being considered, and other possible alternatives for addressing the risk.

2. Any existing standard or portion of a standard which could be issued as a proposed regulation.

3. A statement of intention to modify or develop a voluntary standard to address the risk of injury discussed in this notice, along with a description of a plan (including a schedule) to do so.

In addition, the Commission solicits the following specific information:

1. Information on the useful life of currently produced bath seats;

2. Information on the potential effect of any regulatory action on firms, including small entities;

3. Information on potential loss of consumer utility from any regulatory action;

4. Information on mechanisms to enhance stability/retention, especially in tubs with non-skid surfaces;

5. Information on the appropriate mechanisms to prevent infants from sliding through the bath seat (''submarining'');

6. Any exposure data and/or any calculations relative to the risk of drowning in bath tubs with or without bath seats;

7. Any other information available related to the potential costs and benefits of a rule.

Comments should be mailed, preferably in five copies, to the Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207–0001, or delivered to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East-West Highway, Bethesda, Maryland 20814; telephone (301) 504–0800. Comments also may be filed by telefacsimile to (301) 504–0127 or by email to cpsc–os@cpsc.gov. Comments should be captioned ''ANPR for baby bath seats.'' All comments and submissions should be received no later than October 1, 2001.

Dated: July 26, 2001.

Todd Stevenson,

Acting Secretary, Consumer Product Safety Commission.

List of Relevant Documents

1. Briefing memorandum from Ronald Medford, Assistant Executive Director, Office of Hazard Identification and Reduction and Celestine Kiss, Project Manager, Division of Human Factors, to the Commission, March 30, 2001.

2. Petition HP 00–4 from the Consumer Federation of America, The Drowning Prevention Foundation, et al. to Ban Baby Bath Seats, July 25, 2000.

3. Memorandum from Mary F. Donaldson, Directorate for Economic Analysis, ''Baby Bath Seat Petition, HP–00–4,'' February 16, 2001.

4. Memorandum from Suad W. Nakamura, Ph.D., Physiologist and Sandra E. Inkster, Ph.D., Pharmacologist, Directorate for Health Sciences, ''The Pathophysiology of Drowning,'' December 7, 2000.

5. Memorandum from Debra Sweet, Division of Hazard Analysis, ''Hazard Analysis Memorandum for Bath Seat Petition,'' January 29, 2001.

6. Memorandum from Celestine T. Kiss, Division of Human Factors, ''Human Factors Response to Bath Rings/Seats Petition (HP–00–04),'' January 25, 2001.

7. Memorandum from M. Kumagai, Directorate for Engineering Sciences, ''Review of BATH SEAT ASTM STANDARD F1967 and Response to Comments to Petition HP 00–4,'' March 2, 2001.

8. Memorandum from M. Kumagai, Directorate for Engineering Sciences, ''Evaluation of Bath Seat Design,'' March 2, 2001.

9. Letter dated May 7, 2001 from Dr. Kimberly Thompson to Chairman Ann Brown re: Comments on Briefing Package Petition No. HP 00–4, Request to Ban Baby Bath Seats.

10. Memorandum dated May 21, 2001 to the Commission from Debra Sweet, Statistician, Division of Hazard Analysis, re: Comments from Kimberly M. Thompson, Sc.D., on Briefing Package for Petition HP 00–4, Request to Ban Baby Bath Seats.

[FR Doc. 01–19072 Filed 7–31–01; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

RIN 0720–AA65

Civilian Health and Medical Program of the Uniformed Services; Individual Case Management Program for Persons with Extraordinary Conditions (ICMP–PEC)

AGENCY: Office of the Secretary, DoD.

ACTION: Proposed rule.

SUMMARY: The Department of Defense (DoD) proposes to amend its regulations on the Individual Case Management Program (ICMP) to implement requirements stipulated by Section 703 of the Fiscal Year (FY) 2000 National Defense Authorization Act, Section 8118 of the FY 2000 Defense Appropriations Act, Section 701 of the FY 2001 National Defense Authorization Act and Section 8100 of the FY 2001 Defense Appropriations Act. Other administrative amendments are also proposed to clarify specific policies that relate to the program. Public comments are invited and will be considered for possible revisions to the final rule.

DATES: Written comments will be accepted until October 1, 2001.

ADDRESESES: Please address all comments concerning this proposed rule to Mary Stockdale, Program Development Division, TRICARE Management Activity (TMA), Suite 810, 5111 Leesburg Pike, Falls Church, VA 22041.

FOR FURTHER INFORMATION CONTACT: Mary Stockdale 703–681–0039.

SUPPLEMENTARY INFORMATION:

I. Background

Congressional actions in the last two fiscal years make important changes to the TRICARE Individual Case Management Program (ICMP). These actions continue the long-standing TRICARE/CHAMPUS definition of custodial care for purposes of the statutory exclusion from coverage under the basic TRICARE program. In addition, they reaffirm congressional policy of addressing the health care needs of custodial care patients through the TRICARE ICMP.

To distinguish this special waiver program from other normal case management functions under the basic TRICARE program and to more clearly identify the type of beneficiaries for which it is intended, the program name is now expanded to the Individual Case Management Program for Persons with Extraordinary Conditions (ICMP–PEC). It is also important to distinguish the ICMP–PEC from the Program for Persons with Disabilities (PFPWD). The PFPWD is applicable only to family members of active duty service members and the benefit is limited to $1,000 per month. Its purpose is to provide financial assistance to reduce the effects of mental retardation or a serious physical disability. It is not a stand-alone program, is subject to certain restrictions, and it may be used concurrently with other TRICARE medical programs like the ICMP–PEC.

II. Synopsis

This brief synopsis summarizes the primary requirements that are now applicable to the ICMP–PEC.

A. Custodial care continues to be statutorily excluded as a benefit under the basic TRICARE program.

B. The definition of custodial care in the CHAMPUS regulation remains in effect.

C. In some cases, however, otherwise excluded custodial care benefits may be extended through the ICMP–PEC to eligible beneficiaries who have extraordinary medical or psychological disorders and for whom custodial care services are medically necessary and appropriate and require the supervision of trained health care providers.

To be authorized, such custodial care services must meet specified terms and conditions to ensure they are provided in a cost-effective manner. Such services may *not* include services that provide only for the essentials/activities of daily living unless such services are incidental to the provision of authorized skilled care.

D. The previous 365-day limit to custodial care services under the ICMP–PEC is no longer in effect as of October 5, 1999.

E. ICMP–PEC services are primary to Medicaid, other welfare programs, or charity-based care, but secondary to Medicare or other health insurance. However, benefits may be coordinated with Medicaid, other welfare or charity-based programs to ensure TRICARE beneficiaries receive the maximum level of benefits available to them in their communities as long as the primary payer status of ICMP–PEC services is maintained.

F. The total amount that the Department may pay for services provided to all beneficiaries granted coverage under the ICMP–PEC together with the costs of administering the program may not exceed $100,000,000 within each fiscal year.

III. Statutory History of ICMP–PEC

In 1985, Congress directed the DoD to conduct a demonstration project of providing home health care to certain CHAMPUS beneficiaries. [DoD Appropriations Act, 1986, Pub. L. 99–190, Section 8084.]

In 1987, Congress enacted a similar provision that required the Department to conduct an expanded demonstration project of providing home health care as part of an individualized case-managed program that included a range of benefits that reasonably could deviate from otherwise payable types, amounts and levels of care for patients with exceptionally serious, long-range, costly and incapacitating physical or mental conditions. [DoD Appropriations Act, 1988, Pub. L. 100–202, Section 8071.] A similar provision was enacted the following year. [DoD Appropriations Act, 1989, Pub. L. 100–463, Section 8058.] Based on these two demonstration projects, in 1991 the House and Senate Appropriations Committees directed the Department to investigate the possibility of including comprehensive home health care as a CHAMPUS benefit and report to Congress on its findings. In 1992, the Department provided its Report to Congress: Comprehensive Home Health Care as a CHAMPUS Benefit, H. Rept. No. 102–95, p. 89; S. Rept. No. 102–154, p. 37. The report was based on the findings from the evaluation of the CHAMPUS Home Health Care Case Management Demonstration Program which concluded that the program goals had been achieved. It emphasized the value of case management for those patients who are medically catastrophic and complex to support the provision of high quality and cost-effective care. This led to the provision of Section 704 of the National Defense Act for FY 1993. [Pub. L. 102–484.], which enacted 10 U.S.C. 1079(a)(17) and 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 paragraph (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.

In enacting this provision, Congress took another major step to direct and allow the Department to, in the words of the previous statute [Pub. L. 100–202, Section 8071]:

> Reasonably deviate from the normal, restrictive statutory coverage for health services for patients with exceptionally serious, long-range, costly and incapacitating conditions.

A dominant statutory restriction affecting health care for such patients is the statutory exclusion of custodial care. [10 U.S.C. Section 1077(b)(1).] This exclusion is made applicable to CHAMPUS by 10 U.S.C. Section 1079(a) and is implemented in its most important aspect for CHAMPUS by regulations at 32 CFR 199.2 and 199.4(e)(12).

Because these earlier versions of the regulations could have the effect of limiting otherwise medically necessary services, they have been the subject of litigation from time to time. *See,* for example, Barnett v. Weinberger, 818 F.2d953 (D.C. Cir. 1987. The impact of these regulations is also well understood by Congress, which has moved to authorize reasonable exceptions to the statutory and regulatory exclusion of custodial care under the ICMP–PEC.

This was, in fact, a primary reason Congress established the case management program by enacting section 1079(a)(17), and why the statute expressly authorizes a waiver of the custodial care exclusion section of 1077(b)(1) under the ICMP–PEC when the Secretary determines that such a waiver is cost-effective and appropriate. This congressional purpose was explicitly stated in the explanation of the members of the Conference Committee that agreed to the final version of the section 1079(a)(17). The Conference Report [H. Conf. Rept. 102–966, 102d Cong., 2d Sess., 719] explains:

> The conferees believe the case management program is the best approach to address the needs of beneficiaries for whom regular CHAMPUS benefits are limited by the custodial care exclusion and other restrictions contained in the law and CHAMPUS regulations.

The Department continues to agree with the congressional policy that the case management program is the best approach to address the custodial care issue.

IV. Implementing Regulations

The new statutory authority was implemented by final regulations issued, after a public comment period, 64 FR 7084–89, Feb. 12, 1999. In view of the discretionary nature of the legislation and the requirement for cost-effectiveness, the Department did not view the legislation as creating a long-term health care program. Therefore, certain conditions were established in the regulations for waiving benefit limitations and authorizing otherwise excluded benefits under ICMP–PEC in order to transition the cases to those existing programs providing services to long-term care patients.

Recognizing that the exclusion of health care coverage when a family member requires custodial care services is both a financial and emotional burden, the Department used the ICMP–PEC authority to transition custodial care patients from TRICARE/CHAMPUS coverage to alternate sources of support services such as Medicaid. To ensure transition out of the ICMP–PEC, the Department included a limitation of ICMP–PEC coverage for a maximum lifetime period of 365 calendar days. Because the ICMP–PEC provides for exceptions to otherwise excluded services, a second condition imposed by

the Department required that the ICMP–PEC be secondarily liable, not only to those health care programs for which TRICARE/CHAMPUS is second payer but also to Medicaid and other welfare programs. Both of these conditions were consistent with the concept that this discretionary program was a transition program; otherwise, the patient would not readily transition to alternate sources of support services as long as ICMP–PEC waives the custodial care exclusion and the alternative sources remain last pay. The ICMP–PEC was viewed as a program enabling TRICARE case managers to work with all sources of support services to help maximize available resources for military families without creating a long-term care program subject to significant funding increases.

In the 1999 session, the Congress specifically considered legislation to address the Department's definition of custodial care under CHAMPUS. If adopted, the language would have dramatically changed the long-standing CHAMPUS definition of custodial care as sought by various groups. The proposed language would have changed the definition of custodial care under the TRICARE Basic Program and limited the custodial care exclusion to services that support activities of daily living. It is important to note, however, that the Congress did not enact the proposed legislation. Rather, by action of the Conference Committee, the proposed legislation was replaced with legislation that left intact the basic CHAMPUS definition and exclusion of custodial care. As enacted as Section 8118 of the DoD Appropriations Act, 2000 [Pub. L. 106–79], the following provision specifically applies only to the ICMP–PEC:

> Sec. 8118. Notwithstanding any other provision of law, for the purpose of establishing all DoD policies governing the provision of care provided by and financed under the military health care system's case management program under 10 U.S.C. 1079(a)(17), the term *custodial care* shall be defined as care designed essentially to assist an individual in meeting the activities of daily living and which does not require the supervision of trained medical, nursing, paramedical or other specially trained individuals: Provided, That the case management program shall provide that members and retired members of the military services, and their dependents and survivors, have access to all medically necessary health care through the health care delivery system of the military services regardless of the health care status of the person seeking the health care: Provided further, That the case management program shall be the primary obligor for payment of medically necessary services and shall not be considered as secondarily liable to Title XIX of the Social Security Act, other welfare programs or charity–based care.

Congress once again implicitly confirmed the Department's implementation of the statutory exclusion of custodial care under CHAMPUS while making significant changes to the ICMP–PEC.

The same is true for other action taken by Congress in 1999. Section 703 of the National Defense Authorization Act for FY 2000 addressed the CHAMPUS custodial care exclusion and the ICMP–PEC in several respects. First, it provided *grandfather* coverage to a number of beneficiaries who had been receiving custodial care coverage under the previous demonstration projects and whose continuing needs would be excluded from coverage under the regulations implementing the statutory custodial care exclusion and not adequately met under the ICMP–PEC exception to that exclusion. Second, it eliminated the 365-day limit on custodial care services under the ICMP–PEC. The Department issued an Interim Policy Memorandum on March 28, 2000, as a temporary measure to incorporate the mandated changes. That memorandum was supplemented on May 1, 2000, to include a requirement that an appeals and hearing procedure be included as part of the ICMP–PEC program.

In the 2000 session, Congress again addressed the ICMP–PEC in several respects. Section 8100 of the DoD Appropriations Act, 2001 [Pub. L. 106–259] reenacted for FY 2001 the provision that had been Section 8118 in FY 2000. Section 701(a) of the National Defense Authorization Act for FY 2001 [Pub. L. 106–398] amended Section 703(a)(1) of the National Defense Authorization Act for FY 2000. It removed the prohibition against providing ICMP–PEC services to the *grandfathered* beneficiaries once they were entitled to hospital insurance benefits under Medicare part A. Section 701(c) amended Section 1079(a)(17) of 10 U.S.C. by adding a subparagraph designation of (A) after (17) and a subparagraph (B), which provides:

> The total amount expended under subparagraph (A) for a fiscal year may not exceed $100,000,000.

The cost limitation of $100 million for the ICMP–PEC is effective for fiscal years after 1999.

Finally, in a separate action that affects the ICMP–PEC, section 712 of the FY 2001 National Defense Authorization Act [Pub. L. 106–398] extends eligibility for TRICARE to persons who previously lost their eligibility upon becoming entitled to hospital insurance benefits under part A of Title XVIII of the Social Security Act (42 U.S.C. 1395c et seq.). Eligibility, which becomes effective October 1, 2001, is contingent upon purchase of Medicare part B under Title XVIII of the Social Security Act.

V. Program Scope

Consistent with the authorizing legislation, 10 U.S.C. 1079(a)(17), the ICMP–PEC is a discretionary program that may be established and may waive, for a CHAMPUS-eligible beneficiary, benefit limitations or exclusions otherwise required by law where it is determined that such a waiver is cost-effective and appropriate. It is designed to provide a cost-effective plan of care by targeting appropriate resources to meet the medical needs of a beneficiary with a qualifying medical or psychological disorder.

VI. Case Management

Case management is used in many TRICARE/CHAMPUS settings to organize acute and outpatient health care services. The focus of this proposed rule is specifically on the use of case management to address the complex health care needs of catastrophically ill or injured beneficiaries. The ICMP–PEC offers a system for organizing multidisciplinary services often required for management of extraordinary medical or psychological disorders. The objective is to improve the quality of care, control costs, and support patients and families through catastrophic medical events.

Section 1077b(1) of title 10, U.S.Code, specifically prohibits the Military Health System from providing custodial care. Custodial care is therefore prohibited from being provided under the TRICARE basic program. Congress did not define the term custodial care, but prohibited the provision of such care. The original legislative history of the custodial care exclusion suggested that CHAMPUS be patterned after the Federal Employee health Benefits Program, Blue Cross and Blue Shield ''High Option'' plan. The CHAMPUS present definition of custodial care as set forth in 32 CFR 199.2 was derived from that source. A separate definition of the excluded custodial care services for the ICMP–PEC was provided by Congress for the ICMP–PEC under Section 8118 of the FY 00 Defense Appropriations Act [Pub. L. 106–79] and Section 8100 of the FY 01 Defense Appropriation Act [Pub. L. 106–259]. These sections direct that the scope of services available for coverage under the ICMP–PEC for custodial care cases include all medically necessary services not designed essentially to assist an

individual in meeting the essentials/activities of daily living and which do not require the supervision of trained medical, nursing, paramedical or other specially trained individuals. Therefore, it is the Department's policy that, when a waiver of the benefit limits imposed by the custodial care exclusion is granted under the ICMP–PEC, the scope of services to be covered shall be consistent with the language of the legislation. The services and benefits provided under the ICMP–PEC must be medical services and supplies and they must be medically necessary and appropriate. Under the ICMP–PEC, alternatives to current TRICARE/CHAMPUS benefit limitations or exclusions are considered those that are both cost-effective and clinically appropriate. A waiver of benefit limits must be pre-authorized by case managers and may include, but is not limited to, services or supplies such as home health care, medical supplies, back-up durable medical equipment, and extended skilled nursing care. When a waiver of benefit limits imposed by the exclusion of custodial care is granted any service provided under the ICMP–PEC must require the supervision of trained medical, nursing, paramedical or other specially trained individuals. If a CHAMPUS-eligible beneficiary meets all the parameters for waiving benefit limits under the ICMP–PEC, all medically necessary care, as defined under TRICARE/CHAMPUS, will be covered even if the care will only stabilize or maintain life and comfort but not improve the health care status of the beneficiary.

Services or supplies provided in the home by other than CHAMPUS authorized providers of care must fall under the auspices of a home health care agency that has been either authorized by Medicare or licensed by the State in which it operates. Providers of other services as a result of such waivers must meet CHAMPUS requirements as authorized providers or must obtain a specific waiver of that requirement.

In a limited number of cases otherwise meeting ICMP–PEC parameters, a domiciliary care waiver may be granted, but only when the domiciliary care is directly related and essential to the delivery of medically necessary services and no other alternative is available. A domiciliary care waiver may be granted only when it will provide medically necessary services on a short-term or transitional basis from a high cost, normally inpatient setting, to an outpatient setting.

The Department does not interpret the authorizing legislation and recent congressional action as creating a long-term care benefit under the TRICARE ICMP–PEC for medically unnecessary services. This interpretation is based, in part, upon Section 701 of the National Defense Authorization Act for FY 2001, which limits total annual expenditures under the ICMP–PEC to no more than $100 million.

VII. Eligibility

Participation in the TRICARE ICMP–PEC program is voluntary and is available for CHAMPUS-eligible beneficiaries, Continued Health Care Benefit Program (CHCBP) enrollees, and those beneficiaries who have been granted continuation of care coverage as former participants in the DoD home health demonstration projects under section 703(a) of the National Defense Authorization Act for Fiscal Year 2000 [Pub. L. 106–65], and section 701(a) of the Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001 [Pub. L. 106–398]. Due to the potential for demand for services exceeding authorized expenditures, priority for participation in the ICMP–PEC shall be given first to family members of active duty personnel. This is consistent with longstanding policy firmly established in chapter 55 of title 10, U.S. Code. Authorization for participation by all beneficiaries under the ICMP–PEC shall be subject to availability of funding. At the beginning of each fiscal year, the Department will: (1) Assess available funding and review and prioritize continued coverage for all current participants; and (2) project anticipated new demand by family members of active duty personnel and all other eligible beneficiaries. The Department anticipates that administrative costs for the program will be between one to two percent of the total funds available each fiscal year to cover the cost associated with case management functions. If the current or projected demand is expected to exceed available funding for the fiscal year, a notice of termination will be issued to those participants who will be affected. These notices will include a continued authorization of coverage for a defined transition period not to exceed 60 days. The Department will ensure that all participants are advised when they first enter the program that authorization for services is subject to available funding and may be terminated with a 60-day notice. Should it become necessary, the order of termination from coverage will be: (1) Non-active duty family members participants from last to first authorized; and then (2) active duty family member participants from last to first authorized.

The program covers catastrophically ill or injured beneficiaries who meet the TRICARE definition of custodial care. The parameters for waiving CHAMPUS benefit limits are:

(1) the patient has an existing extraordinary medical or psychological condition;

(2) the patient meets the TRICARE definition of custodial care and can be treated more appropriately and cost effectively at a less intensive level of care;

(3) waiver of certain benefit limits/exclusions is determined to be cost-effective and appropriate;

(4) the ICMP–PEC services have been pre-authorized; and

(5) for patients receiving care at home, there must be a primary caregiver present or the patient must be capable of self-support.

A. Extraordinary Medical or Psychological Condition

In general, an extraordinary medical or psychological condition is a clinical condition contained in the latest revision of the International Classification of Disease Clinical Modification, or the Diagnostic and Statistical Manual of Mental Disorders which is complex.

B. Custodial

For those beneficiaries with extraordinary medical or psychological disorders who have been determined to be custodial care cases under TRICARE, as defined in 32 CFR Section 199.2, the ICMP–PEC permits the waiver of benefit limits/exclusions to provide clinically appropriate care. That provision mandates a custodial care determination if the patient:

(1) is disabled mentally or physically and such disability is expected to continue and be prolonged, and

(2) requires a protected, monitored, or controlled environment whether in an institution or in the home, and

(3) requires assistance to support the activities/essentials of daily living, and

(4) is not under active and specific medical, surgical, or psychiatric treatment that will reduce the disability to the extent necessary to enable the patient to function outside the protected, monitored, or controlled environment.

A determination of custodial care does not imply that the care being rendered is not required by the patient. It only means that it is the kind of care that is not covered under the basic TRICARE/CHAMPUS program. Care rendered to a beneficiary on a hospital

inpatient basis is not custodial care. In addition, a program of physical and mental rehabilitation that is designed to reduce a disability is not custodial care as long as the objective is a reduced level of care. A reduced level of care, in this context, means a reduction in the kinds and extent of services necessary to address the beneficiary's medical needs. We expect patients and their families will require varying levels of support and time to stabilize following a catastrophic illness. Case managers will determine, on a case-by-case basis, the specific need for waivers to custodial care exclusions. When a waiver of the custodial care exclusion is granted under the ICMP–PEC, the services and benefits provided must be medically necessary, and must require the supervision of trained, medical, nursing, paramedical or other specially trained individuals.

VIII. Prior Authorization

Prior authorization from case managers is required before the delivery of any case managed benefits. Because eligibility for a waiver of benefit limits/exclusions 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 without prior authorization will not be covered by TRICARE/CHAMPUS. Retrospective requests for coverage under this program will not be authorized.

IX. Military Health System Case Management Structure

For effective program implementation, the Department requires establishment of case management programs, as described in this rule, in all TRICARE/CHAMPUS managed care support contracts. Managed Care Support Contractors will be authorized to make available case management services to Military Medical Treatment Facilities (MTFs). MTFs will be provided the opportunity to refer potential candidates to the appropriate TRICARE/CHAMPUS case manager. Where possible, MTFs will provide care and services or supplies in support of regional case management programs.

X. Denial/Appeals Process

Beneficiaries and/or providers who dispute either a custodial care determination or a determination of the type or level of care and services authorized under the ICMP–PEC have the right to appeal those decisions under section 199.10 of this Part.

XI. Program Goal.

Since the inception of this special discretionary program, the Department has received many helpful suggestions for improvements and enhancements from our beneficiaries, case managers, clinicians and counterparts in other Federal programs. Their valuable insight and support are reflected in the program changes proposed in this rule. The Department's objective with the ICMP–PEC continues to be to improve the quality of care, control costs, and support patients and families with extraordinary needs that are covered by the program in keeping with the requirements mandated by law.

XII. Regulatory Procedures

Executive Order (EO) 12866 requires that a comprehensive regulatory impact analysis be performed on any economically significant regulatory action, defined as one that would result in an annual effect of $100 million or more on the national economy or which would have other substantial impacts. The Regulatory Flexibility Act (RFA) requires that each Federal agency prepare, and make available for public comment, a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities. This rule will not significantly affect a substantial number of small entities. This rule imposes no burden as defined by the Paperwork Reduction Act of 1995.

List of Subjects in 32 CFR Part 199

Case management, Claims, Custodial care, Health insurance.

For the reasons set forth in the preamble, the DoD proposes to amend 32 CFR part 199 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 is proposed to be amended by adding a new definition of Activities of Daily Living to be placed in alphabetical order as follows:

199.2 Definitions.

* * * * *

Activities of daily living. (See also Essentials of daily living.) Care that consists of providing food (including special diets), clothing, and shelter; personal hygiene services; observation and general monitoring; bowel training or management; safety precautions; general preventive procedures (such as turning to prevent bedsores); passive exercise; companionship; recreation; transportation; and such other elements of personal care that reasonably can be performed by an untrained adult with minimal instruction or supervision.

3. Section 199.4 is proposed to be amended by revising paragraphs (e)(20) and (i) to read as follows:

199.4 Basic program benefits.

* * * * *

(e) *Special benefit information.* * * *

(20) Individual Case Management Program for Persons with Extraordinary Conditions (ICMP–PEC). The Individual Case Management Program for Persons with Extraordinary Conditions (ICMP–PEC), authorizes payment for services or supplies not otherwise covered by Program For Persons With Disabilities (PFPWD) or the basic TRICARE program for beneficiaries with extraordinary medical or psychological conditions when they are approved in accordance with section 199.4(i) of this Part. The ICMP–PEC is subject to a cost limitation not to exceed $100,000,000 per fiscal year (together with the costs of administering the ICMP–PEC) in accordance with the provision of 1079(a)(17)(B) of title 10, United States Code. The cost limitation is effective for fiscal years after fiscal year 1999.

* * * * *

(i) Individual Case Management Program for Persons with Extraordinary Conditions (ICMP–PEC). TRICARE benefit limitations can only be waived under the specific policies and procedures established under the authorizing legislation of 10 U.S.C. 1079(a)(17).

(1) *In general.* Case management, as it applies to the ICMP–PEC, is a collaborative process that includes a case manager, beneficiary, primary caregiver, professional health care provider or providers and funding sources to meet the medical needs of an individual with an extraordinary medical or psychological condition. It is designed to promote quality and cost-effective outcomes through assessing, planning, implementing, monitoring and evaluating the options and services necessary to provide required medically necessary services at an appropriate level of care. Payment for services or supplies that are limited or not otherwise covered by the basic TRICARE/CHAMPUS program may be authorized and cost-shared through participation in the ICMP–PEC when it is demonstrated that the services:

(i) are medically or psychologically necessary, and

(ii) require the supervision of trained medical, nursing, paramedical or other specially trained individuals, and

(iii) are cost effective.

Payments will be determined based on provider reimbursement methods like those applicable to similar services under 32 CFR 199.14.

(2) *Fiscal Year Cost Limitation.* The ICMP–PEC is subject to a cost limitation not to exceed $100,000,000 per fiscal year (together with the costs of administering the ICMP–PEC) in accordance with the provision of 1079(a)(17)(B) of title 10, United States Code. The cost limitation is effective for fiscal years after fiscal year 1999.

(3) *Applicability of case management program.* CHAMPUS eligibility, or enrollment in the Continued Health Care Benefit Program (CHCPB), or continued coverage granted for certain beneficiaries as a participant in the former DoD home health care demonstration projects is a legal pre-requisite for participation in the ICMP–PEC. Priority for coverage under the ICMP–PEC shall be given first to eligible family members of active duty service members. This is consistent with longstanding policy firmly established in chapter 55 of title 10, U.S. Code. Authorization of participation by all beneficiaries will be subject to availability of funding. At the beginning of each fiscal year, the Department will: (1) Assess available funding and review and prioritize continued coverage for all current participants to include both health care services and administrative costs; and (2) project anticipated new demand by family members of active duty personnel and all other eligible beneficiaries. If the current or projected demand is expected to exceed available funding for the fiscal year, a notice of termination will be issued to those participants who will be affected. These notices will include continued coverage for a defined transition period not to exceed 60 days. The Department will ensure that all participants are advised when they first enter the program that authorization for services is subject to available funding and may be terminated with a 60-day notice. Should it become necessary, the order of termination from coverage will be non-active duty family member participants from last to first authorized and then active duty family member participants from last to first authorized.

An eligible beneficiary may participate in the case management program if he/she has an extraordinary condition that is disabling and requires extensive utilization of medical resources. 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; and

(ii) the beneficiary must meet the TRICARE/CHAMPUS definition of custodial care.

(iii) If an eligible beneficiary meets all the parameters for waiving benefit limits under the ICMP–PEC, all medically necessary care, as defined under TRICARE/CHAMPUS, will be covered (subject to availability of funding) even if the care will only stabilize or maintain but not improve the health care status of the beneficiary.

(4) *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 for the ICMP–PEC. Authorized services under the ICMP–PEC for custodial care cases may *not* include services that provide only for the essentials/activities of daily living unless such services are incidental to the provision of authorized skilled care. Services for the activities/essentials of daily living include services that do not require the supervision of trained medical personnel. Examples of activities/essential of daily living include basic functions such as dressing, feeding, continence training and care, and transferring in and out of a chair or bed, grooming, and bathing. Retrospective requests for authorization of a waiver of benefit limits/exclusions will not be considered. Authorization of a waiver of benefit limits/exclusions is allowed only when determined to be clinically appropriate and cost-effective.

(5) *Cost effective requirement.* The statutory requirement for cost-effectiveness of the treatment under a waiver of a benefit exclusion or limitation shall be based on a determination that the necessary care is provided in the most cost-effective manner. If a beneficiary is receiving skilled nursing services in the home, and a determination is made that the services could be provided in a more cost-effective manner in a skilled nursing facility, TRICARE will authorize a continuation of benefits under the ICMP–PEC in a skilled nursing facility, or, if benefits are continued in the home, TRICARE cost-sharing will be limited to the amount for which TRICARE would be liable if the services were provided in a skilled nursing facility. The proposed treatment must also meet the requirements of medically or psychologically necessary and appropriate medical care as defined in section 199.2 of this Part.

(6) *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 ICMP–PEC described in paragraph (i) this section. The Director, TRICARE Management Activity may grant a patient-specific waiver 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 section 199.2 of this Part) or back-up durable medical equipment may be covered when determined to be cost-effective and clinically appropriate. Such equipment must be required in the assessment or treatment of the beneficiary's medical condition.

(ii) In home services. The cost of the following in-home services may be covered when determined to be cost-effective and clinically appropriate: nursing care, physical, occupational, speech therapy, medical social services, intermittent 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 848.36. For patients receiving authorized care at home under the ICMP–PEC, there must be a primary caregiver present or the patient must be capable of self-support.

(iii) Domiciliary care. The cost of services or supplies rendered to a beneficiary that would otherwise be excluded as domiciliary care (as defined in section 199.2 of this Part) may be covered only when authorized pursuant to paragraph (i)(3)(ii)(B) and only when provided as an essential component of otherwise medically necessary and appropriate treatment in the management of an extraordinary medical or psychological condition. The domiciliary care must be directly related and essential to the delivery of medically necessary services and no other alternative is available. A domiciliary waiver may be granted only when it will provide medically necessary services on a short-term or transitional basis from a high cost,

normally inpatient setting, to an outpatient setting.

(7) *Right of Appeal.* Beneficiaries and/or providers who dispute either a custodial care determination or the type or level of care and services authorized under the ICMP–PEC have the right to appeal those decisions. Such appeals shall be processed under section 199.10, Appeals, of this Part.

(8) *Secondary liability for payment.* By statute, TRICARE/CHAMPUS is second payer to all health care programs other than Medicaid (Title XIX of the Social Security Act) and certain other Federal or state programs. However, under the ICMP–PEC, TRICARE will pay, as primary obligor, for medically necessary services that might otherwise be covered by other welfare or charity based programs, in addition to Medicaid. TRICARE remains secondary payer under the ICMP–PEC for any comparable services under any other program for which the beneficiary is eligible. When in the best interests of the patient or the patient's family, benefits may be coordinated with Medicaid, other welfare or charity-based programs to ensure TRICARE beneficiaries receive the maximum level of benefits available to them in their communities as long as the primary payer status of ICMP–PEC services is maintained.

(9) *Other administrative requirements.*

(i) Qualified providers of services or items not covered under the basic program, or who are not otherwise eligible for TRICARE/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 have been excluded or suspended as a CHAMPUS provider, must hold Medicare or, if available, state certification or licensure appropriate to the service, and must agree to participate on all claims related to the case management treatment.

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

(iii) The Executive Director, OCHAMPUS may establish other procedures for implementation of the case management program under this paragraph (i).

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

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Dated: July 27, 2001.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301140; FRL–6786–4]

RIN 2070–AB78

Oxadiazon and Tetradifon; Proposed Revocation of Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes to revoke specific tolerances for residues of the herbicide oxadiazon and the insecticide tetradifon. EPA expects to determine whether any individuals or groups want to support these tolerances. The regulatory actions proposed in this document are part of the Agency's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the tolerance reassessment requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA). By law, EPA is required to reassess 66% of the tolerances in existence on August 2, 1996, by August 2002, or about 6,400 tolerances. The regulatory actions proposed in this document pertain to the proposed revocation of 47 tolerances which would be counted among tolerance/exemption reassessments made toward the August 2002 review deadline of FFDCA section 408(q), as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: Comments, identified by docket control number OPP–301140, must be received on or before October 1, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–301140 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joseph Nevola, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave, NW., Washington, DC 20460; telephone number: (703) 308–8037; e-mail address: nevola.joseph@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.