulletin refers to Lucas Air Equipment Service Bulletin C23AE01–28–01, Revision 1, dated July 20, 1994, as an additional source of service information for replacing the NRV.

Parts Installation

(g) As of the effective date of this AD, no person may install, on any airplane, a NRV having part number C23AE0102, unless it has been modified according to paragraph (f) of this AD.

Alternative Methods of Compliance (AMOCs)

(h)(1) The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with § 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

Related Information

(i) French airworthiness directive F–2005–197, dated December 7, 2005, also addresses the subject of this AD.

Issued in Renton, Washington, on June 14, 2006.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E6–9631 Filed 6–19–06; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DoD–OS–2006–0054]

RIN 0720–AA98 (previously 0720–AA94)

TRICARE Program; Routine Care Not Directly Related to Study, Grant or Research Program

AGENCY: Office of the Secretary, DoD.

ACTION: Proposed rule.

SUMMARY: This proposed rule amends the exclusion of services and supplies provided as part of or under a research study, grant or research program to add coverage for routine patient care that would have been necessary in the absence of the study as well as care of complications that result from participation in the trial.

DATES: Written comments received at the address indicated below by August 21, 2006 will be accepted.

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: René Morrell, Medical Benefits and Reimbursement Systems, TRICARE Management Activity, telephone (303) 676–3618.

SUPPLEMENTARY INFORMATION: TRICARE supplements the availability of health care in military hospitals and clinics.

This proposed rule revises the exclusion of services and supplies provided as part of or under a research study, grant or research program to allow coverage of routine care not directly associated with the research study or grant.

Research Study, Grant or Research Program

By law, under 10 U.S.C. 1079(a)(13), TRICARE may cost share only medically or psychologically necessary services or supplies. The regulation and program policies currently exclude cost-sharing of services and supplies provided as part of or under a research study, grant or research program, because the medical efficacy and safety of such services and supplies, and as such, the medical necessity, has not yet been established. For people with serious or life-threatening diseases, curative treatment is often not available. A clinical trial or research study offers the potential to provide curative treatment. By participating in a clinical trial, people with serious or life-threatening diseases may benefit from curative treatment. This change will assist eligible TRICARE beneficiaries who participate in clinical trials by providing coverage for medically necessary routine care not directly associated with the treatment under investigation and providing coverage for complications arising from participation in clinical trials.

This exclusion removal applies only to clinical trials that are Phase II, Phase III, or Phase IV patient research studies approved by centers or cooperative groups that are funded by the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Centers for Disease Control (CDC), the Agency for Health Care Research and Quality (AHRQ), or the Department of Veterans Affairs (VA).

In general, there are two types of costs associated with a clinical trial—routine medically necessary patient care costs and research costs. Routine patient care costs can include (but are not limited to) doctor office visits, hospital stays, clinical laboratory tests (*e.g.,* blood tests, CT scans, bone scans) and X-rays. These are the type of costs that will be covered by TRICARE. Research costs are divided into treatment costs and administrative costs. Treatment costs include test performed purely for research purposes, additional research physician and nurse time, and the additional cost of the experimental therapy or treatment itself. Administrative costs include the costs associated with recruiting patients, data collection and management, and statistical analysis of results. These types of administrative costs are almost always paid for by the clinical trial sponsor. All types of research costs will continue to be excluded from TRICARE coverage. This change will make coverage for medically necessary services not directly associated with the treatment under investigation consistent with both the statute and medically necessary services and supplies authorized as an exception to the TRICARE exclusion for unproven medical treatments and procedures under the regulation. Under 32 CFR 199.4(g)(15), unproven drugs, devices, and medical treatments or procedures are excluded. However, coverage is authorized under paragraph (g)(15)(iii) of this section when treatment is not related to the unproven drug, device or medical treatment or procedure, *e.g.,* medically necessary in the absence of the unproven treatment. Treatment is also authorized which is necessary follow-up to the unproven drug, device or medical treatment or procedure but which might have been necessary in the absence of the unproven treatment. This change is also consistent with the coverage of Medicare and private insurance carriers.

Regulatory Procedures

Executive Order 12866 requires that a comprehensive regulatory impact analysis be performed on any economically significant regulatory action, defined as one that would result in an annual effect of $100 million or more on the national economy or which would have other substantial impacts.

The Regulatory Flexibility Act (RFA) requires that each Federal Agency prepare and make available for public comment, a regulatory flexibility analysis when the agency issues a Regulation which would have a significant impact on a substantial number of small entities.

This is neither a significant regulatory action under Executive Order 12886, nor would it have a significant impact on small entities. The changes set forth in the proposed rule are minor revisions to the existing regulation and affect only a small portion of the population who participate in research studies or grants. In addition, the proposed rule does not impose new information collection requirements for purposes of 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 proposed to be amended as follows:

PART 199—TRICARE PROGRAM; ROUTINE CARE NOT DIRECTLY RELATED TO STUDY, GRANT OR RESEARCH PROGRAM.

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 adding new paragraph (g)(14)(i) and by reserving paragraph (g)(14)(ii) to read as follows:

§ 199.4 Basic program benefits.

* * * * *

(g) * * *

(14) * * *

(i) *Care excluded.* This exclusion from benefits includes the investigational item or treatment itself, services and supplies customarily provided by the research sponsors free of charge for any enrollee in the trial, services and supplies provided solely to satisfy data collection and analysis and that are not used in the direct clinical management of the patient, and services and supplies provided to determine eligibility to participate in the study or research program. However, TRICARE may cover routine care not directly associated with the study or grant provided the research study or program is a Phase II, Phase III, or Phase IV patient research study approved by centers or cooperative groups that are funded by the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Centers for Disease Control (CDC), the Agency for Health Care Research and quality (AHRQ), or the Department of Veterans Affairs. Under those circumstances, TRICARE coverage is authorized for:

(A) Treatment that is not directly associated with the study or grant, e.g., medically necessary in the absence of the study or grant.

(B) Services and supplies that are medically necessary for the diagnosis or treatment of complications arising from participation in the research study or program.

(ii) [Reserved]

* * * * *

Dated: June 13, 2006.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 06–5489 Filed 6–19–06; 8:45 am]

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