transferee’s distributive share of income or loss from the contract.

§ 1.751–1 Unrealized receivables and inventory items.
(a) * * *
(2) * * * See § 1.460–4(k)(2)(iv)(E) for rules relating to the amount of ordinary income or loss attributable to a contract accounted for under a long-term contract method of accounting.

Par. 11. In § 1.751–1, a sentence is added at the end of paragraph (a)(2) to read as follows:

§ 1.751–1 Unrealized receivables and inventory items.
(a) * * *
(2) * * * See § 1.460–4(k)(2)(iv)(E) for rules relating to the amount of ordinary income or loss attributable to a contract accounted for under a long-term contract method of accounting.

Par. 12. Section 1.755–1 is amended as follows.
1. Adding a sentence at the end of paragraph (b)(1)(ii).
2. Paragraph (c)(5) is redesignated as paragraph (c)(6).
3. New paragraph (c)(5) is added.

The additions read as follows:

§ 1.755–1 Rules for allocation of basis.
(a) * * *
(b) * * *
(1) * * *
(ii) * * * See § 1.460–4(k)(3)(v)(B) for a rule relating to the computation of unrealized appreciation or depreciation in a contract accounted for under a long-term contract method of accounting as a result of the hypothetical transaction.
(c) * * *

Dale F. Hart,
Acting Deputy Commissioner for Services and Enforcement.

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DEPARTMENT OF DEFENSE
Office of the Secretary
32 CFR Part 199
RIN 0720–AA78

TRICARE; Individual Case Management Program; Program for Persons with Disabilities; Extended Benefits for Disabled Family Members of Active Duty Service Members; Custodial Care

AGENCY: Office of the Secretary, DoD.

ACTION: Proposed rule.

SUMMARY: The Department is publishing this proposed rule to implement requirements enacted by Congress in section 701(g) of the National Defense Authorization Act for Fiscal Year 2002 (NDAA–02), Pub. L. 107–107, which terminates the Individual Case Management Program. The Department withdraws its proposed rule published at 66 FR 39699–39705, August 1, 2001 regarding the Individual Case Management Program. This rule also implements section 701(b) of the NDAA–02 which provides additional benefits for certain eligible active duty dependents by amending the TRICARE regulations at 32 CFR 199.5 governing the Program for Persons with Disabilities. The Program for Persons with Disabilities will now be called the Extended Care Health Option. Other administrative amendments are included to clarify specific policies that relate to the Extended Care Health Option, custodial care, and to update related definitions.

Public comments are invited and will be considered for possible revisions to the Final Rule.

DATES: Written comments received at the address indicated below by October 6, 2003 will be accepted.

ADDRESSES: Because of staff and resource limitation, we cannot accept comments by facsimile (FAX) transmission or electronic mail (e-mail). Mail written comments to the following address ONLY: TRICARE Management Activity, telephone (303) 676–3520. Questions regarding payment of specific claims should be addressed to the appropriate TRICARE contractor.

FOR FURTHER INFORMATION CONTACT:
Michael Kottyan, Medical Benefits and Reimbursement Systems, TRICARE Management Activity, telephone (303) 676–3520. Questions regarding payment of specific claims should be addressed to the appropriate TRICARE contractor.

SUPPLEMENTARY INFORMATION:

I. Background

The Individual Case Management Program (ICMP). Under the provisions of section 704(3) of the NDAA–93 [Pub. L. 102–484], 10 U.S.C. 1079(a)(17) was enacted which allowed the DoD to establish the ICMP, also known as the Individual Case Management Program for Persons with Extraordinary Conditions (ICMP–PEC). This allowed a reasonable deviation from the restrictive statutory coverage of health services for patients who had exceptionally serious, long-range, costly and incapacitating conditions. The ICMP was officially implemented in March 1999 as a waiver program that provided coverage for care and services that were normally restricted from coverage under the Basic Program. Specifically, when a beneficiary was determined to meet the TRICARE definition of custodial care, coverage under the Basic Program was limited to one hour of skilled nursing care per day, twelve physician visits per year related to the custodial condition, durable medical equipment and prescription medications. The Department recognized that the exclusion of coverage when a family member is deemed to be a custodial care patient is both a financial and emotional burden. Consequently, the Department used the ICMP/ICMP–PEC authority to cover medically necessary care and to enable TRICARE case managers to maximize available resources for these beneficiaries.

Repeal of the ICMP. Section 701(g) of the NDAA–02 repealed 10 U.S.C. 1079(a)(17), the statutory authority for the ICMP. However, section 701(d) allows the Department to continue to provide payment for home health care or custodial care services not otherwise authorized under the Basic Program as if the ICMP were still in effect. Payment may occur when a determination is made that discontinuation of payment would result in the provision of services inadequate to meet the needs of the eligible beneficiary and would be unjust to the beneficiary. Eligible beneficiaries are defined in section 701(d)(3) as covered beneficiaries who were regarded as custodial patients under the ICMP/ICMP–PEC and received medically necessary skilled services for which the Secretary provided payment before December 28, 2001.

Custodial Care. Section 701(c) of the NDAA–02 provides a statutory definition of custodial care that is more consistent with other federal programs. The change also results in the narrowing of the statutory exclusions of custodial care that has the effect of eliminating current program restrictions on paying for certain medically necessary care. Note: The statutory definition of custodial care under section 701(c) became effective on December 28, 2001, the effective date of the NDAA–02. Public notice of the substitution of the new statutory definition for the former custodial care definition in 32 CFR 199.2 was provided on June 13, 2002 (67 FR 40597–40606).

The Program for Persons with Disabilities (PPPWD). This program is now renamed the Extended Health Care Option (ECHO). The PFPWD was established by Congress in 1966 and
was originally called the Program for the Handicapped (PFTH). The name was changed to PFPWD in 1997 to reflect the national shift away from the label of handicapped and in an effort to be more sensitive to our beneficiaries with special needs. The program was established to provide financial assistance for active duty family members who are moderately or severely mentally retarded or have a serious physical disability. The purpose of the program was to help defray the cost of services not available either through the Basic Program or through other public agencies as a result of state residency requirements. Section 701(b) of the NDAA–02 strikes 10 U.S.C. 1079(d), (e), and (f), which was the statutory authority for the PFPWD, and re-authorizes the program with new subsections (d), (e), and (f). These new subsections add an extraordinary physical or psychological condition as a qualifying condition and remove the requirement to use public facilities to the extent that they are available and adequate in all circumstances. They also include discretion to increase the allowable monthly Government cost-share for allowable services from a maximum of $1,000 per month and expand the benefit to allow for coverage of ECHO home health care and services beyond the Basic program. It also includes the discretion to allow coverage for custodial care and respite care.

II. The Extended Care Health Option (ECHO)

The primary purpose of the ECHO is to provide extended benefits to eligible beneficiaries that are not available through the Basic Program that assist in the reduction of the disabling effects of an ECHO qualifying condition. Under 10 U.S.C. 1079(e), ECHO benefits may be provided only to the extent such service, supply or equipment is not a covered benefit under the Basic Program. This may include comprehensive health care services, including services necessary to maintain, or minimize or prevent deterioration of, function of an eligible beneficiary.

Eligibility. Participation in the ECHO is voluntary and is available only for TRICARE-eligible family members of active duty service members who have a qualifying condition. Qualifying conditions are limited under 10 U.S.C. 1079(d)(3)(B) to beneficiaries who have:

(a) moderate or severe mental retardation; or

(b) a serious physical disability; or

(c) an extraordinary physical or psychological condition, as defined in 32 CFR 199.2.

ECHO Benefits. Benefits available under ECHO detailed herein include diagnostic procedures to establish a qualifying condition, treatment through the use of medical, habilitative or rehabilitative means, training to allow use of assistive technology, special education instruction, institutional care within a State when a residential environment is required, transportation under certain circumstances, and certain adjunct services such as assistive services of a qualified interpreter or translator for deaf or blind beneficiaries in conjunction with receipt of other allowed ECHO benefits, equipment adaptation and maintenance, and ECHO home health care.

ECHO Respite Care. Under 10 U.S.C. 1079(e)(6), the Department may provide respite care under the ECHO program. Respite care is defined in 32 CFR 199.2 as short term care for a patient in order to provide rest and change for those who have been caring for the patient at home, usually the patient’s family. DoD recognizes that caring for a special needs beneficiary poses special challenges, especially for active duty families. DoD proposes an ECHO benefit to provide a maximum of 16 hours per month of respite care. The benefit would be available to the primary caregiver(s), as defined in 32 CFR 199.2, in any month in which the beneficiary is otherwise receiving ECHO benefits. Respite care services would be provided by a TRICARE-authorized home health agency and would be designed to provide health care services for the covered beneficiary, and not babysitting or child-care services for other members of the family. The benefit would not be cumulative, that is, any respite care hours not used in one-month would not be carried over or banked for a subsequent month(s). The government’s cost-share incurred for these services accrue to the proposed maximum monthly benefit of $2,500.

ECHO Home Health Care (EHHC). Under 10 U.S.C. 1079(e), extended benefits may be provided to eligible beneficiaries to the extent such benefits are not provided under provisions of chapter 55, title 10, United States Code, other than under this section. Under 10 U.S.C. 1079(e)(2), the ECHO may include “comprehensive home health care supplies and services which may include cost effective and medically appropriate services other than part-time or intermittent services (within the meaning of section 1861(m) of the Social Security Act).” Section 701(a) of the NDAA–02 requires home health care services under the Basic Program be provided in the manner and under the conditions described in section 1861(m) of the Social Security Act. Therefore, the Department proposes an ECHO Home Health Care (EHHC) benefit for qualifying beneficiaries.

EHHC Eligibility. To qualify for EHHC, the beneficiary must meet all general ECHO program eligibility requirements and must:

(a) physically reside within the 50 United States or the District of Columbia; and

(b) be homebound, as defined in section 199.2 and as modified in this proposed rule;

c) require medically necessary skilled services that exceed the maximum level of coverage provided under the Basic Program’s home health care benefit, or

(d) require frequent interventions, other than skilled medical services, by the primary caregiver(s) such that EHHC services are necessary to allow primary caregiver(s) the opportunity to rest;

(e) be case managed, including a periodic assessment of needs, and receive services as outlined in a written plan of care, and

(f) receive home health care services from a TRICARE-authorized home health agency as described in section 199.6(b)(4)(v).

EHHC Benefit. Covered TRICARE-authorized home health agency services are the same as, and provided under the same conditions as, those services provided under the TRICARE Basic Program under section 199.4(e)(21), with the exception that the EHHC benefit is not limited to part-time or intermittent home health care.

Therefore, DoD proposes that beneficiaries who are eligible for the ECHO and require home health care services beyond the coverage limits under the Basic Program will receive all home health care services under EHHC and no portion will be provided under the Basic Program.

EHHC Plan of Care: The level of ECHO home health care services authorized will be based on a written plan of care that supports the medical necessity of those services in excess of what can be authorized by the Basic Program, or, in the case of a beneficiary who requires frequent interventions, the need for EHHC in order to allow the primary caregiver(s) the opportunity to rest. The plan of care must include identification of the professional qualifications or skill level of the person required to provide the care. Reasonable justification for the medical necessity of the level of provider must be included.
in the plan of care, otherwise, reimbursement will not be authorized.

**EFFC Respite Care.** The DoD proposes to provide respite care within the EHHC benefit specifically tailored for families with a beneficiary who has a medical condition(s) that requires frequent interventions by the primary caregiver. For the purpose of this respite care, the term “frequent” means “more than two interventions during the eight-hour per day period that the primary caregiver would normally be sleeping. The service performed during the interventions may have been taught to the primary caregiver by a medical professional, but the services performed by the primary caregiver are such that they can be performed safely and effectively by the average non-medical person without direct supervision of a licensed nurse or other health care provider. DoD proposes that when an eligible beneficiary’s care plan reflects a need for frequent interventions by the primary caregiver, the beneficiary’s primary caregiver is eligible for EHHC respite services in lieu of the ECHO respite care benefit. Primary caregivers in this situation would be eligible for eight hours per weekday of respite care by a TRICARE-authorized home health agency. The services provided would be designed to provide health care services for the covered beneficiary so that the primary caregiver is relieved of his/her responsibility for providing such care for the duration of that period of respite care in order that the primary caregiver may rest. The TRICARE-authorized home health agency will not provide baby-sitting or child care services for other members of the family. The benefit would not be cumulative, that is, any respite care hours not used in a given day would not be carried over or banked for use on another occasion. The government’s cost-share incurred for these services accrue to the proposed fiscal year maximum ECHO Home Health Care benefit.

**EHHC Government Cost Share.** TRICARE-authorized home health agencies who provide services under the Basic Program are reimbursed under section 199.14(h) using the same methods and rates as used under the Medicare TRICARE-authorized home health agency prospective payment system under section 1895 of the Social Security Act (42 U.S.C. 1385ffh) and 42 CFR part 484, subpart E, except for children under age ten and except as otherwise necessary to recognize distinct characteristics of TRICARE beneficiaries and as described in instructions issued by the Director, TRICARE Management Activity. However, the Medicare home health agency prospective payment system is designed to reimburse providers who provide part-time or intermittent services; it is not designed to reimburse providers for services that exceed those limits. As a result, the Department proposes to pay billed charges or negotiated rates for EHHC services up to an annual fiscal year cap in an amount no greater than what the highest locally wage-adjusted maximum Medicare Resource Utilization Grouping (RUG–III) category cost to the Government would be if services were provided in a TRICARE-authorized skilled nursing facility. (See 67 FR 40597–40606, June 13, 2001, concerning the TRICARE Sub-Acute Care Program: Uniform Skilled Nursing Facility Benefit; Home Health Care Benefit; Adopting Medicare Payment Methods for Skilled Nursing Facilities and Home Health Care Providers). Because the highest RUG–III category is used to determine the fiscal year cap, the Department will not attempt to determine what RUG–III category would apply to the beneficiary if such beneficiary were in fact admitted for care into a TRICARE-authorized skilled nursing facility.

The Maximum monthly Government cost-share to be paid to the home health agency for ECHO home health care will be the billed charge or negotiated rate, but in no case will it exceed one-twelfth of the fiscal year cap calculated as above.

When EHHC beneficiaries move within the 50 United States or the District of Columbia, the annual fiscal year cap, as described above to reflect the correct wage-adjusted maximum RUG–III category cost for the beneficiary’s new location and apply for the remaining portion of that fiscal year and subsequent fiscal years.

**EHHC Reimbursement.** A TRICARE-authorized home health agency must bill for all authorized ECHO home health care services through established TRICARE claims mechanisms. No special billing arrangements will be authorized in coordination with coverage that may be provided by Medicaid (subject to any State Agency Billing Agreements), or other federal, state, community or private programs.

Reimbursement for all EHHC services will be based on the professional level of the TRICARE-authorized home health agency individual(s) providing the authorized care. Specifically, TRICARE will reimburse up to 100% of the CHAMPUS Maximum Allowable Charge (CMAC) rate for a physician or registered nurse; up to 80% of the CMAC rate for a physical therapist, occupational therapist, or vocational nurse; and up to 60% of the CMAC for a home health aide.

**Beneficiary Cost-share Liability for ECHO.** Under 10 U.S.C. 1079(f), members are required to share in the cost of any benefits provided to their dependents under ECHO. ECHO benefits are not subject to a deductible amount. Regardless of the number of ECHO eligible family members, the sponsor’s monthly cost-share for allowed ECHO benefits is based upon the rank of the uniformed service member. Under 10 U.S.C. 1079(f)(1)(A), members with a rank of E–1 are required to pay the first $25 incurred per month, and members with a rank of O–10 are required to pay the first $250 incurred per month. It is proposed that the cost-share for members with ranks in-between would be structured so that the vast majority would pay less than $100 per month, with the most senior enlisted member paying less than $50 per month.

Sponsor rank-based cost-sharing (refer to Table 1, 32 CFR 199.5) applies to benefits covered by the ECHO and these cost-shares do not apply toward the Basic Program’s catastrophic cap under 10 U.S.C. 1079(f)(5). The waiver of cost-shares for active duty family members enrolled in TRICARE Prime does not apply to ECHO, as there is a separate statutory basis for the ECHO program and its cost-shares compared to the Basic Program or Prime.

**Government Cost-share Liability for ECHO.** The Government’s monthly cost-share of all benefits provided to a beneficiary in a particular month under the PFPWD was statutorily limited to $1,000 by 10 U.S.C. 1079(f)(2)(A) to $2,500 for benefits related to training, rehabilitation, special education, assistive technology devices, and institutional care in private, non-profit, public, and state institutions and facilities, and if appropriate, transportation to and from such institutions and agencies. Because the NDAA–02 provided no statutory limitation concerning the amount of the Government’s monthly cost-share for all other benefits under ECHO, the Department has discretion to determine the maximum monthly Government cost-share. Therefore, the Department proposes to increase the monthly Government cost-share from $1,000 to $2,500 for all benefits under ECHO, with the exception of the new ECHO home health care benefit as is detailed herein. The primary reason for this proposed increase is that the maximum government cost-share has not been
adjusted since 1980. We will continue to review this issue to ensure that the government’s cost-share reasonably meets the needs of beneficiaries.

Other Requirements. Other ECHO requirements are as follows:

Registration: Sec 701(b) of the NDAA–02 (10 U.S.C. 1079(d)(1)) requires registration to receive ECHO benefits. Sponsors of potentially qualifying beneficiaries will seek to register their family member(s) for ECHO benefits through the applicable Managed Care Support Contractor who will certify eligibility and update the Defense Eligibility Enrollment Reporting System (DEERS) to reflect ECHO eligibility. No ECHO benefits may be authorized unless the beneficiary is registered in DEERS as ECHO-eligible.

EMFP enrollment: Each of the Services has its own Exceptional Family Member Program (EFMP). The programs are a military personnel program. The purpose of the program is to have personnel offices evaluate the ability of a military and civilian community to provide appropriate medical and/or educational services to service members’ dependents who have special medical or educational needs before the Service reassigns the member to a new location. Although each Service requires its members with special needs to enroll in the EFMP, some members do not comply with this requirement. The result is that some members arrive at assignment locations that are unable to accommodate the special medical and/or educational needs of their dependents. Dependents of members required to be enrolled in EFMP are similar if not identical to those who qualify for the ECHO program. The Services do not routinely provide EFMP enrollments to TRICARE. In accordance with 10 U.S.C. 1079(d)(1), a beneficiary must register with TRICARE in order to qualify for receipt of benefits through the ECHO. We propose that the registration process will be provided by the applicable Managed Care Support Contractor. We also propose that members will be required to provide evidence they are enrolled in their Services’ Exceptional Family Member program when registering for ECHO benefits. This requirement will enhance the probability that personnel are assigned to locations where there are sufficient qualified individual or institutional providers to provide the ECHO benefit to their dependents.

Use of Public Facilities: For ECHO benefits related to training, rehabilitative education and educational technology devices, and institutional care in private, non-profit, public, and state institutions and facilities, and if applicable, transportation to and from such institutions and facilities, the statute expressly requires use of public facilities to be the extent such facilities are available and adequate as determined under this regulation.

III. 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 is not an economically significant regulatory action and will not have a significant impact on a substantial number of small entities for purposes of the RFA. This rule, although not economically significant under Executive Order 12866, is a significant rule under Executive order 12866 and has been reviewed by the Office of Management and Budget.

Paperwork Reduction Act

This rule will not impose additional information collection requirements on the public under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3511). Existing DoD information systems to include the Defense Eligibility Enrollment Reporting System (DEERS) will be upgraded to reflect ECHO registration.

List of Subjects in 32 CFR Part 199:

Case management, Claims, Custodial care, Health insurance, Individuals with disabilities, Military Personnel.

For the reasons set out in the preamble, 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:


2. Section 199.2 is proposed to be amended by removing the definition for the “Program for Persons with Disabilities (PFPWD)” and “Extraordinary Physical or Psychological Condition” and placing them in alphabetical order to read as follows:

§ 199.2 Definitions.

Duplicate Equipment. An item of durable equipment or durable medical equipment, as defined in this section, that serves the same purpose that is previously cost-shared by TRICARE. For example, various models of stationary oxygen concentrators with no primary functional differences are considered duplicate equipment, whereas stationary and portable oxygen concentrators are not considered duplicates of each other because the latter is intended to provide the user with mobility not afforded by the former. Also, a manual wheelchair and an electric wheelchair, both of which otherwise meet the definition of durable equipment or durable medical equipment, would not be considered duplicates of each other if each is found to provide an appropriate level of mobility. For the purpose of TRICARE cost-sharing, durable equipment and durable medical equipment that is essential to provide a fail-safe-in-home life support system is not considered duplicate equipment.

Durable equipment.

(1) A device or apparatus which does not qualify as durable medical equipment and which is essential to the efficient arrest or reduction of functional loss resulting from a qualifying condition as provided in section 199.5; and
(2) is other than duplicate equipment as defined in this section.

Durable medical equipment.

(9) Is other than duplicate equipment as defined in this section.

Extended Care Health Option (ECHO). The TRICARE special program of supplemental benefits for qualifying active duty family members as described in Section 199.5.

Extraordinary Physical or Psychological Condition. A complex physical or psychological clinical condition of such severity which results in the beneficiary being homebound as defined in this section.

Homebound. A beneficiary’s condition is such that there exists a
normal inability to leave home and, consequently, leaving home would require considerable and taxing effort. Any absence of an individual from the home attributable to the need to receive health care treatment, including regular absences for the purpose of participating in therapeutic, psychosocial, or medical treatment or in an adult day-care program certified by a state, or accredited to furnish adult day-care services in the state shall not disqualify an individual from being considered to be confined to his home. Any other absence of an individual from the home shall not disqualify an individual if the absence is infrequent or of relatively short duration. For the purposes of the preceding sentence, any absence for purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration. Also, absences from the home for non-medical purposes, such as an occasional trip to the barber, a walk around the block or a drive, would not necessarily negate the beneficiary’s homebound status if the absences are undertaken on an infrequent basis and are of relatively short duration. In addition to the above, absences, whether regular or infrequent, from the beneficiary’s primary residence for the purpose of attending an educational program in a public or private school that is licensed and/or certified by a state, shall not negate the beneficiary’s homebound status.

3. Section 199.3 is proposed to be amended by removing the term Program for Persons with Disabilities or the acronym PFPWD, and replacing the term Extended Care Health Option or the acronym ECHO in paragraphs (c)(2)(ii)(C), (c)(2)(ii)(B), (c)(2)(iii)(B), (c)(3)(ii)(C), (c)(4)(i)(B), (c)(4)(ii)(B), (c)(4)(iii)(B), (c)(5)(ii)(C), (c)(5)(ii)(B), (c)(5)(iii)(B), (c)(5)(iv)(C)(2), (c)(6)(ii), (c)(7)(i)(C), (c)(7)(ii)(B), (c)(8)(ii), (c)(9)(ii)(B), and (c)(10)(ii) by, wherever they appear.

4. Section 199.4 is proposed to be amended to revise paragraph (e)(12) regarding custodial care; remove and reserve paragraph (e)(2) Case management services; revise paragraph (g)(7) of exclusions; and remove paragraph (j) Case management program in its entirety; to read as follows:

§ 199.4 Basic Program Benefits.

(12) Custodial care. Custodial care is statutorily excluded under the TRICARE Basic Program. The term custodial care means treatment or services, regardless of who recommends such treatment or services or where such treatment or services are provided, that (i) can be rendered safely and reasonably by a person who is not medically skilled; or (ii) is or are designed mainly to help the patient with the activities of daily living.

§ 199.5 TRICARE Extended Care Health Option (ECHO).

(a) General. The ECHO provides financial assistance for certain TRICARE/CHAMPUS beneficiaries to cover an integrated set of services and supplies designed to care for those who have a qualifying condition. The ECHO is not intended to be a stand-alone benefit for those who need only financial assistance but is used to provide benefits not available through the TRICARE Basic Program. The primary purpose is to provide coverage for services that assist in the reduction of the disabling effects of an ECHO qualifying condition, which may include services necessary to maintain, or minimize or prevent deterioration of, function of an ECHO-eligible beneficiary.

(b) Eligibility.

(1) The following categories of TRICARE/CHAMPUS beneficiaries with a qualifying condition are eligible for ECHO benefits:

(i) A child or spouse as described in 10 U.S.C. 1072(a)(A), (D), or (I) of an active duty member of one of the Uniformed Services on active duty for a period of more than 30 days; or

(ii) An abused dependent, as described in section 199.3(b)(2)(iii); or

(iii) A child or spouse as described in 10 U.S.C. 1072(2)(A), (D), or (I) of an active duty member of one of the Uniformed Services on active duty for a period of more than 30 days who dies while on active duty, remains eligible for benefits under the ECHO for a period of three years from the date the active duty sponsor dies; or

(iv) A child or spouse as described in 10 U.S.C. 1072(2)(A), (D), or (I) of a deceased active duty member of one of the Uniformed Services who at the time of the member’s death was receiving benefits under ECHO, and the member at the time was eligible for receipt of hostile-fire pay, or died as a result of a disease or injury incurred while eligible for such pay. In such circumstances, the dependent shall be eligible through midnight of the beneficiary’s twenty-first birthday.

(2) Qualifying condition. The eligible dependent must have one of the following qualifying conditions:

(i) Mental retardation. A diagnosis of moderate or severe mental retardation made in accordance with the criteria of the current edition of the “Diagnostic and Statistical Manual of Mental Disorders” published by the American Psychiatric Association.

(ii) Serious physical disability. A serious physical disability as defined in section 199.2.

(iii) Extraordinary physical or psychological condition. An extraordinary physical or psychological condition as defined in section 199.2.

(iv) Infant/toddler. TRICARE/CHAMPUS beneficiaries under the age of three years who are diagnosed with a neuromuscular developmental condition or other condition that can be reasonably expected to precede a diagnosis of moderate or severe mental retardation or be considered as a serious physical disability shall be deemed to have a qualifying condition for the ECHO. The Director, TRICARE Management Activity or designee shall establish criteria for ECHO eligibility in lieu of the requirements of paragraphs (b)(2)(i), (ii) or (iii) of this section.

(v) Multiple disabilities. The cumulative effect of multiple disabilities as determined by the Director, TRICARE Management Activity or designee shall be used in the determination of a qualifying condition when the beneficiary has two or more disabilities involving separate body systems.

(3) Loss of ECHO eligibility. Eligibility for ECHO benefits ceases as of 12:01 a.m. of the day following the day that:

(i) The sponsor ceases to be an active duty member for any reason other than death; or

(ii) Eligibility based upon the abused dependent provisions of paragraph (b)(1) of this section expires; or

(iii) Eligibility based upon the deceased sponsor provisions of paragraph (b)(1) of this section expires; or

(iv) Eligibility based upon a beneficiary’s participation in the Transitional Assistance Management Program ends; or
(v) the Director, TRICARE Management Activity or designee determines that the beneficiary no longer has a qualifying condition.

(4) Continuity of eligibility. A TRICARE beneficiary who has an outstanding Program for Persons with Disabilities (PPFWD) benefit authorization prior to the effective date of the ECHO program shall be deemed to have an ECHO qualifying condition for the duration of the authorization period during which the beneficiary is otherwise eligible for ECHO and the beneficiary continues to meet the applicable qualifying condition criteria. Upon termination of such an existing authorization for services the beneficiary shall re-establish eligibility for the ECHO in accordance with this section.

(c) ECHO Benefit. Items or services which the Director, TRICARE Management Activity or designee has determined to be intrinsic to the following benefit categories and which are determined to be capable of confirming, arresting, or reducing the severity of the effects of a qualifying condition, and that are not otherwise available through the TRICARE Basic Program or excluded by the ECHO, may be allowed.

(1) Diagnostic procedures to establish a qualifying condition diagnosis or to measure the extent of functional loss.

(2) Treatment through the use of such medical, habilitative, or rehabilitative methods, techniques, therapies, and durable equipment and durable medical equipment which otherwise meet the requirements of the ECHO. Allowable treatment may be rendered in-home, or as inpatient or outpatient care, or other environment as appropriate.

(3) Training which allows the use of an assistive technology device or to acquire skills which are expected to reduce the effects of a qualifying condition and for parents or guardians and siblings of an ECHO beneficiary when required as an integral part of the management of the qualifying condition. Vocational training, in the beneficiary’s home environment providing such, is also allowed.

(4) Special education as provided by the Individuals with Disabilities Education Act and defined at 34 CFR 300.26 and which is specifically designed to accommodate the disabling effects of qualifying condition.

(5) Institutional care within a state, as defined in section 199.2, when the severity of the qualifying condition requires protective custody or training in a residential environment.

(6) Transit. When required to convey an ECHO beneficiary to or from a facility or institution to receive allowable ECHO services or items. Transportation for a medical attendant may be approved when medically necessary for the safe transport of the ECHO beneficiary to receive an authorized ECHO benefit.

(7) Adjunct services. (i) Assistive services. Services of a qualified interpreter or translator for ECHO beneficiaries who are deaf and readers for ECHO beneficiaries who are blind, and personal assistants for ECHO beneficiaries with other types of qualifying conditions, when such services are necessary in order for the ECHO beneficiary to receive authorized ECHO benefits.

(ii) Equipment adaptation. The allowable equipment purchase shall include such services and modifications to the equipment as necessary to make the equipment useable for a particular ECHO beneficiary.

(iii) Equipment maintenance. Reasonable repairs and maintenance of beneficiary owned or rented durable equipment or durable medical equipment otherwise allowable by this section shall be allowable while a beneficiary is registered in the ECHO.

(8) Respite Care. The primary caregiver is eligible for respite care, as defined in section 199.2, of 16 hours per month in any month in which the qualified beneficiary otherwise receives an ECHO benefits. Respite care services will be provided by a TRICARE-authorized home health agency and will be designed to provide health care services for the covered beneficiary, and not baby-sitter-like services for other members of the family. The benefit will not be cumulative, that is, any respite care hours not used in one month will not be carried over or banked for use on another occasion. The government’s cost-share incurred for these services accrue to the maximum monthly benefit of $2,500.

(d) ECHO Benefit Exclusions. (1) Benefits allowed under the TRICARE Basic Program will not be provided through the ECHO.

(2) Unproven drugs, devices, and medical treatments or therapeutic or diagnostic procedures. Services and items whose safety and efficacy have not been established in accordance with section 199.4 are excluded.

(3) Structural alterations. Alterations to living space and permanent fixtures attached thereto, including alterations necessary to accommodate installation of equipment or to facilitate entrance or exit, are excluded.

(4) Homemaker services. Services that predominantly provide assistance with household chores are excluded.

(5) Dental care or orthodontic treatment. Both are excluded.

(6) Non-domestic travel. Travel that originates or terminates outside of a state is excluded.

(7) Deluxe travel accommodation. The difference between the price for a type of accommodation which provides services or features which exceed the requirements of the beneficiary’s condition for safe transport and the price for a type of accommodation without those services or features, is excluded.

(8) Equipment. Exclusions for durable medical equipment at section 199.4(d)(3)(i)(D) apply to all ECHO allowable equipment. Except as otherwise provided in this part, duplicate items of durable equipment and durable medical equipment shall not be authorized. Reasonable repairs and maintenance shall be allowable for equipment otherwise allowable by this section, however, maintenance agreements are excluded.

(9) No obligation to pay. Services or items for which the beneficiary or sponsor has no legal obligation to pay, or for which no charge would be made if the beneficiary was not eligible for TRICARE, are excluded.

(10) Public facility or Federal government. Services or items paid for, or eligible for payment, directly or indirectly by a public facility, as defined in section 199.2, or by the Federal government, other than the Department of Defense, are excluded for training, rehabilitation, special education, assistive technology, and institutional care in private nonprofit, public, and state institutions and facilities, and if appropriate, transportation to and from such institutions and facilities except when such services or items are eligible for payment under a state plan for medical assistance under Title XIX of the Social Security Act (Medicaid). Rehabilitation and assistive technology services or supplies may be available under the TRICARE Basic Program.

(11) Study, grant, or research programs. Services and items provided as a part of a scientific clinical study, grant, or research program are excluded.

(12) Unproven drugs, devices, and medical treatments or therapeutic or diagnostic procedures. Services and items whose safety and efficacy have not been established in accordance with section 199.4 are excluded.

(13) Immediate family or household. Services or items provided or prescribed by a member of the beneficiary’s immediate family, or a person living in the beneficiary’s or sponsor’s household, are excluded.

(14) Court or agency ordered care. Services or items ordered by a court or other government agency, which are not
otherwise an allowable ECHO benefit, are excluded.

(15) Excursions. Additional or special charges for excursions, other than otherwise allowable transportation, are excluded even though part of a program offered by a TRICARE-authorized provider.

(16) Drugs and medicines. Drugs and medicines that do not meet the benefit requirements of section 199.4 or 199.21 are excluded.

(17) Therapeutic absences. Therapeutic absences from an inpatient facility or from home for a homebound beneficiary are excluded.

(e) ECHO Home Health Care (EHHC).

Home health care services and supplies are authorized for those beneficiaries who meet all applicable ECHO eligibility requirements and who also:

(1) physically reside within the 50 United States or the District of Columbia; and

(2) are homebound, as defined in section 199.2; and

(3) require medically necessary skilled services that exceed the level of coverage provided under the Basic Program’s home health care benefit, or

(4) require frequent interventions (other than skilled medical services), usually provided by the primary caregiver(s), as defined in section 199.2, such that EHHC services are necessary to allow the primary caregiver(s) the opportunity to rest.

(5) are case managed to include a reassessment at least every ninety (90) days, and receive services as outlined in a written plan of care; and

(6) receive all home health care services from a TRICARE-authorized home health agency as described in section 199.6(b)(4)(xv) in the beneficiary’s primary residence.

(f) EHHC Benefit. Covered home health services are the same as, and provided under the same conditions as, those services described in section 199.4(e)(21)(i), except that they are not limited to part-time or intermittent services. Custodial care services, as defined in section 199.2, may be provided to the extent such services are provided in conjunction with authorized ECHO home health care services. Beneficiaries who are authorized EHHC will receive all home health care services under EHHC and no portion will be provided under the Basic Program. TRICARE-authorized home health agencies are not required to use the Outcome and Assessment Information Set (OASIS) to assess beneficiaries who are authorized EHHC.

(3) EHHC Government Cost-Share.

The maximum annual Government cost-share, using a billed charges or negotiated rate payment methodology, for ECHO home health care services may not exceed the local wage-adjusted highest Medicare Resource Utilization Group (RUG–III) category. (i) The maximum monthly Government cost-share for EHHC will be based on the actual number of hours of ECHO home health care services rendered in the month, but in no case will it exceed one-twelfth of the annual maximum Government cost-share as determined in this section.

(ii) When a beneficiary moves to a different locality within the 50 United States or the District of Columbia, the annual fiscal year cap will be recalculated to reflect the wage-adjusted highest Medicare RUG–III category cost for the beneficiary’s new location and will apply to the EHHC benefit for the remaining portion of that and subsequent fiscal years.

(4) EHHC Reimbursement. TRICARE-authorized home health agencies must provide and bill for all authorized home health care services through established TRICARE claims mechanisms. No special billing arrangements will be authorized in conjunction with coverage that may be provided by Medicaid or other federal, state, community or private programs. Reimbursement will be based on the professional level of the person providing the authorized care as indicated in the beneficiary’s plan of care. Specifically, TRICARE will reimburse up to 100% of the CHAMPUS Maximum Allowable Charge (CMAC) or negotiated rate for a physician or registered nurse; up to 80% of the CMAC for a licensed practical or vocational nurse; and up to 60% of the CMAC for a home health aide.

(5) EHHC Exclusions.

(i) Respite care. Respite care for the purpose of covering primary caregiver absences due to deployment, employment, seeking of employment or for pursuit of education is excluded. Authorized respite care covers only the ECHO beneficiary, not siblings or others who may reside in or be visiting in the beneficiary’s residence.

(ii) ECHO home health care for former Individual Case Management Program for Persons with Extraordinary Conditions (ICMP–PEC) or Case Management Demonstration Participants. ECHO home health care services and supplies are excluded for those beneficiaries being provided continuing coverage for home health care as participants of the previous case management demonstration or the ICMP–PEC.

(g) Cost-share liability—

(1) No deductible. ECHO benefits are not subject to a deductible amount.

(2) Sponsor cost-share liability.

(i) Regardless of the number of ECHO eligible family members, the sponsor’s cost-share for ECHO benefits, including ECHO Home Health Care, in a given month is according to the following table:

<table>
<thead>
<tr>
<th>Table 1.—MONTHLY COST-SHARE BY MEMBER’S PAY GRADE</th>
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<tbody>
<tr>
<td>E-1 through E-5 ...................................</td>
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<tr>
<td>E-6 .............................................</td>
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<tr>
<td>E-7 and O-1 ...................................</td>
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<td>E-8 and O-2 ...................................</td>
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<td>E-9, W-1, W-2 and O-3 .........................</td>
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<td>W-3, W-4 and O-4 .............................</td>
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<td>W-5, O-5 and O-6 .............................</td>
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<td>O-6 .............................................</td>
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(ii) The sponsor’s cost-share shown in Table 1 in paragraph (g)(2)(i) will be applied to the first allowed ECHO charges in any given month. The Government’s share will be paid, up to the maximum amount specified in paragraph (g)(3) of this section, for allowed charges after the sponsor’s cost-share has been applied.

(iii) The provisions of 32 CFR 199.18(d)(1) and (e)(1) regarding elimination of copayments for active duty families enrolled in TRICARE Prime do not eliminate, reduce, or otherwise affect the sponsor’s cost-share shown in Table 1 in paragraph (g)(2)(i).

(iv) The sponsor’s cost-share shown in Table 1 in paragraph (g)(2)(i) does not accrue to the Basic Program’s Catastrophic Loss Protection under 10 U.S.C. 1079(b)(5) as shown at 32 CFR 199.4(f)(10) and 199.18(f).

(3) Government cost-share liability.

(i) The total government share of the cost of all ECHO benefits, except for ECHO home health care, provided in a given month to a beneficiary may not exceed $2,500 after application of the allowable payment methodology.

(ii) The total government share of the cost of authorized ECHO home health care provided in a month to a beneficiary may not exceed one-twelfth of the annual maximum Government cost-share as determined in this section.

(h) Benefit payment.

(1) Transportation. The allowable amount for transportation of an ECHO beneficiary is limited to the actual cost of the standard published fare plus any standard surcharge made to accommodate any person with a similar disability or to the actual cost of specialized medical transportation when non-specialized transport cannot accommodate the beneficiary’s qualifying condition related needs, or when specialized transport is more economical than non-specialized transport. When transport is by private vehicle, the allowable amount is limited to the Federal government employee mileage reimbursement rate in effect on the date the transportation is provided.

(2) Equipment.

(i) The TRICARE allowable amount for durable equipment and durable medical equipment shall be calculated in the same manner as durable medical equipment allowable through section 199.4.

(ii) Allocating equipment expense. The ECHO beneficiary (or sponsor or guardian acting on the beneficiary’s behalf) may, only at the time of the request for authorization of equipment, specify how the allowable cost of the equipment is to be allocated as an ECHO benefit. The entire allowable cost of the authorized equipment may be allocated in the month of purchase provided the allowable cost does not exceed the ECHO maximum monthly benefit of $2,500, or it may be prorated regardless of the allowable cost. Prorating permits the allowable cost of ECHO-authorized equipment to be allocated such that the amount allocated each month does not exceed the maximum monthly benefit.

(A) Maximum period. The maximum number of consecutive months during which the allowable cost may be prorated is the lesser of:

(1) The number of months calculated by dividing the allowable cost for the item by 2,500 and then doubling the resulting quotient, rounded off to the nearest whole number; or

(2) The number of months of expected useful life of the equipment for the requesting beneficiary, as determined by the Director, TRICARE Management Activity or designee.

(B) Alternative allocation period. The allowable equipment cost may be allocated monthly in any amount such that the maximum allowable monthly ECHO benefit of $2,500, or the maximum period under (i), is not exceeded.

(C) Authorization.

(1) The amount allocated each month under (i) or (ii) will be separately authorized as an ECHO benefit.

(2) An item of durable equipment or durable medical equipment shall not be authorized when such authorization would allow concurrent ECHO cost-sharing of duplicate equipment, as defined in section 199.2, for the same beneficiary.

(D) Cost-share. A cost-share, as provided by (g) of this section, is required for each month in which a prorated amount is authorized.

(E) Termination. Prorated payments shall be terminated as of the first day of the month following the death of a beneficiary or as of the effective date of a beneficiary’s loss of ECHO eligibility for any other reason.

(3) For-profit institutional care provider. Institutional care provided by a for-profit entity may be allowed only when the care for a specific ECHO beneficiary.

(i) is contracted for by a public facility as a part of a publicly funded long-term inpatient care program; and

(ii) is provided based upon the ECHO beneficiary’s being eligible for the publicly funded program which has contracted for the care; and

(iii) is authorized by the public facility as a part of a publicly funded program;

(iv) would cause a cost-share liability in the absence of TRICARE eligibility; and

(v) produces an ECHO beneficiary cost-share liability that does not exceed the maximum charge by the provider to the public facility for the contracted level of care.

(i) Other ECHO Requirements.

(1) All provisions of this part, except the provisions of section 199.4 unless otherwise provided by this section, apply to the ECHO.

(2) Registration. Active duty sponsors must register potential ECHO eligible beneficiaries through the Director, TRICARE Management Activity or designee prior to receiving ECHO benefits. The Director, TRICARE Management Activity or designee will determine ECHO eligibility and update the Defense Eligibility Enrollment Reporting System (DEERS) accordingly. Sponsors must provide evidence of enrollment in their respective branch of services Exceptional Family Member Program at the time they register their family member(s) for the ECHO.

(3) Benefit authorization. All ECHO benefits require authorization by the Director, TRICARE Management Activity or designee prior to receipt of such benefits.

(4) Documentation. The sponsor shall provide such documentation as the Director, TRICARE Management Activity or designee requires as a prerequisite to authorizing ECHO benefits. Such documentation shall describe how the requested benefit will contribute to confirming, arresting, or reducing the disabling effects of the qualifying condition, including maintenance of function or prevention of further deterioration of function, of the beneficiary.

(ii) Format. An authorization issued by the Director, TRICARE Management Activity or designee shall specify such description, dates, amounts, requirements, limitations or information as necessary for exact identification of approved benefits and efficient adjudication of resulting claims.

(iii) Valid period. An authorization for ECHO benefits shall be valid until such time as the Director, TRICARE Management Activity or designee determines that the authorized services are no longer appropriate or required.

(iv) Authorization waiver. The Director, TRICARE Management Activity or designee may authorize payment without prior receipt of an authorization.

TABLE 1.—MONTHLY COST-SHARE BY MEMBER’S PAY GRADE—Continued

<table>
<thead>
<tr>
<th>PAY GRADE</th>
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<td>O-9</td>
<td>200</td>
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<td>O-10</td>
<td>250</td>
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</tbody>
</table>

(i) Table 1 in paragraph (g)(2)(i) will be applied to the first allowed ECHO charges in any given month. The Government’s share will be paid, up to the maximum amount specified in paragraph (g)(3) of this section, for allowed charges after the sponsor’s cost-share has been applied.
Activity or designee may waive the requirement for a written authorization for rendered ECHO benefits that, except for the absence of the written authorization, would be allowable as an ECHO benefit.

(v) Public facility use.

(A) An ECHO beneficiary residing within a state must demonstrate that a public facility is not available and adequate to meet the needs of their qualifying condition. Such requirement shall apply for beneficiaries who request authorization for training, rehabilitation, special education, assistive technology, and institutional care in private nonprofit, public, and state institutions and facilities, and if appropriate, transportation to and from such institutions and facilities. The maximum Government cost-share for services that require demonstration of public facility non-availability or inadequacy is limited to $2,500 per month per beneficiary. State-administered plans for medical assistance under Title XIX of the Social Security Act (Medicaid) are not considered available and adequate facilities for the purpose of this section.

(B) The domicile of the beneficiary shall be the basis for the determination of public facility availability when the sponsor and beneficiary are separately domiciled due to the sponsor’s move to a new permanent duty station or due to legal custody requirements.

(C) Written certification, in accordance with information requirements, formats, and procedures established by the Director, TRICARE Management Activity or designee that requested ECHO services or items cannot be obtained from public facilities because the services or items are not available and adequate, is a prerequisite for ECHO benefit payment for training, rehabilitation, special education, assistive technology, and institutional care in private nonprofit, public, and state institutions and facilities, and if appropriate, transportation to and from such institutions and facilities.

(1) An administrator or designee of a public facility may make such certification for a beneficiary residing within the service area of that public facility.

(2) The Director, TRICARE Management Activity or designee may determine, on a case-by-case basis, that apparent public facility availability for a requested type of service or item cannot be substantiated for a specific beneficiary’s request for ECHO benefits and therefore is not available.

(j) Implementing instructions. The Director, TRICARE Management Activity or designee shall issue TRICARE policies, instructions, procedures, guidelines, standards, and criteria as may be necessary to implement the intent of this section.

§ 199.6 TRICARE—authorized providers.

(e) Extended Care Health Option Providers—

(1) General. * * * *

(ii) A Program for Persons with Disabilities (PPPWD) provider with TRICARE-authorized status on the effective date for the Extended Care Health Option (ECHO) Program shall be deemed to be a TRICARE-authorized provider until the expiration of all outstanding PFPWD benefit authorizations for services or items being rendered by the provider.

(ii) ECHO inpatient care provider. A provider of residential institutional care, which is otherwise an ECHO benefit shall be:

(A) A not-for-profit entity or a public facility, or

(B) Located within a state; and

(C) Be certified as eligible for Medicaid payment in accordance with a state plan for medical assistance under Title XIX of the Social Security Act (Medicaid) as a Medicaid Nursing Facility, or Intermediate Care Facility for the Mentally Retarded, or be a TRICARE-authorized institutional provider as defined in paragraph (b) of this section, or be approved by a state educational agency as a training institution.

(iii) ECHO outpatient provider. A provider of ECHO outpatient, ambulatory, or in-home services shall be:

(A) A TRICARE-authorized provider of services as defined in this section; or

(B) An individual, corporation, foundation, or public entity that predominantly renders services of a type uniquely allowable as an ECHO benefit and not otherwise allowable as a benefit of section 199.4, that meets all applicable licensing or other regulatory requirements of the state, county, municipality, or other political jurisdiction in which the ECHO service is rendered.

(iii) ECHO vendor. A provider of an allowable ECHO item, such as supplies or equipment, shall be deemed to be a TRICARE-authorized vendor for the provision of the specific item, supply or equipment when the vendor supplies such information as the Director, TRICARE Management Activity or designee determines necessary to adjudicate a specific claim.

(3) ECHO provider exclusion or suspension. A provider of ECHO services or items may be excluded or suspended for a pattern of discrimination on the basis of disability. Such exclusion or suspension shall be accomplished according to the provisions of section 199.9.
beneficiary) does not have the option of waiving the full use of public facilities which are determined by the Director, TRICARE Management Activity or designee to be available and adequate to meet a disability related need for which an ECHO benefit was requested. Benefits eligible for payment under a state plan for medical assistance under Title XIX of the Social Security Act (Medicaid) are never considered to be available in the adjudication of ECHO benefits.


L.M. Bynum,
Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 03–19822 Filed 8–5–03; 8:45 am]

BILLING CODE 5001–08–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Chapter I
[OPP–2003–0132; FRL–7322–3]

RIN: 2070–AD57
Human Testing; Advance Notice of Proposed Rulemaking; Reopening of a Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Advance notice of proposed rulemaking; reopening of comment period.

SUMMARY: On May 7, 2003, EPA announced the availability for comment of an advance notice of proposed rulemaking (ANPR) discussing EPA’s plan to conduct rulemaking about criteria and standards EPA would apply in deciding the extent to which it will consider or rely on various types of research with human subjects to support its actions. The Agency received a request to extend the comment period. EPA is hereby reopening the comment period, which ended on August 5, 2003. The new comment period will end August 20, 2003.

DATES: Comments, identified by the docket ID number OPP–2003–0132, must be received on or before August 20, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I.C. of the SUPPLEMENTARY INFORMATION of the May 7, 2003 Federal Register document.

FOR FURTHER INFORMATION CONTACT: William L. Jordan, Mail code 7501C, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–1049; fax number: (703) 308–4776; e-mail address: jordan.william@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of particular interest to those who conduct testing of substances regulated by EPA. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any 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 Copies of this Document and Other Related Information?

1. Docket. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0132. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. Electronic access. You may access this Federal Register document electronically through the EPA Internet under the “Federal Register” listings at http://www.epa.gov/fedrgstr/.

An electronic version of the public docket is available through EPA’s electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select “search,” then key in the appropriate docket ID number.

C. How and to Whom Do I Submit Comments?

To submit comments, or access the official public docket, please follow the detailed instructions as provided in Unit I.C. of the SUPPLEMENTARY INFORMATION of the May 7, 2003 Federal Register document. If you have questions, consult the person listed under FOR FURTHER INFORMATION CONTACT.

II. What Action is EPA taking?

This document reopens the public comment period established in the Federal Register of May 7, 2003 (68 FR 24410) (FRL–7322–8). In that document, EPA sought comment on its plan to conduct rulemaking about criteria and standards the Agency would apply in deciding the extent to which it will consider or rely on various types of research with human subjects to support its actions. The Agency received a request to extend the comment period. EPA is hereby reopening the comment period, which ended on August 5, 2003. The new comment period will end August 20, 2003. The public is strongly encouraged to submit comments as early as possible so that EPA may make them available for consideration by a committee of the National Academy of Sciences, which is preparing a report for EPA on these issues.

III. What is the Agency’s Authority for Taking this Action?

Section 25(a) of FIFRA gives the Administrator authority to “prescribe regulations to carry out the purposes of [FIFRA].” Such a rule would implement EPA’s authority to require data in support of registration of pesticides (see, for example, FIFRA sections 3(c)(1)(F) and 3(c)(2)(B)) and to interpret the provision making it unlawful for any person “to use any pesticide in tests on human beings unless such human beings (i) are fully informed of the nature and purposes of the test and of any physical and mental health consequences which are reasonably foreseeable therefrom, and (ii) freely volunteer to participate in the test.” (FIFRA section 12(a)(2)(P)). In addition, section 408(e)(1)(C) of the FFDCA authorizes the Administrator to issue a regulation establishing “general procedures and requirements to implement this section.”