

regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
“De Novo Classification Process (Evaluation of Automatic Class III Designation)”.	De Novo classification process	0910–0844
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
“Medical Device Accessories—Describing Accessories and Classification Pathways for New Accessory Types”.	Medical Device Accessories	0910–0823

Dated: August 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17731 Filed 8–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–131186–17]

RIN 1545–BO05

Proposed Removal of Temporary Regulations on a Partner’s Share of a Partnership Liability for Disguised Sale Purposes; Hearing Cancellation

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Cancellation of notice of public hearing on proposed rulemaking.

SUMMARY: This document cancels a public hearing on proposed regulations concerning how partnership liabilities are allocated for disguised sale purposes.

DATES: The public hearing, originally scheduled for August 21, 2018 at 10:00 a.m. is cancelled.

FOR FURTHER INFORMATION CONTACT: Regina Johnson of the Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration) at (202) 317–6901 (not a toll-free number).

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking and notice of public hearing that appeared in the **Federal Register** on Tuesday, June 19, 2018 (83 FR 28397) announced that a public hearing was scheduled for August 21, 2018 at 10:00 a.m. in the IRS Auditorium, Internal Revenue Service Building, 1111 Constitution Avenue NW, Washington, DC. The subject of the public hearing is under section 707 of the Internal Revenue Code.

The public comment period for these regulations expired on July 19, 2018. The notice of proposed rulemaking and notice of hearing instructed those interested in testifying at the public hearing to submit a request to speak and an outline of the topics to be discussed. The outline of topics to be discussed was due by August 3, 2018. As of August 3, 2018, no one has requested to speak. Therefore, the public hearing scheduled for August 21, 2018 at 10:00 a.m. is cancelled.

Martin V. Franks,

Branch Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2018–17792 Filed 8–16–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[Docket ID DOD–2016–HA–0112]

RIN 0720–AB69

TRICARE; Extended Care Health Option (ECHO) Respite Care

AGENCY: Office of the Secretary, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: This proposed rule requests public comment on a proposed revision to the TRICARE Extended Care Health Option (ECHO) respite care benefit. Under the current program, TRICARE beneficiaries enrolled in ECHO are eligible for 16 hours of respite care per month in any month during which the beneficiary receives another ECHO authorized benefit (other than the ECHC benefit). This proposed rule seeks to eliminate the concurrent ECHO benefit requirement and allow beneficiaries enrolled in ECHO to receive a maximum of 16 hours of respite care per month,

regardless of whether another ECHO benefit is received in the same month.

DATES: Written comments received at the address indicated below by October 16, 2018 will be accepted.

ADDRESSES: You may submit comments, identified by docket number or Regulatory Information Number (RIN) and title, by either of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail:* Department of Defense, Office of the Deputy Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name and docket number or RIN for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Trish Reilly, Defense Health Agency, TRICARE Clinical Policy Division, telephone (619) 236–5332.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose of the Proposed Rule

This proposed rule seeks to amend the TRICARE ECHO program regulation to expand beneficiary access to ECHO respite care services. This proposed rule, if implemented, would eliminate the concurrent ECHO benefit requirement and allow beneficiaries enrolled in ECHO to receive a maximum of 16 hours of respite care per month, regardless of whether another ECHO benefit is received in the same month.

This regulation is proposed under the authority of 5 U.S.C. 301 which allows

the Secretary of Defense to prescribe regulations for the government of DoD and 10 U.S.C. 1079(d) and (e), which directs the Secretary of Defense to establish a program to provide extended benefits for eligible active duty dependents, which may include the provision of comprehensive health care services, including case management services, to assist in the reduction of the disabling effects of a qualifying condition of an eligible dependent. The Department is authorized to provide “respite care for the primary caregiver of the eligible dependent” as one of the specifically enumerated extended benefits under the ECHO program pursuant to 10 U.S.C. 1079(e)(6). The ECHO program has been implemented through regulation at 32 CFR 199.5.

B. Summary of the Major Provisions of the Proposed Rule

Per 32 CFR 199.5(c)(7), ECHO beneficiaries are eligible for a maximum of 16 hours of respite care per month in any month during which the beneficiary otherwise receives an ECHO benefit(s). This requirement for a concurrent ECHO benefit was originally implemented to ensure optimal medical management of the beneficiary’s ECHO-qualifying condition. TRICARE proposes to eliminate the requirement for a beneficiary to receive a concurrent ECHO benefit in order to qualify for respite care. This change will expand access to respite care services (as recommended by the Military Compensation and Retirement Modernization Commission (MCRMC)), allowing families to access those hours without receiving another ECHO benefit during the same month the respite care is received.

C. Expected Costs

The proposed rule is estimated to cost the Department of Defense \$5.7 million annually (based on FY17 data). If the proposed rule is implemented, it is anticipated that 2,924 ECHO beneficiaries will participate in the respite care program at an average cost of \$1,937 per beneficiary (this number does not include homebound beneficiaries who receive respite care under the ECHO Home Health Care (EHHC) program). These beneficiaries are already in ECHO and, therefore, have completed all registration requirements. This expansion of the benefit requires nothing additional from the beneficiaries and will not result in an increased burden to the public. Currently, beneficiaries may not access ECHO respite care services if they are not utilizing another ECHO benefit during the same month, and this

rulemaking action will eliminate this barrier to care.

II. Discussion of the Proposed Rule

A. Background

Military families face unique challenges in caring for family members with special medical or educational needs that are complicated by frequent moves and repeated deployments. Support for these families involves a multi-faceted system coordinated across numerous functional areas within the Department of Defense and Military Services to include: The Military Health System (MHS); military personnel support services; housing programs; dependents’ education programs; child and youth services; morale, welfare, and recreation activities; and community support activities, among others.

The Exceptional Family Member Program (EFMP) is designed to identify active duty military family members with special medical and/or educational needs to ensure coordination of care and continuity of benefits throughout the military assignment and relocation process. EFMP provides additional support to these active duty military families to alleviate some of the challenges associated with frequent family relocations and deployments of their sponsoring service member as required by military duties. EFMP family support services have traditionally included respite care provided by certified day care providers in order to provide temporary relief to military family members who are responsible for the regular care of dependent family members with special needs. The Office of the Under Secretary of Defense for Personnel and Readiness published a proposed rule entitled “Exceptional Family Member Program (EFMP)” in the **Federal Register** (80 FR 76881–76889) on December 11, 2015, that provides additional details. The Assistant Secretary of Defense for Health Affairs is tasked with advising on the availability of specialized medical services to families with special needs in the Military Health System and ensuring there is a medical case management program to support eligible beneficiaries’ medical needs.

Active Duty families enrolled in EFMP may be eligible, based on qualifying conditions, for TRICARE Extended Health Care Option (ECHO) expanded benefits. ECHO is a supplemental program to the TRICARE Basic Program that provides eligible Active Duty Family Members extended benefits to include comprehensive health care services (including services necessary to maintain, or minimize or

prevent deterioration of function of the patient) and case management services with respect to the qualifying condition which include serious physical disabilities and extraordinary physical or psychological conditions as defined in 32 CFR 199.2. The purpose of ECHO is to provide an additional financial resource for an integrated set of services and supplies designed to assist in the reduction of the disabling effects of the beneficiary’s qualifying condition. The ECHO program provides coverage for medical, habilitative, and rehabilitative services and supplies not covered under the TRICARE Basic Program; durable medical equipment, including adaptation and maintenance; assistive technologies devices and training to use the devices; comprehensive home health care services (e.g., ventilator support, medication administration); and other services to support eligible family members.

The final rule implementing the ECHO Program (which was previously called the Program for Persons with Disabilities (PFPWD) from 1997–2004, and before that the Program for the Handicapped (PFTH) from origination in 1966–1997), amended the TRICARE regulations governing the PFPWD and was published in the **Federal Register** (69 FR 44947) on July 28, 2004.

ECHO-registered beneficiaries who are not receiving ECHO Home Health Care (EHHC) services currently are eligible to receive a maximum of 16 hours of respite care in any calendar month in which they also receive any other ECHO authorized benefit other than the EHHC benefit. Respite care consists of providing skilled and non-skilled health care services for the covered beneficiary such that in the absence of the primary caregiver, management of the beneficiary’s ECHO qualifying condition and safety are provided. In order to assure the quality of care for beneficiaries enrolled in ECHO, all ECHO respite care services must be provided by Medicare or Medicaid certified Home Health Agencies (HHAs) who have in effect at the time of services a valid agreement to participate in the TRICARE program. The ECHO respite care program (which provides health care services by a home health agency) should not be considered a substitute for EFMP respite care (which provides day care services by a certified day care provider), because not all EFMP family members qualify for ECHO or require specific health care services in the absence of the primary caregiver. The goal is to ensure that these families have access to the appropriate services to meet their specific needs while still ensuring

fiscally prudent expenditures of appropriated funds.

In addition to EFMP respite care and ECHO respite care, there is a third type of respite care, EHHC respite care. The EHHC benefit provides coverage of home health care services and respite care services for ECHO eligible beneficiaries who require more than intermittent or part-time home health services covered under the TRICARE Basic Program. This would include ventilator-dependent beneficiaries and others with extraordinary physical conditions. EHHC beneficiaries whose plan of care includes frequent interventions by the primary caregiver(s) (e.g., frequent suctioning, tube feeding, medication administration etc.) are eligible for respite services under EHHC in lieu of the ECHO general respite benefit. EHHC respite care may include a maximum of 8 hours per day, 5 days per week, by a TRICARE-authorized home health agency. The Department is not proposing any changes to the robust EHHC respite care benefit as part of this proposed rule, but includes a description of the program in order to clarify the full spectrum of respite care programs available to active duty military families with special needs.

B. Proposed Change to the ECHO Respite Care Benefit

The Department of Defense remains committed to supporting Service members and their family members with special needs. Together, the Office of Community Support for Military Families with Special Needs, the Services, and the MHS, are working to enhance and improve support for these families, including everything from complex medical management to non-clinical case management and family support services. The Department is also committed to eliminating unnecessary requirements that act as barriers to care. Consistent with these principles, the Department is proposing this specific amendment to the existing regulations governing the ECHO program.

The requirement to receive a concurrent ECHO benefit in order to be entitled to ECHO respite care was originally imposed as a medical management tool. We now conclude that this specific requirement is no longer necessary and may serve as an inappropriate barrier to receipt of respite services for some families. Even in those months where no other ECHO services are provided (where all needed care may already be covered under the Basic Program or under demonstration authority), there may still be some health care services rendered to the

beneficiary enrolled in ECHO by the primary caregiver for which respite care provided by a home health agency is warranted.

We note that the January 2015 Report of the MCRMC cited a need to improve support for military members with special needs dependents and made a number of recommendations. We have already implemented or are taking steps to implement several of their specific recommendations, including the recommendation to allow families to access ECHO respite care without receiving another ECHO benefit during the same month that respite care is received which is proposed in this rule. The Department is still studying some of the other recommendations that were made in order to identify and implement, as appropriate, ECHO enhancements that will be of greatest benefit to our beneficiaries. Finally, we believe some of the recommendations fall outside the purview of the ECHO program specifically, and the Military Health System in general, and are more appropriately directed to the Office of Community Support for Military Families with Special Needs, including the provision of respite care that does not involve health care services (i.e., EFMP respite).

We propose that elimination of the requirement for a simultaneous ECHO benefit will provide maximum flexibility to families without sacrificing the goal of ensuring the safe and effective management of the beneficiary's ECHO qualifying condition. First, we note that TRICARE beneficiaries with complex medical needs may receive case management services including medical management, disease management and chronic care coordination, under the TRICARE Basic Program, regardless of whether the beneficiary is an ECHO eligible beneficiary. As the TRICARE program has evolved over time, continuing to require an ECHO eligible beneficiary to receive a concurrent ECHO benefit as a medical management tool is no longer necessary. Based on our current program structure, beneficiaries should already be receiving medical management services and the receipt of any ECHO benefit, including ECHO respite care, provides an additional opportunity to ensure the safe and effective management of the beneficiary's qualifying condition. Furthermore, in accordance with 32 CFR 199.5(h)(3), all ECHO benefits, including ECHO respite care, require authorization prior to receipt of such benefits. Paragraph (i) discusses required documentation as a prerequisite to authorizing ECHO

benefits. As a practical matter, the home health agency providing the respite services must document the health care services needed by the ECHO beneficiary in the absence of the family caregiver and the schedule for the services during the provision of respite care in order to ensure an appropriately trained provider is sent and the beneficiary's needs are met. If this regulatory change is enacted, after public comment, additional details regarding required documentation to be provided to the Managed Care Support Contractor and home health agency for authorization of ECHO respite services will be published in the TRICARE Policy Manual available at <http://manuals.tricare.osd.mil>. We believe that this approach will provide greater flexibility and eliminate unnecessary barriers for families to access to ECHO respite care services while still ensuring the safe and effective medical management of the beneficiary's medical condition(s).

III. Regulatory Procedures

Executive Order 12866, "Regulatory Planning and Review" and Executive Order 13563, "Improving Regulation and Regulatory Review"

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. A regulatory impact analysis must be prepared for major rules with economically significant effects (\$100 million or more in any one year). This rulemaking is neither "economically significant" as measured by the \$100 million threshold, nor is it otherwise significant.

Executive Order 13771, "Reducing Regulation and Controlling Regulatory Costs"

This proposed rule is not expected to be an E.O. 13771 regulatory action because it is not significant under E.O. 12866.

Congressional Review Act, 5 U.S.C. 804(2)

Under the Congressional Review Act, a major rule may not take effect until at least 60 days after submission to Congress of a report regarding the rule.

A major rule is one that would have an annual effect on the economy of \$100 million or more or have certain other impacts. This proposed rule is not a major rule under the Congressional Review Act.

Public Law 96–354, “Regulatory Flexibility Act” (RFA), (Title 5, U.S.C., Sec. 601)

The Regulatory Flexibility Act requires that each Federal agency analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. This proposed rule is not an economically significant regulatory action, and it will not have a significant impact on a substantial number of small entities. Therefore, this rule is not subject to the requirements of the RFA.

Public Law 104–4, Sec. 202, “Unfunded Mandates Reform Act”

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$140 million. This final rule will not mandate any requirements for state, local, or tribal governments or the private sector.

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

This rule will not impose significant additional information collection requirements on the public under the Paperwork Reduction Act of 1995 (44 U.S.C. 3502–3511). Existing information collection requirements of the TRICARE and Medicare programs will be utilized. TRICARE ECHO respite care providers will be coding and filing claims in the same manner as they currently are with TRICARE.

Executive Order 13132, “Federalism”

This rule has been examined for its impact under E.O. 13132, and it does not contain policies that have federalism implications that would have substantial direct effects on the States, on the relationship between the national Government and the States, or on the distribution of powers and responsibilities among the various levels of Government. Therefore, consultation with State and local officials is not required.

List of Subjects in 32 CFR Part 199

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

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

PART 199—CIVILIAN HEALTH AND MEDICAL PROGRAM OF THE UNIFORMED SERVICES (CHAMPUS)

- 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. Revise § 199.5(c)(7) introductory text to read as follows:

§ 199.5 TRICARE Extended Care Health Option (ECHO).

* * * * *

(c) * * *

(7) *Respite care.* TRICARE beneficiaries enrolled in ECHO are eligible for a maximum of 16 hours of respite care per month. Respite care is defined in § 199.2. 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-sitting or child-care services for other members of the family. The benefit will not be cumulative, that is, any respite hours not used in one month will not be carried over or banked for use on another occasion.

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Dated: August 9, 2018.

Shelly E. Finke,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2018–17463 Filed 8–16–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2018–0577]

RIN 1625–AA08

Special Local Regulation; Choptank River, Talbot and Dorchester Counties, MD

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish special local regulations for certain navigable waters of the Choptank River. This action is necessary to provide for the safety of life on these

waters near Oxford, MD, from October 7, 2018, through October 15, 2018, during a sailboat regatta. This proposed rule would prohibit persons and vessels from being in the regulated area unless authorized by the Captain of the Port Maryland-National Capital Region or the Coast Guard Patrol Commander. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before September 17, 2018.

ADDRESSES: You may submit comments identified by docket number USCG–2018–0577 using the Federal eRulemaking Portal at <http://www.regulations.gov>. See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Mr. Ronald Houck, U.S. Coast Guard Sector Maryland-National Capital Region; telephone 410–576–2674, email Ronald.L.Houck@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
PATCOM Patrol Commander
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

On February 13, 2018, the Tred Avon Yacht Club of Oxford, MD, notified the Coast Guard through submission of a marine event application that it is planning to conduct a sailboat regatta from October 5, 2018, through October 15, 2018, the 2018 Star World Championship. Race activities on navigable waters are planned each afternoon of the regatta beginning on October 7th. The regatta consists of approximately 100 2-person, 23-foot long International Star Class sailboats. These vessels will operate along a designated and marked 2.5 nautical mile long course. The course is located on the Choptank River, in Talbot and Dorchester Counties, near Oxford, MD. Hazards from the sailboat regatta include participants operating within and adjacent to a designated navigation channel and interfering with vessels intending to operate within that channel, as well as injury to persons and damage to property that involve