

Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) that are submitted timely to the IRS. All comments will be available for public inspection and copying.

A public hearing has been scheduled for May 8, 1996, at 10:00 a.m., at the IRS Auditorium. Because of access restrictions, visitors will not be admitted beyond the building lobby more than 15 minutes before the hearing starts.

The rules of 26 CFR 601.601(a)(3) apply to the hearing.

Persons who wish to present oral comments at the hearing must submit written comments by April 1, 1996, and submit an outline of the topics to be discussed and the time to be devoted to each topic (signed original and eight (8) copies) by April 1, 1996.

A period of 10 minutes will be allotted to each person for making comments.

An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving comments has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal author of these regulations is Margaret A. Owens, Office of the Assistant Chief Counsel (Income Tax & Accounting), IRS. However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 301 are proposed to be amended as follows:

PART 1—INCOME TAXES

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

Authority: 26 U.S.C. 7805. * * *

Par. 2. Section 1.6081-4 is amended by:

1. Revising paragraph (a).

2. Adding paragraph (d).

The revised and added provisions read as follows:

§ 1.6081-4 Automatic extension of time for filing individual income tax returns.

[The text of proposed paragraphs (a) and (d) are the same as the text of § 1.6081-4T (a) and (d) published elsewhere in this issue of the Federal Register].

PART 301—PROCEDURE AND ADMINISTRATION

Par. 3. The authority citation for part 301 continues to read in part as follows:

Authority: 26 U.S.C. 7805. * * *

Par. 4. In § 301.6651-1, paragraph (c)(3) is revised to read as follows:

§ 301.6651-1 Failure to file tax return or to pay tax.

* * * * *

(c)(3) [The text of this proposed paragraph (c)(3) is the same as the text of § 301.6651-1T(c)(3) published elsewhere in this issue of the Federal Register].

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Margaret Milner Richardson,

Commissioner of Internal Revenue.

[FR Doc. 96-115 Filed 1-3-96; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DoD 6010.8-R]

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Individual Case Management

AGENCY: Office of the Secretary, DoD.

ACTION: Proposed rule.

SUMMARY: This proposed rule implements provisions of the 1993 National Defense Authorization Act which allows the Secretary of Defense to establish a case management program for CHAMPUS beneficiaries with extraordinary medical or psychological disorders and to allow such beneficiaries medical or psychological services, supplies, or durable medical equipment excluded by law or regulation as a CHAMPUS benefit. Under this program, waiver of benefit limits to the Basic CHAMPUS program may be authorized for beneficiaries when the provision of such services or supplies is cost effective and clinically

appropriate, as compared to historical or projected CHAMPUS/MTF utilization of health care services. It is designed to develop a cost-effective plan of care by targeting appropriate resources to meet the individual needs of the beneficiary.

DATES: Written public comments must be received on or before March 4, 1996.

FOR FURTHER INFORMATION CONTACT: CAPT Deborah Kamin, Office of the Assistant Secretary of Defense (Health Affairs), (703)-697-8975.

SUPPLEMENTARY INFORMATION: The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) supplements the availability of health care in military hospitals and clinics. Case management centering on a multidisciplinary treatment approach offers the beneficiary and provider assurance that specific services and supplies are allowable as CHAMPUS benefits and provides an opportunity to use those benefits efficiently.

Statutory Authority

The case management program is based on the authority of 10 U.S.C. 1079(a)(17), which provides:

The Secretary of Defense may establish a program for the individual case management of a person covered by this section or section 1086 of this title who has extraordinary medical or psychological disorders and, under such a program, may waive benefit limitations contained in paragraphs (5) and (13) of this subsection or section 1077(b)(1) of this title and authorize the payment for comprehensive home health care services, supplies, and equipment if the Secretary determines that such a waiver is cost effective and appropriate.

Case Management

The CHAMPUS individual case management program seeks to achieve cost effective quality health care by considering alternatives to inpatient hospitalization and by recommending a waiver of the current CHAMPUS benefit limits that, when provided in lieu of inpatient care (or to prevent recurrent hospitalizations), are cost effective and clinically appropriate. Waivers of benefit limits must be approved and coordinated by the case manager and may include, but not be limited to services or supplies such as home health care, medical supplies, back-up durable medical equipment, extended skilled nursing care and home health aides. CHAMPUS case managers will be employees or contractors of the Department of Defense. We propose to add to section 199.4 authorization, as a case management related benefit and on a case-by-case basis, services or supplies that would otherwise be excluded as non-medical or duplicate durable

equipment, custodial care, or domiciliary care. We also propose to add definitions for waiver of benefit limits, case management, case manager, case management multidisciplinary team, extraordinary condition, and primary caregiver.

Eligibility

A beneficiary's eligibility for participation in the CHAMPUS case management program is dependent on:

- (1) The presence of an extraordinary medical or psychological condition which has resulted in high utilization of CHAMPUS/MTF resources in an inpatient setting,
- (2) the cost-effectiveness of providing services of supplies outside inpatient settings, and
- (3) the willingness of the beneficiary to participate, and
- (4) the presence of a primary caregiver in the home when the services provided include home health care.

Role/Purpose of a Primary Caregiver

Candidates for this program will require a level of support which cannot occur safely outside an inpatient setting unless there is a primary caregiver in the home. Therefore, the presence of a primary caregiver to provide services is a pre-condition of participation. We envision that, in most cases, the role of primary caregiver will fall to members of the beneficiary's family.

Covered Services

A list of services or supplies that may be covered as a waiver of benefit limits will not be established. Rather, we propose that, under the case management program, clinically appropriate services and/or supplies may be provided when those services or supplies are cost effective.

Custodial Care

The provision of custodial care as a waiver of benefit limits is proposed as a transitional benefit for patients and families facing extraordinary medical or psychological conditions. To qualify for this waiver of benefit limits, the following conditions must be met: (1) The patient must have been rehospitalized for exacerbations or complications of his/her custodial condition on a recurring basis in the prior year, (2) The proposed treatment must be cost effective when compared to alternative treatment which would otherwise occur, (3) The patient's condition at referral for case management is either acute or there are indicators of a rapidly approaching acute episode, and (4) There must be a primary caregiver.

We expect individual patients will require varying levels of support and time to stabilize in the home environment. We propose a maximum of 30 (thirty) days for custodial care under case management. However, this rule would allow case managers to extend the period of time beyond thirty days when it is considered cost effective to do so.

Prior Authorization

Prior authorization from case managers will be required before the delivery of any case managed benefits. Because eligibility for a waiver of benefit limits is based on an in-depth assessment of medical needs, as well as the cost effectiveness and clinical appropriateness of alternate services, any services provided absent prior authorization will not be covered by CHAMPUS. Retrospective requests for coverage under this program will not be authorized.

Military Health Services System Resource Management

To ensure cost efficient as well as cost effective use of resources, the Department of Defense will include case management requirements, as described in this rule, in nationwide managed care support contracts now being procured. Managed care support contractors will be authorized to make available case management services to Military Medical Treatment Facilities. In areas where transition to managed care support contracts has not occurred, case management services will be provided through existing regional peer review organizations (Regional Review Centers, or RRCs). MTFs will be provided the opportunity to refer potential candidates to the appropriate CHAMPUS case manager. Where possible, Military Medical Treatment Facilities will provide care and services or supplies in support of regional case management programs.

Beneficiary Acknowledgment

Case management is a collaborative process among the case manager, beneficiary, primary caregiver, and professional health care providers. For case management to be successful, the beneficiary and primary caregiver must participate in the process and be aware of and agree with the requirements of the program. To document the understanding of their roles, rights and responsibilities, a standard acknowledgment, signed by the beneficiary (or representative) and the primary caregiver, will be required prior to the start of case management services.

CHAMPUS HHC/HHC-CM Demonstration

The 1986 Home Health Care and 1988 Home Health Care-Case Management Demonstration projects were developed to test whether case management, coupled with home health care benefits, could reduce medical costs and improve services to CHAMPUS beneficiaries. Under the 1986 demonstration, case management services were limited to beneficiaries who, in the absence of case managed home health care, would have remained hospitalized. The 1988 program was less restrictive and no longer required case management services only as a substitute for continued hospitalization. The effectiveness of methods for identifying potentially eligible beneficiaries and establishing the clinical appropriateness and cost-effectiveness of services provided was addressed by the General Accounting Office (GAO). In their report, "DEFENSE HEALTH CARE: Further Testing and Evaluation of Case Management Home Care Is Needed," the GAO identified a need for stronger cost controls and improved targeting of potential candidates before implementation of a permanent case management program under CHAMPUS. While the GAO identified some weaknesses in both demonstrations, the more restrictive design of the 1986 program was seen as one which presented an acceptable level of risk to the government. With the GAO's recommendations and observations in mind, the Department is proposing a CHAMPUS case management program which is limited to beneficiaries who would remain hospitalized in the absence of such a program, or who have demonstrated a recent history of multiple inpatient episodes.

Regulatory Procedures

Executive Order (EO) 12866 requires that a comprehensive regulatory impact analysis be performed on any economically significant regulatory action, defined as one which 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 proposed rule is a significant regulatory action under EO 12866 and has been reviewed by the Office of

Management and Budget. In addition, we certify that this proposed rule will not significantly affect a substantial number of small entities.

Paperwork Reduction Act

This rule, as written, imposes no burden as defined by the Paperwork Reduction Act of 1995. If however, any program implemented under this rule causes such a burden to be imposed, approval therefore will be sought of the Office of Management and Budget in accordance with the Act, prior to implementation.

List of Subjects in 32 CFR Part 199

Claims, handicapped, health insurance, and military personnel.

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

PART 199—[AMENDED]

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

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.

2. Section 199.2(b) is amended by adding new definitions in alphabetical order:

§ 199.2 Definitions.

* * * * *

Case management. Case management is a collaborative process which assesses, plans, implements, coordinates, monitors, and evaluates the options and services required to meet an individual's health needs, using communication and available resources to promote quality, cost effective outcomes.

Case manager. A licensed register nurse or licensed social worker who has a minimum of two (2) years of case management experience.

* * * * *

Extraordinary condition. A complex clinical condition which resulted, or is expected to result, in inpatient CHAMPUS/MTF costs or utilization above a threshold established by the Director, OCHAMPUS, or designee.

* * * * *

Primary caregiver. An individual who renders to a beneficiary services to support the essentials of daily living (as defined in § 199.2) and specific services essential to the safe management of the beneficiary's condition.

* * * * *

Waiver of benefit limits. Coverage, under the Case Management Program, of medical care, services, and or equipment not otherwise a benefit under the Basis CHAMPUS program.

* * * * *

3. Section 199.4 is amended by adding new paragraphs (e)(20) and (i) as follows:

§ 199.4 Basic program benefits.

* * * * *

(e) *Special benefit information.*

* * * * *

(20) *Case management services.* As part of case management for beneficiaries with complex medical or psychological conditions, payment for services or supplies not otherwise covered by the Basic CHAMPUS program may be authorized when they are provided in accordance with § 199.4(i). Waiver of benefit limits to the basic CHAMPUS program may be cost shared where it is demonstrated that the absence of such services would result in the exacerbation of an existing extraordinary condition, as defined in § 199.2, to the extent that frequent or extensive institutional services are required; and such services are a cost effective alternative to the Basic CHAMPUS program.

* * * * *

(i) *Case management program.*

(1) *In general.* Case management, as it applies to this program, provides a collaborative process among the case manager, beneficiary, primary caregiver, professional health care providers and funding sources to meet the medical needs of an individual with an extraordinary condition. It is designed to promote quality and cost-effective outcomes through assessment, planning, implementing, monitoring and evaluating the options and services required. Payment for services or supplies not otherwise covered by the basic CHAMPUS program may be authorized when they are provided in accordance with this paragraph (i). Waiver of benefit limits may be cost-shared where it is demonstrated that the absence of such services would result in the exacerbation of an existing extraordinary condition, as defined in § 199.2, to the extent that frequent or extensive hospitalizations are required; and such services are a cost-effective alternative to the Basic CHAMPUS program.

(2) *Applicability of case management program.* A CHAMPUS eligible beneficiary may participate in the case management program if he/she has an extraordinary condition which is disabling and requires inpatient care at a CHAMPUS-covered level-of-care. The medical or psychological condition must also:

(i) Be contained in the latest revision of the International Classification of Diseases Clinical Modification, or the

Diagnostic and Statistical Manual of Mental Disorders;

(ii) Meet at least one of the following:

(A) Demonstrate a prior history of frequent, multiple inpatient admissions, generating high CHAMPUS costs in the year immediately preceding eligibility for the case management program; or

(B) Require clinically appropriate services or supplies from multiple providers to address an extraordinary condition; and

(iii) More cost effectively and in a more clinically appropriate manner be treated at a less resource intensive level of care.

(3) *Prior authorization required.* Services or supplies allowable as a benefit exception under this Section shall be cost-shared only when a beneficiary's entire treatment has received prior authorization through an individual case management program.

(4) *Cost effectiveness requirement.* Treatment cost effectiveness shall be calculated as the reduction in the cost to the Department of Defense for proposed treatment which substitutes individual case management services for more expensive care which would have otherwise been reimbursed under the basic program. Generally, cost effectiveness determinations will involve comparisons between treatments primarily using an inpatient setting and those primarily using an outpatient or in-home setting. Treatment must meet the requirements of appropriate medical care as defined in § 199.2.

(5) *Limited waiver of exclusions and limitations.* Limited waivers of exclusions and limitations normally applicable to the basic program may be granted for specific services or supplies only when a beneficiary's entire treatment has received prior authorization through the individual case management program described in this paragraph (i). The Director, OCHAMPUS may grant a patient-specific waiver of benefit limits for services or supplies in the following categories, subject to the waiver requirements of this section.

(i) *Durable equipment.* The cost of a device or apparatus which does not qualify as Durable Medical Equipment (as defined in § 199.2) or back-up durable medical equipment may be shared when determined by the Director, OCHAMPUS to be cost-effective and clinically appropriate.

(ii) *Custodial Care.* The cost of services or supplies rendered to a beneficiary that would otherwise be excluded as custodial care (as defined in § 199.2) may be cost-shared for a period of 30 (thirty) days when determined by

the Director, OCHAMPUS, to be cost effective and clinically appropriate. To qualify for a waiver of benefit limits of custodial care, the patient must meet all eligibility requirements of this paragraph (i), including an acute condition or an acute exacerbation of a chronic condition.

(A) The patient must have been rehospitalized for exacerbations or complications of his/her custodial condition on a recurring basis in the prior year;

(B) The proposed case management treatment must be cost effective when compared to alternative treatment which would otherwise occur;

(C) The patient's condition at referral for case management is either acute or there are indicators of a rapidly approaching acute episode; and

(D) There is a primary caregiver.

(iii) *Domiciliary care.* The cost of services or supplies rendered to a beneficiary that would otherwise be excluded as domiciliary care (as defined in § 199.2) may be shared when determined by the Director, OCHAMPUS to be cost effective and clinically appropriate.

(iv) *In home services.* The cost of the following in-home services may be shared when determined by the Director, OCHAMPUS to be cost effective and clinically appropriate: nursing care, physical, occupational, speech therapy, medical social services, intermittent or part-time services of a home health aide, beneficiary transportation required for treatment plan implementation, and training for the beneficiary and primary caregiver sufficient to allow them to assume all feasible responsibility for the care of the beneficiary that will facilitate movement of the beneficiary to the least resource-intensive, clinically appropriate setting. (Qualifications for home health aides shall be based on the standards at 42 CFR 484.36.)

(v) *Waiver of custodial care limits.* The Director, OCHAMPUS may, in extraordinary cases, waive the custodial care day limits described in paragraph (e)(5)(ii) of this section and authorize this exception to benefits beyond the 30-day limit. The criteria for waiver of the 30-day limit shall be those set in paragraph (e)(5)(ii) of this section. Additionally, there must be a specific determination that discontinuation of this waiver of benefit limits will result in immediate onset or exacerbation of an acute care episode and require hospitalization or services or supplies which increase significantly the cost and intensity of care.

(6) *Case management acknowledgment.* The beneficiary, or

representative, and the primary caregiver, shall sign a case management acknowledgment as a prerequisite to prior authorization of case management services. The acknowledgment shall include, in part, all of the following provisions:

(i) The right to participate fully in the development and ongoing assessment of the treatment;

(ii) That all health care services for which CHAMPUS cost sharing is sought shall be authorized by the case manager prior to their delivery;

(iii) That there are limitations in scope and duration of the planned case management treatment, including provisions to transition to other arrangements;

(iv) The conditions under which case management services are provided, including the requirement that the services must be cost effective and clinically appropriate; and

(v) That a beneficiary's participation in the case management program shall be discontinued for any of the following reasons:

(A) The loss of CHAMPUS eligibility;

(B) A determination that the services or supplies provided are not cost effective or clinically appropriate;

(C) The beneficiary, or representative, and/or primary caregiver, terminates participation in writing;

(D) The beneficiary and/or primary caregiver's failure to comply with requirements in this paragraph (i); or

(E) A determination that the beneficiary's condition no longer meets the requirements of participation as described in this paragraph (i).

(7) *Other administrative requirements.*

(i) Qualified providers of services or items not covered under the basic program, or who are not otherwise eligible for CHAMPUS-authorized status, may be authorized for a time-limited period when such authorization is essential to implement the planned treatment under case management. Such providers must not be excluded or suspended as a CHAMPUS provider, and must agree to participate on all claims related to the case management treatment.

(ii) Retrospective requests for authorization of waiver of benefit limits will not be considered. Authorization of waiver of benefit limits is allowed only after all other options for services or supplies have been considered and either appropriately utilized or determined to be clinically inappropriate and/or not cost-effective.

(iii) Experimental or investigational treatment or procedures shall not be cost-shared as an exception to standard benefits under this part.

(iv) CHAMPUS case management services may be provided by contractors designated by the Director, OCHAMPUS.

Dated: December 28, 1995.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

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BILLING CODE 5000-04-M

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Part 195

[Docket PS-140(b), Notice 4]

RIN 2137-AC34

Areas Unusually Sensitive to Environmental Damage

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Public workshop.

SUMMARY: RSPA invites industry, government representatives, and the public to a third workshop on unusually sensitive areas (USAs). The workshop's purpose is to openly discuss the guiding principles for determining areas unusually sensitive to environmental damage from a hazardous liquid pipeline release. This workshop is a continuation of the June 15-16, 1995 and October 17, 1995 workshops on USAs.

DATES: The workshop will be held on January 18, 1996 from 8:30 a.m. to 4 p.m. Persons who are unable to attend may submit written comments in duplicate by February 5, 1996. However, persons submitting guiding principles to be considered at the January 18 workshop must do so by January 12, 1996. Interested persons should submit as part of their written comments all material that is relevant to a statement of fact or argument. Late filed comments will be considered so far as practicable.

ADDRESSES: The workshop will be held at the U.S. Department of Transportation, Nassif Building, 400 Seventh Street, SW, Room 6200-04, Washington, DC. Non-federal employee visitors are admitted into the DOT headquarters building through the southwest entrance at Seventh and E Streets, SW. Persons who want to participate in the workshop should call (202) 366-2392 or e-mail their name, affiliation, and phone number to samesc@rspa.dot.gov before close of business January 12, 1996. The