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MANAGEMENT ACTIVITY

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The Department of Defense, Office of the Secretary, has authorized the following addition(s)/revision(s) to 32 CFR Part 199, reissued April 2005.

**CHANGE TITLE: TRICARE: UNFORTUNATE SEQUELAE FROM NONCOVERED SERVICES  
IN A MILITARY TREATMENT FACILITY**

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WHEN PRESCRIBED ACTION HAS BEEN TAKEN, FILE THIS TRANSMITTAL WITH BASIC DOCUMENT.

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CIVILIAN HEALTH AND MEDICAL PROGRAM OF THE UNIFORMED SERVICES (CHAMPUS)

PART 199.4

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(A) Any procedure performed for personal reasons to improve the appearance of an obvious feature or part of the body that would be considered by an average observer to be normal and acceptable for the patient's age or ethnic or racial background.

(B) Cosmetic, reconstructive, or plastic surgical procedures that are justified primarily on the basis of a psychological or psychiatric need.

(C) Augmentation mammoplasties. Augmentation mammoplasties, except for breast reconstruction following a covered mastectomy and those specifically authorized in paragraph (e)(8)(i) of this section.

(D) Face lifts and other procedures related to the aging process.

(E) Reduction mammoplasties. Reduction mammoplasties (unless there is medical documentation of intractable pain, not amenable to other forms of treatment, resulting from large, pendulous breasts or unless performed as an integral part of an authorized breast reconstruction procedure under paragraph (e)(8)(i) of this section, including reduction of the collateral breast for purposes of ensuring breast symmetry)

(F) Panniculectomy; body sculpture procedures.

(G) Repair of sagging eyelids (without demonstrated and medically documented significant impairment of vision).

(H) Rhinoplasties (without evidence of accidental injury occurring within the previous 6 months that resulted in significant obstruction of breathing).

(I) Chemical peeling for facial wrinkles.

(J) Dermabrasion of the face.

(K) Elective correction of minor dermatological blemishes and marks or minor anatomical anomalies.

(L) Revision of scars resulting from surgery or a disease process, except disfiguring and extensive scars resulting from neoplastic surgery.

(M) Removal of tattoos.

(N) Hair transplants.

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- (O) Electrolysis.
- (P) Any procedures related to transsexualism or such other conditions as gender dysphoria except as provided in paragraph (e)(7) of this section.
- (Q) Penile implant procedure for psychological impotency, transsexualism, or such other conditions as gender dysphoria.
- (R) Insertion of prosthetic testicles for transsexualism, or such other conditions as gender dysphoria.
- (9) Complications (unfortunate sequelae) resulting from noncovered initial surgery or treatment. (i) Benefits are available for otherwise covered services and supplies required in the treatment of complications resulting from a noncovered incident of treatment (such as nonadjunctive dental care, transsexual surgery, and cosmetic surgery) but only if the later complication represents a separate medical condition such as a systemic infection, cardiac arrest, and acute drug reaction. Benefits may not be extended for any later care or procedures related to the complication that essentially is similar to the initial noncovered care. Examples of complications similar to the initial episode of care (and thus not covered) would be repair of facial scarring resulting from dermabrasion for acne or repair of a prolapsed vagina in a biological male who had undergone transsexual surgery.
  - (ii) Benefits are available for otherwise covered services and supplies required in the treatment of complications (unfortunate sequelae) resulting from a noncovered incident of treatment provided in an MTF, when the initial noncovered service has been authorized by the MTF Commander and the MTF is unable to provide the necessary treatment of the complications, according to the guidelines adopted by the Director, TMA, or a designee.
- (10) Dental. TRICARE/CHAMPUS does not include a dental benefit. However, in connection with dental treatment for patients with developmental, mental, or physical disabilities or for pediatric patients age 5 or under, only institutional and anesthesia services may be provided as a benefit.
  - (i) Adjunctive dental care: Limited. Adjunctive dental care is limited to those services and supplies provided under the following conditions:
    - (A) Dental care which is medically necessary in the treatment of an otherwise covered medical (not dental) condition, is an integral part of the treatment of such medical condition and is essential to the control of the primary medical condition. The following is a list of conditions for which CHAMPUS benefits are payable under this provision:
      - (1) Intraoral abscesses which extend beyond the dental alveolus.
      - (2) Extraoral abscesses.
      - (3) Cellulitis and osteitis which is clearly exacerbating and directly affecting a medical condition currently under treatment.
      - (4) Removal of teeth and tooth fragments in order to treat and repair facial trauma resulting from an accidental injury.

- (5) Myofacial Pain Dysfunction Syndrome.
- (6) Total or complete ankyloglossia.
- (7) Adjunctive dental and orthodontic support for cleft palate.
- (8) The prosthetic replacement of either the maxilla or the mandible due to the reduction of body tissues associated with traumatic injury (e.g., impact, gun shot wound), in addition to services related to treating neoplasms or iatrogenic dental trauma.

NOTE: The test of whether dental trauma is covered is whether the trauma is solely dental trauma. Dental trauma, in order to be covered, must be related to, and an integral part of medical trauma; or a result of medically necessary treatment of an injury or disease.

(B) Dental care required in preparation for medical treatment of a disease or disorder or required as the result of dental trauma caused by the medically necessary treatment of an injury or disease (iatrogenic).

(1) Necessary dental care including prophylaxis and extractions when performed in preparation for or as a result of in-line radiation therapy for oral or facial cancer.

(2) Treatment of gingival hyperplasia, with or without periodontal disease, as a direct result of prolonged therapy with Dilantin (diphenylhydantoin) or related compounds.

(C) Dental care is limited to the above and similar conditions specifically prescribed by the Director, OCHAMPUS, as meeting the requirements for coverage under the provisions of this section.

(ii) General exclusions.(A) Dental care which is routine, preventative, restorative, prosthodontic, periodontic or emergency does not qualify as adjunctive dental care for the purposes of CHAMPUS except when performed in preparation for or as a result of dental trauma caused by medically necessary treatment of an injury or disease.

(B) The adding or modifying of bridgework and dentures.

(C) Orthodontia, except when directly related to and an integral part of the medical or surgical correction of a cleft palate or when required in preparation for, or as a result of, trauma to the teeth and supporting structures caused by medically necessary treatment of an injury or disease.

(iii) Preauthorization required. In order to be covered, adjunctive dental care requires preauthorization from the Director, TRICARE Management Activity, or a designee, in accordance with paragraph (a)(12) of this section. When adjunctive dental care involves a medical (not dental) emergency (such as facial injuries resulting from an accident), the requirement for preauthorization is waived. Such waiver, however, is limited to the essential adjunctive dental care related to the medical condition requiring the immediate emergency treatment. A complete explanation, with supporting medical documentation, must be submitted with claims for emergency adjunctive dental care.

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(iv) Covered oral surgery. Notwithstanding the above limitations on dental care, there are certain oral surgical procedures that are performed by both physicians and dentists, and that are essentially medical rather than dental care. For the purposes of CHAMPUS, the following procedures, whether performed by a physician or dentist, are considered to be in this category and benefits may be extended for otherwise covered services and supplies without preauthorization:

(A) Excision of tumors and cysts of the jaws, cheeks, lips, tongue, and roof and floor of the mouth, when such conditions require a pathological (histological) examination.

(B) Surgical procedures required to correct accidental injuries of the jaws, cheeks, lips, tongue, and roof and floor of the mouth.

(C) Treatment of oral or facial cancer.

(D) Treatment of fractures of facial bones.

(E) External (extra-oral) incision and drainage of cellulitis.

(F) Surgery of accessory sinuses, salivary glands, or ducts.

(G) Reduction of dislocations and the excision of the temporomandibular joints, when surgery is a necessary part of the reduction.

(H) Any oral surgical procedure that falls within the cosmetic, reconstructive, or plastic surgery definition is subject to the limitations and requirements set forth in paragraph (e)(8) of this section.

NOTE: Extraction of unerupted or partially erupted, malposed or impacted teeth, with or without the attached follicular or development tissues, is not a covered oral surgery procedure except when the care is indicated in preparation for medical treatment of a disease or disorder or required as a result of dental trauma caused by the necessary medical treatment of an injury or illness. Surgical preparation of the mouth for dentures is not covered by CHAMPUS.

(v) Inpatient hospital stay in connection with non-adjunctive, noncovered dental care. Institutional benefits specified in paragraph (b) of this section may be extended for inpatient hospital stays related to noncovered, nonadjunctive dental care when such inpatient stay is medically necessary to safeguard the life of the patient from the effects of dentistry because of the existence of a specific and serious nondental organic impairment currently under active treatment. (Hemophilia is an example of a condition that could be considered a serious nondental impairment.) Preauthorization by the Director, OCHAMPUS, or a designee, is required for such inpatient stays to be covered in the same manner as required for adjunctive dental care described in paragraph (e)(10)(iii) of this section. Regardless of whether or not the preauthorization request for the hospital admission is approved and thus qualifies for institutional benefits, the professional service related to the nonadjunctive dental care is not covered.

(vi) Anesthesia and institutional costs for dental care for children and certain other patients. Institutional benefits specified in paragraph (b) of this section may be extended for hospital and in-out surgery settings related to noncovered, nonadjunctive dental care when such outpatient care or inpatient stay is in conjunction with dental treatment for patients with developmental, mental, or physical disabilities or for pediatric patients age 5 or under. For these patients, anesthesia services will be limited to the administration of general anesthesia only. Patients with developmental, mental, or physical disabilities are those patients with conditions that prohibit dental treatment in a safe and effective manner. Therefore, it is medically or psychologically necessary for these patients to require general anesthesia for dental treatment. Patients with physical disabilities include those patients having disabilities as defined in Sec. 199.2 as a serious physical disability. Preauthorization by the Director, TRICARE Management Activity, or a designee, is required for such outpatient care or inpatient stays to be covered in the same manner as required for adjunctive dental care described in paragraph (e)(10)(iii) of this section. Regardless of whether or not the preauthorization request for outpatient care or hospital admission is approved and thus qualifies for institutional benefits, the professional service related to the nonadjunctive dental care is not covered, with the exception of coverage for anesthesia services.

(11) Drug abuse. Under the Basic Program, benefits may be extended for medically necessary prescription drugs required in the treatment of an illness or injury or in connection with maternity care (refer to paragraph (d) of this section). However, CHAMPUS benefits cannot be authorized to support or maintain an existing or potential drug abuse situation, whether or not the drugs (under other circumstances) are eligible for benefit consideration and whether or not obtained by legal means.

(i) Limitations on who can prescribe drugs. CHAMPUS benefits are not available for any drugs prescribed by a member of the beneficiary's family or by a nonfamily member residing in the same household with the beneficiary or sponsor.

(ii) Drug maintenance programs excluded. Drug maintenance programs when one addictive drug is substituted for another on a maintenance basis (such as methadone substituted for heroin) are not covered. This exclusion applies even in areas outside the United States where addictive drugs are dispensed legally by physicians on a maintenance dosage level.

(iii) Kinds of prescription drugs that are monitored carefully by CHAMPUS for possible abuse situations--(A) Narcotics. Examples are Morphine and Demerol.

(B) Nonnarcotic analgesics. Examples are Talwin and Darvon.

(C) Tranquilizers. Examples are Valium, Librium, and Meprobamate.

(D) Barbiturates. Examples are Seconal and Nembuttal.

(E) Nonbarbituate hypnotics. Examples are Doriden and Chloral Hydrate.

(F) Stimulants. Examples are amphetamines.

(iv) CHAMPUS fiscal intermediary responsibilities. CHAMPUS fiscal intermediaries are responsible for implementing utilization control and quality assurance procedures designed

to identify possible drug abuse situations. The CHAMPUS fiscal intermediary is directed to screen all drug claims for potential overutilization and irrational prescribing of drugs, and to subject any such cases to extensive review to establish the necessity for the drugs and their appropriateness on the basis of diagnosis or definitive symptoms.

(A) When a possible drug abuse situation is identified, all claims for drugs for that specific beneficiary or provider will be suspended pending the results of a review.

(B) If the review determines that a drug abuse situation does in fact exist, all drug claims held in suspense will be denied.

(C) If the record indicates previously paid drug benefits, the prior claims for that beneficiary or provider will be reopened and the circumstances involved reviewed to determine whether or not drug abuse also existed at the time the earlier claims were adjudicated. If drug abuse is later ascertained, benefit payments made previously will be considered to have been extended in error and the amounts so paid recouped.

(D) Inpatient stays primarily for the purpose of obtaining drugs and any other services and supplies related to drug abuse also are excluded.

(v) Unethical or illegal provider practices related to drugs. Any such investigation into a possible drug abuse that uncovers unethical or illegal drug dispensing practices on the part of an institution, a pharmacy, or physician will be referred to the professional or investigative agency having jurisdiction. CHAMPUS fiscal intermediaries are directed to withhold payment of all CHAMPUS claims for services and supplies rendered by a provider under active investigation for possible unethical or illegal drug dispensing activities.

(vi) Detoxification. The above monitoring and control of drug abuse situations shall in no way be construed to deny otherwise covered medical services and supplies related to drug detoxification (including newborn, addicted infants) when medical supervision is required.

(12) (Reserved)

(13) Domiciliary care. The statute under which CHAMPUS operates also specifically excludes domiciliary care (refer to Sec. 199.2 of this part for the definition of "Domiciliary Care").

(i) Examples of domiciliary care situations. The following are examples of domiciliary care for which CHAMPUS benefits are not payable.

(A) Home care is not available. Institutionalization primarily because parents work, or extension of a hospital stay beyond what is medically necessary because the patient lives alone, are examples of domiciliary care provided because there is no other family member or other person available in the home.

(B) Home care is not suitable. Institutionalization of a child because a parent (or parents) is an alcoholic who is not responsible enough to care for the child, or because someone in the home has a contagious disease, are examples of domiciliary care being provided because the home setting is unsuitable.

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(C) Family unwilling to care for a person in the home. A child who is difficult to manage may be placed in an institution, not because institutional care is medically necessary, but because the family does not want to handle him or her in the home. Such institutionalization would represent domiciliary care, that is, the family being unwilling to assume responsibility for the child.

(ii) Benefits available in connection with a domiciliary care case. Should the beneficiary receive otherwise covered medical services or supplies while also being in a domiciliary care situation, CHAMPUS benefits are payable for those medical services or supplies, or both, in the same manner as though the beneficiary resided in his or her own home. Such benefits would be cost-shared as though rendered to an outpatient.

(iii) General exclusion. Domiciliary care is institutionalization essentially to provide a substitute home--not because it is medically necessary for the beneficiary to be in the institution (although there may be conditions present that have contributed to the fact that domiciliary care is being rendered). CHAMPUS benefits are not payable for any costs or charges related to the provision of domiciliary care. While a substitute home or assistance may be necessary for the beneficiary, domiciliary care does not represent the kind of care for which CHAMPUS benefits can be provided.

(14) CT scanning--(i) Approved CT scan services. Benefits may be extended for medically necessary CT scans of the head or other anatomical regions of the body when all of the following conditions are met:

(A) The patient is referred for the diagnostic procedure by a physician.

(B) The CT scan procedure is consistent with the preliminary diagnosis or symptoms.

(C) Other noninvasive and less costly means of diagnosis have been attempted or are not appropriate.

(D) The CT scan equipment is licensed or registered by the appropriate state agency responsible for licensing or registering medical equipment that emits ionizing radiation.

(E) The CT scan equipment is operated under the general supervision and direction of a physician.

(F) The results of the CT scan diagnostic procedure are interpreted by a physician.

(ii) Review guidelines and criteria. The Director, OCHAMPUS, or a designee, will issue specific guidelines and criteria for CHAMPUS coverage of medically necessary head and body part CT scans.

(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. (See the definition of reliable evidence in Sec. 199.2 of this part for the procedures used in determining if a medical treatment or procedure is unproven.)

(i) Conditions for coverage.

(A) Payment for bariatric surgical procedures is determined by the requirements specified in paragraph (g)(15) of this section, and as defined in Sec. 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/m<sup>2</sup> and has previously been unsuccessful with medical treatment for obesity.

(2) The patient has a BMI of 35 to 39.9 kg/m<sup>2</sup>, 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, shall issue guidelines for review of the specific high-risk co-morbid conditions, exacerbated or caused by obesity based on the Reliable Evidence Standard as defined in Sec. 199.2 of this part.

(ii) Treatment of complications.

(A) Payment may be extended for repeat bariatric surgery when medically necessary to correct or treat complications from the initial covered bariatric surgery (a takedown). For instance, the surgeon in many cases will do a gastric bypass or gastroplasty 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 aggravated by the obesity.

(iii) Exclusions. CHAMPUS payment may not be extended for weight control services, weight control/loss programs, dietary regimens and supplements, appetite suppressants and other medications; food or food supplements, exercise and exercise programs, or other programs and equipment that are primarily intended to control weight or for the purpose of weight reduction, regardless of the existence of co-morbid conditions.

(16) Maternity care.(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:

(A) Inpatient cost-share formula applies to maternity care ending in childbirth in, or on the way to, a hospital inpatient childbirth unit, and for maternity care ending in a non-birth outcome not otherwise excluded by this part.

(B) Ambulatory surgery cost-share formula applies to maternity care ending in childbirth in, or on the way to, a birthing center to which the beneficiary is admitted and from which the beneficiary has received prenatal care, or a hospital-based outpatient birthing room.

(C) Outpatient cost-share formula applies to maternity care which terminates in a planned childbirth at home.

(D) Otherwise covered medical services and supplies directly related to "Complications of pregnancy," as defined in Sec. 199.2 of this part, will be cost-shared on the same basis as the related maternity care for a period not to exceed 42 days following termination of the pregnancy and thereafter cost-shared on the basis of the inpatient or outpatient status of the beneficiary when medically necessary services and supplies are received.

(17) Biofeedback Therapy. Biofeedback therapy is a technique by which a person is taught to exercise control over a physiologic process occurring within the body. By using modern biomedical instruments the patient learns how a specific physiologic system within his body operates and how to modify the performance of this particular system.

(i) Benefits Provided. CHAMPUS benefits are payable for services and supplies in connection with electrothermal, electromyograph and electrodermal biofeedback therapy when there is documentation that the patient has undergone an appropriate medical evaluation, that their present condition is not responding to or no longer responds to other forms of conventional treatment, and only when provided as treatment for the following conditions:

(A) Adjunctive treatment for Raynaud's Syndrome.

(B) Adjunctive treatment for muscle re-education of specific muscle groups or for treating pathological muscle abnormalities of spasticity, or incapacitating muscle spasm or weakness.

(ii) Limitations. Payable benefits include initial intake evaluation. Treatment following the initial intake evaluation is limited to a maximum of 20 inpatient and outpatient biofeedback treatments per calendar year.

(iii) Exclusions. Benefits are excluded for biofeedback therapy for the treatment of ordinary muscle tension states or for psychosomatic conditions. Benefits are also excluded for the rental or purchase of biofeedback equipment.

(iv) Provider Requirements. A provider of biofeedback therapy must be a CHAMPUS-authorized provider. (Refer to Sec. 199.6, "Authorized Providers). If biofeedback treatment is provided by other than a physician, the patient must be referred by a physician.

(v) Implementation Guidelines. The Director of OCHAMPUS shall issue guidelines as are necessary to implement the provision of this paragraph.

(18) Cardiac rehabilitation. Cardiac rehabilitation is the process by which individuals are restored to their optimal physical, medical, and psychological status, after a cardiac event. Cardiac rehabilitation is often divided into three phases. Phase I begins during inpatient hospitalization and is managed by the patient's personal physician. Phase II is a medically supervised outpatient program which begins following discharge. Phase III is a lifetime

maintenance program emphasizing continuation of physical fitness with periodic follow up. Each phase includes an exercise component, patient education, and risk factor modification. There may be considerable variation in program components, intensity, and duration.

(i) Benefits Provided. CHAMPUS benefits are available on an inpatient or outpatient basis for services and supplies provided in connection with a cardiac rehabilitation program when ordered by a physician and provided as treatment for patients who have experienced the following cardiac events within the preceding twelve (12) months:

- (A) Myocardial Infarction.
- (B) Coronary Artery Bypass Graft.
- (C) Coronary Angioplasty.
- (D) Percutaneous Transluminal Coronary Angioplasty
- (E) Chronic Stable Angina (see limitations below).
- (F) Heart valve surgery.
- (G) Heart or Heart-lung Transplantation.

(ii) Limitations. Payable benefits include separate allowance for the initial evaluation and testing. Outpatient treatment following the initial intake evaluation and testing is limited to a maximum of thirty-six (36) sessions per cardiac event, usually provided 3 sessions per week for twelve (12) weeks. Patients diagnosed with chronic stable angina are limited to one treatment episode (36 sessions) in a calendar year.

(iii) Exclusions. Phase III cardiac rehabilitation lifetime maintenance programs performed at home or in medically unsupervised settings are not covered.

(iv) Providers. A provider of cardiac rehabilitation services must be a TRICARE authorized hospital (see Sec. 199.6 (b)(4)(i)) or a freestanding cardiac rehabilitation facility that meets the requirements of Sec. 199.6 (f). All cardiac rehabilitation services must be ordered by a physician.

(v) Payment. Payment for outpatient treatment will be based on an all inclusive allowable charge per session. Inpatient treatment will be paid based upon the reimbursement system in place for the hospital where the services are rendered.

(vi) Implementation Guidelines. The Director of OCHAMPUS shall issue guidelines as are necessary to implement the provisions of this paragraph.

(19) Hospice care. Hospice care is a program which provides an integrated set of services and supplies designed to care for the terminally ill. This type of care emphasizes palliative care and supportive services, such as pain control and home care, rather than cure-oriented services provided in institutions that are otherwise the primary focus under CHAMPUS. The benefit provides coverage for a humane and sensible approach to care during the last days of life for some terminally ill patients.

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(i) Benefit coverage. CHAMPUS beneficiaries who are terminally ill (that is, a life expectancy of six months or less if the disease runs its normal course) will be eligible for the following services and supplies in lieu of most other CHAMPUS benefits:

(A) Physician services.

(B) Nursing care provided by or under the supervision of a registered professional nurse.

(C) Medical social services provided by a social worker who has at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education, and who is working under the direction of a physician. Medical social services include, but are not limited to the following:

(1) Assessment of social and emotional factors related to the beneficiary's illness, need for care, response to treatment, and adjustment to care.

(2) Assessment of the relationship of the beneficiary's medical and nursing requirements to the individual's home situation, financial resources, and availability of community resources.

(3) Appropriate action to obtain available community resources to assist in resolving the beneficiary's problem.

(4) Counseling services that are required by the beneficiary.

(D) Counseling services provided to the terminally ill individual and the family member or other persons caring for the individual at home. Counseling, including dietary counseling, may be provided both for the purpose of training the individual's family or other care-giver to provide care, and for the purpose of helping the individual and those caring for him or her to adjust to the individual's approaching death. Bereavement counseling, which consists of counseling services provided to the individual's family after the individual's death, is a required hospice service but it is not reimbursable.

(E) Home health aide services furnished by qualified aides and homemaker services. Home health aides may provide personal care services. Aides also may perform household services to maintain a safe and sanitary environment in areas of the home used by the patient. Examples of such services are changing the bed or light cleaning and laundering essential to the comfort and cleanliness of the patient. Aide services must be provided under the general supervision of a registered nurse. Homemaker services may include assistance in personal care, maintenance of a safe and healthy environment, and services to enable the individual to carry out the plan of care. Qualifications for home health aides can be found in 42 CFR 484.36.

(F) Medical appliances and supplies, including drugs and biologicals. Only drugs that are used primarily for the relief of pain and symptom control related to the individual's terminal illness are covered. Appliances may include covered durable medical equipment, as well as other self-help and personal comfort items related to the palliation or management of the patient's condition while he or she is under hospice care. Equipment is provided by the hospice for use in the beneficiary's home while he or she is under hospice care. Medical supplies include those that are part of the written plan of care. Medical appliances and supplies are included within the hospice all-inclusive rates.

(G) Physical therapy, occupational therapy and speech-language pathology services provided for purposes of symptom control or to enable the individual to maintain activities of daily living and basic functional skills.

(H) Short-term inpatient care provided in a Medicare participating hospice inpatient unit, or a Medicare participating hospital, skilled nursing facility (SNF) or, in the case of respite care, a Medicaid-certified nursing facility that additionally meets the special hospice standards regarding staffing and patient areas. Services provided in an inpatient setting must conform to the written plan of care. Inpatient care may be required for procedures necessary for pain control or acute or chronic symptom management. Inpatient care may also be furnished to provide respite for the individual's family or other persons caring for the individual at home. Respite care is the only type of inpatient care that may be provided in a Medicaid-certified nursing facility. The limitations on custodial care and personal comfort items applicable to other CHAMPUS services are not applicable to hospice care.

(ii) Core services. The hospice must ensure that substantially all core services are routinely provided directly by hospice employees; i.e., physician services, nursing care, medical social services, and counseling for individuals and care givers. Refer to paragraphs (e)(19)(i)(A), (e)(19)(i)(B), (e)(19)(i)(C), and (e)(19)(i)(D) of this section.

(iii) Non-core services. While non-core services (i.e., home health aide services, medical appliances and supplies, drugs and biologicals, physical therapy, occupational therapy, speech-language pathology and short-term inpatient care) may be provided under arrangements with other agencies or organizations, the hospice must maintain professional management of the patient at all times and in all settings. Refer to paragraphs (e)(19)(i)(E), (e)(19)(i)(F), (e)(19)(i)(G), and (e)(19)(i)(H) of this section.

(iv) Availability of services. The hospice must make nursing services, physician services, and drugs and biologicals routinely available on a 24-hour basis. All other covered services must be made available on a 24-hour basis to the extent necessary to meet the needs of individuals for care that is reasonable and necessary for the palliation and management of the terminal illness and related condition. These services must be provided in a manner consistent with accepted standards of practice.

(v) Periods of care. Hospice care is divided into distinct periods/episodes of care. The terminally ill beneficiary may elect to receive hospice benefits for an initial period of 90 days, a subsequent period of 90 days, a second subsequent period of 30 days, and a final period of unlimited duration.

(vi) Conditions for coverage. The CHAMPUS beneficiary must meet the following conditions/criteria in order to be eligible for the hospice benefits and services referenced in paragraph (e)(19)(i) of this section.

(A) There must be written certification in the medical record that the CHAMPUS beneficiary is terminally ill with a life expectancy of six months or less if the terminal illness runs its normal course.

(1) Timing of certification. The hospice must obtain written certification of terminal illness for each of the election periods described in paragraph (e)(19)(vi)(B) of this section, even if a single election continues in effect for two, three or four periods.

(i) Basic requirement. Except as provided in paragraph (e)(19)(vi)(A)(1)(ii) of this section the hospice must obtain the written certification no later than two calendar days after the period begins.

(ii) Exception. For the initial 90-day period, if the hospice cannot obtain the written certifications within two calendar days, it must obtain oral certifications within two calendar days, and written certifications no later than eight calendar days after the period begins.

(2) Sources of certification. Physician certification is required for both initial and subsequent election periods.

(i) For the initial 90-day period, the hospice must obtain written certification statements (and oral certification statements if required under paragraph (e)(19)(vi)(A)(1)(ii) of this section) from:

(A) The individual's attending physician if the individual has an attending physician; and

(B) The medical director of the hospice or the physician member of the hospice interdisciplinary group.

(ii) For subsequent periods, the only requirement is certification by one of the physicians listed in paragraph (e)(19)(vi)(A)(2)(i)(B) of this section.

(B) The terminally ill beneficiary must elect to receive hospice care for each specified period of time; i.e., the two 90-day periods, a subsequent 30-day period, and a final period of unlimited duration. If the individual is found to be mentally incompetent, his or her representative may file the election statement. Representative means an individual who has been authorized under State law to terminate medical care or to elect or revoke the election of hospice care on behalf of a terminally ill individual who is found to be mentally incompetent.

(1) The episodes of care must be used consecutively; i.e., the two 90-day periods first, then the 30-day period, followed by the final period. The periods of care may be elected separately at different times.

(2) The initial election will continue through subsequent election periods without a break in care as long as the individual remains in the care of the hospice and does not revoke the election.

(3) The effective date of the election may begin on the first day of hospice care or any subsequent day of care, but the effective date cannot be made prior to the date that the election was made.

(4) The beneficiary or representative may revoke a hospice election at any time, but in doing so, the remaining days of that particular election period are forfeited and standard CHAMPUS coverage resumes. To revoke the hospice benefit, the beneficiary or representative must file a signed statement of revocation with the hospice. The statement must provide the date that the revocation is to be effective. An individual or representative may not designate an effective date earlier than the date that the revocation is made.

(5) If an election of hospice benefits has been revoked, the individual, or his or her representative may at any time file a hospice election for any period of time still available to the individual, in accordance with Sec. 199.4(e)(19)(vi)(B).

(6) A CHAMPUS beneficiary may change, once in each election period, the designation of the particular hospice from which he or she elects to receive hospice care. To change the designation of hospice programs the individual or representative must file, with the hospice from which care has been received and with the newly designated hospice, a statement that includes the following information:

(i) The name of the hospice from which the individual has received care and the name of the hospice from which he or she plans to receive care.

(ii) The date the change is to be effective.

(7) Each hospice will design and print its own election statement to include the following information:

(i) Identification of the particular hospice that will provide care to the individual.

(ii) The individual's or representative's acknowledgment that he or she has been given a full understanding of the palliative rather than curative nature of hospice care, as it relates to the individual's terminal illness.

(iii) The individual's or representative's acknowledgment that he or she understands that certain other CHAMPUS services are waived by the election.

(iv) The effective date of the election.

(v) The signature of the individual or representative, and the date signed.

(8) The hospice must notify the CHAMPUS contractor of the initiation, change or revocation of any election.

(C) The beneficiary must waive all rights to other CHAMPUS payments for the duration of the election period for:

(1) Care provided by any hospice program other than the elected hospice unless provided under arrangements made by the elected hospice; and

(2) Other CHAMPUS basic program services/benefits related to the treatment of the terminal illness for which hospice care was elected, or to a related condition, or that are equivalent to hospice care, except for services provided by:

(i) The designated hospice;

(ii) Another hospice under arrangement made by the designated hospice; or

(iii) An attending physician who is not employed by or under contract with the hospice program.

- (3) Basic CHAMPUS coverage will be reinstated upon revocation of the hospice election.
- (D) A written plan of care must be established by a member of the basic interdisciplinary group assessing the patient's needs. This group must have at least one physician, one registered professional nurse, one social worker, and one pastoral or other counselor.
- (1) In establishing the initial plan of care the member of the basic interdisciplinary group who assesses the patient's needs must meet or call at least one other group member before writing the initial plan of care.
- (2) At least one of the persons involved in developing the initial plan must be a nurse or physician.
- (3) The plan must be established on the same day as the assessment if the day of assessment is to be a covered day of hospice care.
- (4) The other two members of the basic interdisciplinary group--the attending physician and the medical director or physician designee--must review the initial plan of care and provide their input to the process of establishing the plan of care within two calendar days following the day of assessment. A meeting of group members is not required within this 2-day period. Input may be provided by telephone.
- (5) Hospice services must be consistent with the plan of care for coverage to be extended.
- (6) The plan must be reviewed and updated, at intervals specified in the plan, by the attending physician, medical director or physician designee and interdisciplinary group. These reviews must be documented in the medical records.
- (7) The hospice must designate a registered nurse to coordinate the implementation of the plan of care for each patient.
- (8) The plan must include an assessment of the individual's needs and identification of the services, including the management of discomfort and symptom relief. It must state in detail the scope and frequency of services needed to meet the patient's and family's needs.
- (E) Complete medical records and all supporting documentation must be submitted to the CHAMPUS contractor within 30 days of the date of its request. If records are not received within the designated time frame, authorization of the hospice benefit will be denied and any prior payments made will be recouped. A denial issued for this reason is not an initial determination under Sec. 199.10, and is not appealable.
- (vii) Appeal rights under hospice benefit. A beneficiary or provider is entitled to appeal rights for cases involving a denial of benefits in accordance with the provisions of this part and Sec. 199.10.
- (20) (Reserved)
- (21) Home health services. Home health services are covered when furnished by, or under arrangement with, a home health agency (HHA) that participates in the TRICARE program, and provides care on a visiting basis in the beneficiary's home. Covered HHA

services are the same as those provided under Medicare under section 1861(m) of the Social Security Act (42 U.S.C. 1395x(m)) and 42 CFR part 409, subpart E.

(i) Benefit coverage. Coverage will be extended for the following home health services subject to the conditions of coverage prescribed in paragraph (e)(21)(ii) of this section:

(A) Part-time or intermittent skilled nursing care furnished by a registered nurse or a licensed practical (vocational) nurse under the supervision of a registered nurse;

(B) Physical therapy, speech-language pathology, and occupational therapy;

(C) Medical social services under the direction of a physician;

(D) Part-time or intermittent services of a home health aide who has successfully completed a state-established or other training program that meets the requirements of 42 CFR Part 484;

(E) Medical supplies, a covered osteoporosis drug (as defined in the Social Security Act 1861(kk), but excluding other drugs and biologicals) and durable medical equipment;

(F) Medical services provided by an interim or resident-in-training of a hospital, under an approved teaching program of the hospital in the case of an HHA that is affiliated or under common control of a hospital; and

(G) Services at hospitals, SNFs or rehabilitation centers when they involve equipment too cumbersome to bring to the home but not including transportation of the individual in connection with any such item or service.

(ii) Conditions for Coverage. The following conditions/criteria must be met in order to be eligible for the HHA benefits and services referenced in paragraph (e)(21)(i) of this section:

(A) The person for whom the services are provided is an eligible TRICARE beneficiary.

(B) The HHA that is providing the services to the beneficiary has in effect a valid agreement to participate in the TRICARE program.

(C) Physician certifies the need for home health services because the beneficiary is homebound.

(D) The services are provided under a plan of care established and approved by a physician.

(1) The plan of care must contain all pertinent diagnoses, including the patient's mental status, the types of services, supplies, and equipment required, the frequency of visits to be made, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, all medications and treatments, safety measures to protect against injury, instructions for timely discharge or referral, and any additional items the HHA or physician chooses to include.

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(2) The orders on the plan of care must specify the type of services to be provided to the beneficiary, both with respect to the professional who will provide them and the nature of the individual services, as well as the frequency of the services.

(E) The beneficiary must need skilled nursing care on an intermittent basis or physical therapy or speech-language pathology services, or have continued need for occupational therapy after the need for skilled nursing care, physical therapy, or speech-language pathology services has ceased.

(F) The beneficiary must receive, and an HHA must provide, a patient-specific, comprehensive assessment that:

(1) Accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward achievement of desired outcomes;

(2) Identifies the beneficiary's continuing need for home care and meets the beneficiary's medical, nursing, rehabilitative, social, and discharge planning needs.

(3) Incorporates the use of the current version of the Outcome and Assessment Information Set (OASIS) items, using the language and groupings of the OASIS items, as specified by the Director, TRICARE Management Activity.

(G) TRICARE is the appropriate payer.

(H) The services for which payment is claimed are not otherwise excluded from payment.

(I) Any other conditions of coverage/participation that may be required under Medicare's HHA benefit; i.e., coverage guidelines as prescribed under Sections 1861(o) and 1891 of the Social Security Act (42 U.S.C. 1395x(o) and 1395bbb), 42 CFR Part 409, Subpart E and 42 CFR Part 484.

(22) Pulmonary rehabilitation. TRICARE benefits are payable for beneficiaries whose conditions are considered appropriate for pulmonary rehabilitation according to guidelines adopted by the Executive Director, TMA, or a designee.

(23) A speech generating device (SGD) as defined in Sec. 199.2 of this part is covered as a voice prosthesis. The prosthesis provisions found in paragraph (d)(3)(vii) of this section apply.

(24) A hearing aid, but only for a dependent of a member of the uniformed services on active duty and only if the dependent has a profound hearing loss as defined in Sec. 199.2 of this part. Medically necessary and appropriate services and supplies, including hearing examinations, required in connection with this hearing aid benefit are covered.

(25) Rehabilitation therapy as defined in Sec. 199.2 of this part to improve, restore, or maintain function, or to minimize or prevent deterioration of function, of a patient when prescribed by a physician. The rehabilitation therapy must be medically necessary and appropriate medical care, rendered by an authorized provider, necessary to the establishment of a safe and effective maintenance program in connection with a specific medical condition, and must not be custodial care or otherwise excluded from coverage.

(26) National Institutes of Health clinical trials. By law, the general prohibition against CHAMPUS cost-sharing of unproven drugs, devices, and medical treatments or procedures may be waived in connection with clinical trials sponsored or approved by the National Institutes of Health National Cancer Institute if it is determined that such a waiver will promote access by covered beneficiaries to promising new treatments and contribute to the development of such treatments. A waiver shall only be exercised as authorized under this paragraph.

(i) Demonstration waiver. A waiver may be granted through a demonstration project established in accordance with Sec. 199.1(o) of this part.

(ii) Continuous waiver.(A) General. As a result of a demonstration project under which a waiver has been granted in connection with a National Institutes of Health National Cancer Institute clinical trial, a determination may be made that it is in the best interest of the government and CHAMPUS beneficiaries to end the demonstration and continue to provide a waiver for CHAMPUS cost-sharing of the specific clinical trial. Only those specified clinical trials identified under paragraph (e)(26)(ii) of this section have been authorized a continuous waiver under CHAMPUS.

(B) National Cancer Institute (NCI) sponsored cancer prevention, screening, and early detection clinical trials. A continuous waiver under paragraph (e)(26) of this regulation has been granted for CHAMPUS cost-sharing for those CHAMPUS-eligible patients selected to participate in NCI sponsored Phase II and Phase III studies for the prevention and treatment of cancer. Additionally, Phase I studies may be approved on a case by case basis when the requirements below are met.

(1) TRICARE will cost-share all medical care and testing required to determine eligibility for an NCI-sponsored trial, including the evaluation for eligibility at the institution conducting the NCI-sponsored study. TRICARE will cost-share all medical care required as a result of participation in NCI-sponsored studies. This includes purchasing and administering all approved chemotherapy agents (except for NCI-funded investigational drugs), all inpatient and outpatient care, including diagnostic and laboratory services not otherwise reimbursed under an NCI grant program if the following conditions are met:

(i) The provider seeking treatment for a CHAMPUS-eligible patient in an NCI approved protocol has obtained pre-authorization for the proposed treatment before initial evaluation; and,

(ii) Such treatments are NCI sponsored Phase I, Phase II or Phase III protocols; and

(iii) The patient continues to meet entry criteria for said protocol; and,

(iv) The institutional and individual providers are CHAMPUS authorized providers; and,

(v) The requirements for Phase I protocols in paragraph (e)(26)(ii)(B)(2) of this section are met:

(2) Requirements for Phase I protocols are:

(i) Standard treatment has been or would be ineffective, does not exist, or there is no

superior non-investigational treatment alternative; and,

(ii) The available clinical or preclinical data provide a reasonable expectation that the treatment will be at least as effective as the non-investigational alternative; and,

(iii) The facility and personnel providing the treatment are capable of doing so by virtue of their experience, training, and volume of patients treated to maintain expertise; and,

(iv) The referring physician has concluded that the enrollee's participation in such a trial would be appropriate based upon the satisfaction of paragraphs (e)(26)(ii)(B)(2)(i) through (iii) of this section.

(3) TRICARE will not provide reimbursement for care rendered in the National Institutes of Health Clinical Center or costs associated with non-treatment research activities associated with the clinical trials.

(4) Cost-shares and deductibles applicable to CHAMPUS will also apply under the NCI-sponsored clinical trials.

(5) The Director, TRICARE (or designee), shall issue procedures and guidelines establishing NCI-sponsorship of clinical trials and the administrative process by which individual patients apply for and receive cost-sharing under NCI-sponsored cancer clinical trials.

(27) TRICARE will cost share forensic examinations following a sexual assault or domestic violence. The forensic examination includes a history of the event and a complete physical and collection of forensic evidence, and medical and psychological follow-up care. The examination for sexual assault also includes, but is not limited to, a test kit to retrieve forensic evidence, testing for pregnancy, testing for sexually transmitted disease and HIV, and medical services and supplies for prevention of sexually transmitted diseases, HIV, pregnancy, and counseling services.

**(f) Beneficiary or sponsor liability--(1) General.** As stated in the introductory paragraph to this section, the Basic Program is essentially a supplemental program to the Uniformed Services direct medical care system. To encourage use of the Uniformed Services direct medical care system wherever its facilities are available and appropriate, the Basic Program benefits are designed so that it is to the financial advantage of a CHAMPUS beneficiary or sponsor to use the direct medical care system. When medical care is received from civilian sources, a CHAMPUS beneficiary is responsible for payment of certain deductible and cost-sharing amounts in connection with otherwise covered services and supplies. By statute, this joint financial responsibility between the beneficiary or sponsor and CHAMPUS is more favorable for dependents of members than for other classes of beneficiaries.

(2) Dependents of members of the Uniformed Services. CHAMPUS beneficiary or sponsor liability set forth for dependents of members is as follows:

(i) Annual fiscal year deductible for outpatient services and supplies.

(A) For care rendered all eligible beneficiaries prior to April 1, 1991, or when the active duty

sponsor's pay grade is E-4 or below, regardless of the date of care:

(1) Individual Deductible: Each beneficiary is liable for the first fifty dollars (\$50.00) of the CHAMPUS-determined allowable amount on claims for care provided in the same fiscal year.

(2) Family Deductible: The total deductible amount for all members of a family with the same sponsor during one fiscal year shall not exceed one hundred dollars (\$100.00).

(B) For care rendered on or after April 1, 1991, for all CHAMPUS beneficiaries except dependents of active duty sponsors in pay grades E-4 or below.

(1) Individual Deductible: Each beneficiary is liable for the first one hundred and fifty dollars (\$150.00) of the CHAMPUS-determined allowable amount on claims for care provided in the same fiscal year.

(2) Family Deductible: The total deductible amount for all members of a family with the same sponsor during one fiscal year shall not exceed three hundred dollars (\$300.00).

(C) CHAMPUS-approved Ambulatory Surgical Centers or Birthing Centers. No deductible shall be applied to allowable amounts for services or items rendered to active duty for authorized NATO dependents.

(D) Allowable Amount does not exceed Deductible Amount. If fiscal year allowable amounts for two or more beneficiary members of a family total less than \$100.00 (\$300.00 if paragraph (f) (2)(i)(B)(2) of this section applies), but more of the beneficiary members submit a claim for over \$50.00 (\$150.00 if paragraph (f)(2)(i)(B)(1) of this section applies), neither the family nor the individual deductible will have been met and no CHAMPUS benefits are payable.

(E) For any family the outpatient deductible amounts will be applied sequentially as the CHAMPUS claims are processed.

(F) If the fiscal year outpatient deductible under either paragraphs (f)(2)(i)(A) or (f)(2)(i)(B) of this section has been met by a beneficiary or a family through the submission of a claim or claims to a CHAMPUS fiscal intermediary in another geographic location from the location where a current claim is being submitted, the beneficiary or sponsor must obtain a deductible certificate from the CHAMPUS fiscal intermediary where the applicable beneficiary or family fiscal year deductible was met. Such deductible certificate must be attached to the current claim being submitted for benefits. Failure to obtain a deductible certificate under such circumstances will result in a second beneficiary or family fiscal year deductible being applied. However, this second deductible may be reimbursed once appropriate documentation, as described in paragraph (f)(2)(i)(F) of this section, is supplied to the CHAMPUS fiscal intermediary applying the second deductible.

(G) Notwithstanding the dates specified in paragraphs (f)(2)(i)(A) and (f)(2)(i)(B) of this section in the case of dependents of active duty members of rank E-5 or above with Persian Gulf Conflict service, dependents of service members who were killed in the Gulf, or who died subsequent to Gulf service, and of members who retired prior to October 1, 1991, after having served in the Gulf War, the deductible shall be the amount specified in paragraph

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made by OCHAMPUS or the fiscal intermediaries which are not based on medical necessity determinations made under the PRO program.

(2) Payment for certain potentially excludable expenses. Services determined under the PRO program to be potentially excludable by reason of the exclusions in paragraph (g) of this section for not medically necessary services will not be determined to be excludable if neither the beneficiary to whom the services were provided nor the provider (institutional or individual) who furnished the services knew, or could reasonably have been expected to know, that the services were subject to those exclusions. Payment may be made for such services as if the exclusions did not apply.

(3) Liability for certain excludable services. In any case in which items or services are determined excludable by the PRO program by reason of being not medically necessary and payment may not be made under paragraph (h)(2) of this section because the requirements of paragraph (h)(2) of this section are not met, the beneficiary may not be held liable (and shall be entitled to a full refund from the provider of the amount excluded and any cost share amount already paid) if:

(i) The beneficiary did not know and could not reasonably have been expected to know that the services were excludable by reason of being not medically necessary; and

(ii) The provider knew or could reasonably have been expected to know that the items or services were excludable by reason of being not medically necessary.

(4) Criteria for determining that beneficiary knew or could reasonably have been expected to have known that services were excludable. A beneficiary who receives services excludable by reason of being not medically necessary will be found to have known that the services were excludable if the beneficiary has been given written notice that the services were excludable or that similar or comparable services provided on a previous occasion were excludable and that notice was given by the OCHAMPUS, CHAMPUS PRO or fiscal intermediary, a group or committee responsible for utilization review for the provider, or the provider who provided the services.

(5) Criteria for determining that provider knew or could reasonably have been expected to have known that services were excludable. An institutional or individual provider will be found to have known or been reasonably expected to have known that services were excludable under this subsection under any one of the following circumstances:

(i) The PRO or fiscal intermediary had informed the provider that the services provided were excludable or that similar or reasonably comparable services were excludable.

(ii) The utilization review group or committee for an institutional provider or the beneficiary's attending physician had informed the provider that the services provided were excludable.

(iii) The provider had informed the beneficiary that the services were excludable.

(iv) The provider had received written materials, including notices, manual issuances, bulletins, guides, directives or other materials, providing notification of PRO screening

criteria specific to the condition of the beneficiary. Attending physicians who are members of the medical staff of an institutional provider will be found to have also received written materials provided to the institutional provider.

(v) The services that are at issue are the subject of what are generally considered acceptable standards of practice by the local medical community.

(vi) Preadmission authorization was available but not requested, or concurrent review requirements were not followed.

[51 FR 24008, Jul. 1, 1986; 67 FR 15725, Apr. 3, 2002; 67 FR 18826, Apr. 17, 2002; 67 FR 40602, Jun. 13, 2002; 67 FR 42720, Jun. 25, 2002; 67 FR 45311, Jul. 9, 2002; 68 FR 44880, Jul. 31, 2003; 68 FR 44883, Jul. 31, 2003; 68 FR 65173, Nov. 19, 2003; 69 FR 29229, May 21, 2004; 69 FR 44947, Jul. 28, 2004; 69 FR 51564, Aug. 20, 2004; 69 FR 55359, Sep. 14, 2004; 69 FR 60554, Oct. 12, 2004; 70 FR 12802, Mar. 16, 2005; 70 FR 61377, Oct. 24, 2005; 71 FR 31944, Jun. 2, 2006; 71 FR 35390, Jun. 20, 2006; 72 FR 54353, Sep. 25, 2007; 73 FR 46809, Aug. 12, 2008; 73 FR 74965, Dec. 10, 2008; 74 FR 34696, Jul. 17, 2009; 75 FR 47459, Aug. 6, 2010; 75 FR 47461, Aug. 6, 2010; 75 FR 50882, Aug. 18, 2010; 75 FR 2253, Jan. 13, 2011; 76 FR 8297, Feb. 14, 2011; **76 FR 57642, Sep. 16, 2011**]

**EDITORIAL NOTE:** For Federal Register citations affecting Sec. 199.4, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

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