

meets the hierarchy of reliable evidence as well as the evidence outlined above which meet the requirements for analytical validity, and clinical validity and utility. The definition of reliable evidence which will be used by the LJWG is defined in 32 CFR 199.2(b) and includes: “(i) Well-controlled trials of clinically meaningful endpoints, published in refereed medical literature, (ii) Published formal technology assessments, (iii) Published reports of national medical policy organization positions, (iv) Published national professional associations, and (v) Published reports of national expert opinion organizations.” The hierarchy of reliable evidence of proven medical effectiveness, established by (i) through (v) of this paragraph, is the order of the relative weight to be given to any particular source. With respect to clinical studies, only those reports and articles containing scientifically valid data and published in the refereed medical and scientific literature shall be considered as meeting the requirements of reliable evidence. Specifically not included in the meaning of reliable evidence are reports, articles, or statements by providers or groups of providers containing only abstracts, anecdotal evidence or personal professional opinions. Also not included in the meaning of reliable evidence is the fact that a provider or a number of providers have elected to adopt a drug, device, or medical treatment or procedure as their personal treatment or procedure of choice or standard of practice. By majority vote the LJWG would recommend approval or disapproval to the Director, TMA. Approved LDTs would be available for cost-sharing with TRICARE beneficiaries.

### C. Final Coverage Decisions

LDTs (evaluated under the demonstration project) determined by the LJWG to meet the TRICARE hierarchy of evidence for safety and effectiveness will be recommended to the Director, TMA for decision for acceptance for cost-sharing during the demonstration period. LDTs approved by the Director, TMA for cost-sharing will follow existing processes for inclusion as a TRICARE benefit. Additional information on payment methodologies will be included in the operational procedures for this Demonstration and will be published in the TRICARE Operations Manual found at <http://manuals.tricare.osd.mil/>.

### D. Implementation

The demonstration is effective 30 days after publication in the **Federal**

**Register** and will continue for a period of three years from the date of the original demonstration unless terminated earlier by the Director, TMA. LDTs approved by the Director, TMA during the demonstration period will become available for cost-sharing for qualified TRICARE beneficiaries during the demonstration period. Should the FDA issue final guidance on and or enforcement of the requirement for prior marketing approval, the Director TMA will terminate the demonstration and the DoD will ensure compliance with applicable federal law and regulations.

### E. Evaluation

An evaluation will be conducted during the third year of the demonstration period to determine how many TRICARE approved LDTs were provided to beneficiaries across all TRICARE Regions. The evaluation will also include a review of the LDT review and recommendation process. These results of the evaluation will provide a valuation of the potential improvement of the quality of healthcare services for beneficiaries who would not otherwise had access to these safe and effective tests. Based on the utilization results, a decision will be made to modify 32 CFR 199.4(g)(15)(i)(A) to remove the restriction for non-FDA approved devices and allow TRICARE cost-sharing of CMS approved LDTs determined to meet the TRICARE criteria for safety and effectiveness.

Dated: December 21, 2011.

**Aaron Siegel,**

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

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## DEPARTMENT OF DEFENSE

### Office of the Secretary

### TRICARE Prime Urgent Care Demonstration Project

**AGENCY:** Department of Defense.

**ACTION:** Notice of demonstration.

**SUMMARY:** This notice is to advise interested parties of a Military Health System (MHS) Demonstration project under the authority of title 10, U.S. Code, section 1092, entitled Department Of Defense TRICARE Prime Urgent Care Demonstration Project. The demonstration project is intended to test whether allowing four visits to an urgent care center without requiring a referral from the Primary Care Manager (PCM) will improve access to urgent care including minor illness or injury

for Active Duty Family Members enrolled in TRICARE Prime or TRICARE Prime Remote while reducing the overall costs of such care to the DoD. The Department currently has a demonstration to test this same provision for U.S. Coast Guard personnel. However, this demonstration is being conducted outside of the Coast Guard population in order to be able to evaluate the impact on ADFMs who tend to be a more mobile population than the Coast Guard members and their families. Current data indicates that the ADFMs frequently need urgent care while traveling to new duty stations for permanent orders or training and when traveling to temporary locations while a member is deployed. Under the demonstration, ADFMs who are enrolled in TRICARE Prime or TRICARE Prime Remote would be allowed to self-refer, without an authorization, to a TRICARE network provider such as an Urgent Care Clinic (UCC) or Convenience Center for up to four urgent care visits per year. No referral from their PCM or authorization by a Health Care Finder will be required and no Point of Service (POS) deductibles and cost shares shall apply to these four unmanaged visits. The ADFMs will be required to notify their PCM of any urgent/acute care visits to other than their PCM within 24 hours of the visit and schedule any follow-up treatment that might be indicated with their PCM. If more than the four (4) authorized urgent care visits are used, or if the beneficiary seeks care from a non TRICARE network or non TRICARE authorized provider, POS deductibles and cost shares as required by Title 32, Code of Federal Regulations, Section 199.17 (n)(3) may apply. Referral requirements for specialty care and inpatient authorizations will remain as currently required by MHS policy. At the conclusion of the demonstration, data will be analyzed to determine if use of this ability to seek urgent care without a referral is used more or less frequently by a more mobile population than a stable population in order to determine whether the overall costs to the government have decreased due to a reduced usage of emergency care facilities by this same population.

**DATES:** This demonstration will be effective 60 days from the date of this notice in the **Federal Register** for a period of thirty-six (36) months.

**ADDRESSES:** TRICARE Management Activity (TMA), Health Plan Operations, 5111 Leesburg Pike, Suite 810, Falls Church, VA 22041.

**FOR FURTHER INFORMATION CONTACT:** For questions pertaining to this

demonstration project, please contact Ms. Shane Pham at (703) 681-0039.

#### SUPPLEMENTARY INFORMATION:

##### a. Background

Access for acute episodic primary care continues to be in high demand by TRICARE Prime beneficiaries. The current regulations require that if a Prime beneficiary seeks care from a provider other than their Primary Care Manager (PCM), they must first obtain a referral. Otherwise, the care will be covered under the point-of-service option at greater out-of-pocket cost to the Prime beneficiary. This includes urgent care which TRICARE defines as medically necessary treatment for an illness or injury that would not result in further disability or death if not treated immediately but that requires professional attention within 24 hours. On the other hand, emergency care defined as a medical, maternity or psychiatric condition that would lead a "prudent layperson" (someone with average knowledge of health and medicine) to believe that a serious medical condition existed, or the absence of medical attention would result in a threat to his or her life, limb or sight and requires immediate medical treatment or which has painful symptoms requiring immediate attention to relieve suffering, does not require an authorization. Often when a Prime beneficiary needs urgent care after hours or when the PCM does not have available appointments, the Prime beneficiary will seek care from civilian sources such as emergency rooms (ER). While many Prime beneficiaries pay no out-of-pocket costs for ER services, the average cost for an ER visit is much higher than an urgent care visit. In many cases, using the ER is not necessary, and a patient's condition can be treated through urgent care. Additionally for our ADFMs in transition, the Department has seen a higher incident of ER usage by this population. It appears that the difficulty in contacting the PMS while traveling or in a new location may result in the beneficiary's higher hospital ER services for care that might be suitably be obtained at an urgent care center.

In 2010, we examined the degree to which ADFMs used ERs for the top 14 medical conditions for which they sought care. We found that ADFM military treatment facility enrollees received about 7 percent of their visits from ERs while civilian prime enrollees received 4 percent of their care from emergency rooms. Because many of the top 14 conditions are acute in nature,

we consider the ADFMs' use of ERs to be too high.

##### b. Implementation

This demonstration will be effective 60 days from the date of this notice in the **Federal Register** for a period of thirty-six (36) months.

##### c. Evaluation

The results of this Demonstration will allow a focused study of the impact of this process on: (1) The reduction of ER utilization and resulting costs, (2) assessment of the availability and accessibility of less expensive acute care services such as UCCs, (3) reduction of administrative processes. The evaluation/analysis of the demonstration would use Fiscal Year 2011 as the base line with follow-up data analysis conducted at each 6-month interval throughout the 36 month period to monitor of ER and TRICARE authorized UCC utilization workload and cost (claims data). Success of the demonstration would be determined by consistent shifts in health care utilization from ERs to a TRICARE authorized UCCs by 15-20%. A less than 5% shift in utilization from the ER to a TRICARE authorized UCCs would be considered insignificant.

Dated: December 21, 2011.

**Aaron Siegel,**

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

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## DEPARTMENT OF DEFENSE

### Department of the Army

[Docket ID USA-2007-0014]

#### Proposed Collection; Comment Request

**AGENCY:** Army Corps of Engineers, Engineer Research and Development Center/Construction Engineering Research Laboratory (ERDC/CERL), DoD.

**ACTION:** Notice.

In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995*, the U.S. Army Corps of Engineers—ERDC/CERL announces a proposed new public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the

agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

**DATES:** Consideration will be given to all comments received by February 27, 2012.

**ADDRESSES:** You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301-1160.

*Instructions:* All submissions received must include the agency name, docket number and title 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:** To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to: Larry Pater, Ph.D., P.E., Program/Project Manager, Noise R&D, U.S. Army Engineer Research and Development Center (ERDC), Construction Engineering Research Laboratory (CERL), 2902 Farber Drive, Champaign, IL 61821.

*Title and OMB Number:* Assessing Human Response to Military Impulse Noise; OMB Control Number 0710-0015.

*Needs and Uses:* The information collection requirement is necessary to obtain information on the relationship between community annoyance and complaints, related to impulsive noise from military installations. The information will provide the necessary tools and guidance for military installations to effectively balance the need for training operations at military installations with public safety and welfare. Participation by respondents is strictly voluntary, and the surveys are intended solely (or primarily) to ensure that facilities can adequately respond to any concerns the public may have.

*Affected Public:* Individuals and households.