Section 106, describes the authority for the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency’s authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes additional controlled airspace at Grand Junction Regional, Grand Junction, CO.

List of Subjects in 14 CFR Part 71
Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment
Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:


§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the FAA Order 7400.9T, Airspace Designations and Reporting Points, signed August 27, 2009, and effective September 15, 2009 is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

§ 71.1 [Amended]

ANM CO E5 Grand Junction, CO

[Modified]

Grand Junction Regional, Grand Junction, CO

(Lat. 39°07′21″N, long. 108°31′36″W.) Grand Junction VORTAC

(Lat. 39°07′24″N, long. 108°47′33″W.) Grand Junction Localizer

(Lat. 39°07′04″N, long. 108°30′48″W.)

That airspace extending upward from 700 feet above the surface within 7 miles northwest and 4.3 miles southeast of the Grand Junction VORTAC 247° and 067° radicals extending from 11.4 miles southwest to 12.1 miles northeast of the VORTAC, and within 1.8 miles south and 9.2 miles north of the Grand Junction VORTAC 110° radial extending from the VORTAC to 19.2 miles southeast of the VORTAC; that airspace extending upward from 1,200 feet above the surface within a 30.5-mile radius of the Grand Junction VORTAC, within 6.5 miles each side of the Grand Junction VORTAC 099° radial extending from the 30.5-mile radius to 58 miles east of the VORTAC, and within 4.3 miles each side of the Grand Junction VORTAC 166° radial extending from the 30.5-mile radius to 33.1 miles south of the VORTAC, and within 4.3 miles northeast and 4.9 miles southwest of the Grand Junction ILS localizer northwest course extending from the 30.5-mile radius to the intersection of the locator northwest course and the Grand Junction VORTAC 318° radial.


H. Steve Karnes,
Acting Manager, Operations Support Group, Western Service Center.

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DEPARTMENT OF DEFENSE
Office of the Secretary
32 CFR Part 199

[DOD–2008–HA–0057]

RIN 0720–AB24

TRICARE Program; Morbid Obesity

AGENCY: Office of the Secretary, DoD.

ACTION: Proposed rule.

SUMMARY: The Department of Defense (DoD) proposes to amend the TRICARE regulation on surgery for morbid obesity to allow benefit consideration for the newest bariatric surgical procedures that are considered appropriate medical care. The amendment also removes language that limits the types of surgical procedures to treat co-morbid conditions associated with morbid obesity, revises the TRICARE Program definition of morbid obesity, and retains the TRICARE Program exclusion of nonsurgical interventions related to morbid obesity, obesity and/or weight reduction. These changes are necessary to allow coverage for other surgical procedures that reduce or resolve co-morbid conditions associated with morbid obesity and the use of the Body Mass Index (BMI), which is the more accurate measure for excess weight to estimate relative risk of disease. Additionally, as new technologies or procedures evolve from investigational into generally accepted norms for medical practice, beneficiaries are entitled to TRICARE coverage of the new technology or procedures.

DATES: Comments must be received on or before December 28, 2009. Do not submit comments directly to the point of contact or mail your comments to any address other than what is shown below. Doing so will delay the posting of the submission.

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.


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://www.regulations.gov as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Gail L. Jones (303) 676–3401.

SUPPLEMENTARY INFORMATION:

I. Background

This document contains proposed regulation amending the requirements and procedures in 32 CFR, part 199 relating to surgery for morbid obesity, under section 2 (Definitions) and section 4 (Basic Program Benefits) of the regulation. On December 27, 1982, the DoD published a final rule in the Federal Register (47 FR 57491–57493) that restricted surgical intervention for morbid obesity to gastric bypass, gastric stapling, or gastroplasty method (excluding all other types) when the primary purpose of surgery is to treat a severe related medical illness or medical condition. The severe medical conditions or illness associated with morbid obesity included diabetes mellitus, hypertension, cholecystitis, narcolepsy, Pickwickian Syndrome (and other severe respiratory disease), hypothalamic disorders, and severe arthritis of the weight-bearing joints. The DoD also limited program payments to two categories of patients: (1) Those that weigh 100 pound over their ideal weight with a specific severe medical condition; and (2) those who are 200 percent or more over their ideal weight with no medical complications required. Program payment was made available as well for special consideration of those unique cases in which the patient received an intestinal bypass, or other surgery for obesity and, because of complications, required a...
second surgery. Payment is allowed even though the patient’s condition may not technically meet the definition of morbid obesity because of the weight that was already lost following the initial surgery. All other surgeries including non-surgical treatment related to morbid obesity, obesity, and/or weight reduction are excluded.

The DoD did not revise the definition of morbid obesity, which is based on the Metropolitan Life Table and used then by other major health care plan, as well as reflected the 1982 general opinion regarding which cases justify surgical intervention. The DoD decided, at the time, that it was necessary to be very specific in benefit parameters due to fiscal responsibility and to ensure that Program beneficiaries were not being exposed to less than fully developed medical technology or procedures.

II. Explanation for Proposed Provisions

Overview

At the time the current regulation was written, gastric bypass, gastric stapling, and gastroplasty methods were the recognized surgeries for morbid obesity. In recent years, other bariatric surgical procedures have been used more and more frequently, and some have a substantial body of literature to support their safety and efficacy. Rather than list the specific surgical procedures that may be covered under the TRICARE Program and the clinical conditions for which coverage may be extended, this proposed rule authorizes benefit consideration for those bariatric surgical procedures that have moved from the unproven status to the position of nationally accepted medical practice, as determined by the Program standard of reliable evidence.

Also during development of the current regulation for morbid obesity, overweight and obesity were typically measured with height-weight tables (such as the Metropolitan Life Table). The regulation (as currently written) restricts eligibility for bariatric surgery to individuals who exceed their ideal weight for height by 100 pounds with an associated severe medical condition, or 200 percent or more over their ideal body weight with no associated medical condition required. This proposed amendment changes the Program definition of morbid obesity to reflect the nationally accepted medical use of the BMI, rather than the typical assessed height-weight table (i.e., the Metropolitan Life Table), to determine an individual’s eligibility for bariatric surgical treatment. The BMI is the more accurate measure for excess weight to estimate relative risk of disease. Since there now are more than 30 major diseases associated with obesity, the Director, TMA, or a designee, will issue specific criteria for co-morbid conditions exacerbated or caused by (morbid) obesity.

This proposed rule does not expand the TRICARE benefit for morbid obesity surgery. However, it does make the specific procedures that are covered, as well as the clinical conditions for which coverage may be extended, a matter of policy. In other words, new bariatric surgery procedures may be added to the TRICARE benefit structure as such procedures are proven safe and effective and are established as nationally accepted medical practice as determined by the Program standard of reliable evidence.

This amendment is being published for proposed rulemaking at the same time as it is being coordinated within the DoD, with the Department of Health and Human Services, and with other interested agencies, in order that consideration of both internal and external comments and publication of the final rulemaking document can be expedited.

III. Response to Comments

Because of the large number of public comments generally received on Federal Register documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the DATES section of this preamble, and, when we proceed with a subsequent document, we will respond to the major comments in the preamble to that document. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

IV. Regulatory Procedures

Executive Order 12866, “Regulatory Planning and Review”

It has been determined that this proposed rule is not a significant regulatory action. This rule does not:

1. Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy; a section of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities;

2. Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency;

3. Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or

4. Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive Order.

Unfunded Mandates Reform Act (Sec. 202, Pub. L. 104–4)

It has been certified that this proposed rule does not contain a Federal mandate that may result in the expenditure by State, local and tribal governments, in aggregate, or by the private sector, of $100 million or more in any one year.


It has been certified that this proposed rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. Set forth in the proposed rule are minor revisions to the existing regulation. The DoD does not anticipate a significant impact on the Program. The change from height-weight tables to the BMI should have a minimal impact on the number of beneficiaries eligible for surgery.

Public Law. 96–511, “Paperwork Reduction Act” (44 U.S.C. Chapter 35)

It has been certified that this proposed rule does not impose reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995.

Executive Order 13132, Federalism

It has been certified that this proposed rule does not have federalism implications, as set forth in Executive Order 13132. This rule does not have substantial direct effects on:

1. The States;

2. The relationship between the National Government and the States; or

3. The distribution of power and responsibilities among the various levels of Government.

List of Subjects in 32 CFR Part 199

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, and Military personnel.

Accordingly, 32 CFR Part 199 is proposed to be amended to read as follows:

PART 199—[AMENDED]

1. The authority citation for part 199 continues to read as follows:


2. Section 199.2, paragraph (b) is amended by adding the definition of
“Bariatric Surgery” and revising the definition of “Morbid Obesity” to read as follows:

§ 199.2 Definitions.
* * * * *
(b) * * *
Bariatric Surgery. Surgical procedures performed to treat co-morbid conditions associated with morbid obesity. Bariatric surgery is based on two principles:
(1) Divert food from the stomach to a lower part of the digestive tract where the normal mixing of digestive fluids and adsorption of nutrients cannot occur (i.e., Malabsorptive surgical procedures); or
(2) Restrict the size of the stomach and decrease intake (i.e., Restrictive surgical procedures).

* * * * *

Morbid obesity. A body mass index (BMI) equal to or greater than 40 kilograms per meter squared (kg/m²), or a BMI equal to or greater than 35 kg/m² in conjunction with high-risk co-morbidities, which is based on the guidelines established by the National Heart, Lung and Blood Institute Federal on the Identification and Management of Patients with Obesity.

Note: Body mass index is equal to weight in kilograms divided by height in meters squared.
* * * * *

3. Section 199.4 is amended by revising paragraphs (e)(15) and (g)(28) to read as follows:

§ 199.4 Basic program benefits.
* * * * *
(e) * * *
(15) Morbid obesity. The TRICARE morbid obesity benefit is limited to those bariatric surgical procedures for which the safety and efficacy has been proven comparable or superior to conventional therapies and is consistent with the generally accepted norms for medical practice in the United States medical community.

(i) Conditions for coverage. (A) Payment for bariatric surgical procedures are determined by the requirements specified in paragraph (g)(15) of this section, and as defined in § 199.2(b) of this part.

(B) Covered bariatric surgical procedures are payable only when the patient has completed growth (18 years of age or documentation of completion of bone growth) and has met one of the following selection criteria:
(1) The patient has a BMI that is equal to or exceeds 40 kg/m², and has previously been unsuccessful with medical treatment for obesity.

(2) The patient has a BMI of 35 to 39.9 kg/m², has at least one high-risk co-morbid condition associated with morbid obesity, and has previously been unsuccessful with medical treatment for obesity.

Note: The Director, TMA, or a designee, shall issue guidelines for review or the specific high-risk co-morbid conditions, exacerbated or, caused by obesity.

(ii) Treatment of complications. (A) Payment may be extended for repeat bariatric surgery when medically necessary to correct or treat complications from the initial bariatric surgery (a takedown). For instance, the surgeon in many cases will do a gastric bypass or gastropasty to help the patient avoid regaining the weight that was lost. In this situation, payment is authorized even though the patient’s condition technically may not meet the definition of morbid obesity because of the weight that was already lost following the initial surgery.

(B) Payment is authorized for otherwise covered medical services and supplies directly related to complications of obesity when such services and supplies are an integral and necessary part of the course of treatment that was aggravataed by the obesity.

(g) * * *
(28) Obesity, weight reduction. Service and supplies related “solely” to obesity or weight reduction or weight control whether surgical or nonsurgical; wiring of the jaw or any procedure of similar purpose, regardless of the existence of co-morbid conditions.
* * * * *


Patricia L. Toppings,
OSD Federal Register Liaison Officer,
Department of Defense.

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