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DEPARTMENT OF DEFENSE

Office of the Secretary

TRICARE Over-the-Counter Drug Demonstration Project

AGENCY: Office of the Secretary, DoD.

ACTION: Notice of modification to the TRICARE Over-the-Counter Drug Demonstration Project.

SUMMARY: This notice is to advise interested parties of a modification of the demonstration project in which the Department of Defense (DoD) evaluates allowing selected over-the-counter (OTC) drugs to be included on the TRICARE uniform formulary. The Department has been engaged in a demonstration project relating to Over the Counter (OTC) drugs since 2009. This demonstration project has been evaluating the costs/benefits and beneficiary satisfaction of providing selected OTC drugs under the pharmacy benefits program when the selected OTC drugs are determined to be clinically effective and when recommended by the Pharmacy and Therapeutics Committed and approved by the Assistant Secretary of Defense (Health Affairs). Under the current demonstration, the eligible drugs have been limited to those drugs for which the beneficiary has a prescription for a drug in the same class and for which a clinically effective OTC drug is also available. The current demonstration is scheduled to end in November 2014. In the National Defense Authorization Act for Fiscal Year 2013, Congress authorized the Department to provide Over the Counter (OTC) drugs to beneficiaries under regulations prescribed by the Secretary. Although the Department could now cease the demonstration and implement this new Congressional authority, it is now considering the viability of adding some drugs, such as the Plan B One-Step (levonorgestrel) which is an OTC product for all women of

child-bearing potential that does not require a prescription. It was decided that the most efficient method of testing this new criteria was by modification to the current demonstration.

DATES: This demonstration project will continue through until November 30, 2016 in order to provide adequate time to implement and evaluate the substantive changes allowing the DoD to provide drugs, such as the Plan B One-Step, that are in the class of drugs normally requiring a prescription but which the FDA has granted an exception to the prescription requirement.

FOR FURTHER INFORMATION CONTACT: Captain Nita Sood, TRICARE Management Activity, Pharmaceutical Operations Directorate, telephone (703) 681-2890.

SUPPLEMENTARY INFORMATION:

Background

Section 705 of the John Warner National Defense Authorization Act for 2007 directed the Secretary to conduct a demonstration project under 10 United States Code (U.S.C.) 1092 to allow certain over-the-counter (OTC) medications to be included on the uniform formulary under 10 U.S.C. 1074g. On June 15, 2007, the Department of Defense published a notice in the Federal Register (FR) (72 FR 33208-33210) implementing the demonstration project until the implementation of the combined TRICARE mail and retail contract (TPharm) which was on November 4, 2009. In order to more thoroughly evaluate the clinical and cost effectiveness of OTC drugs as well as beneficiary satisfaction with the project, the Department published a notice in the FR (74 FR 66626-66627) on December 16, 2009 that extended the demonstration project through November 4, 2012. The Department determined that continuation of the demonstration project for an additional 2 years was necessary to provide the Secretary with sufficient information to fully evaluate the project. The demonstration project continues to be authorized by 10 U.S.C. 1092. Section 702 of the National Defense Authorization Act for Fiscal Year 2013

authorized the Department to provide OTC pharmaceuticals under terms prescribed by the Secretary. This authorization would allow the Department to implement its current demonstration under its current terms. These terms have been to authorize the provision of OTC drugs when the beneficiary had been receiving prescription drugs in the same class and a clinically effective OTC was available. These drugs were treated as generic prescription medications, except that the need for a prescription and/or a copay were waived. The OTC drugs must have been recommended by the DoD Pharmacy and Therapeutics Committee and approved by the Assistant Secretary of Defense, (Health Affairs) prior to inclusion on the formulary.

On June 20, 2013, the Food and Drug Administration (FDA) announced the use of Plan B One-Step (levonorgestrel) emergency contraceptive as an over-the-counter product "for all women of child-bearing potential without age or point-of-sale restrictions." Contraceptive drugs are a type of drug which normally would require a prescription prior to dispensing, however the FDA made an exception for this particular drug. The statute governing the Department's pharmacy program, 10 U.S.C. 1074g, requires the Department to make available to its beneficiaries all prescription drugs approved by the FDA. The current issue for the Department regarding this drug, and any drugs for which the FDA might issue similar exceptions and mandates, is to determine how best to implement this requirement in our regulations. The modifications to the current demonstration are designed to help the Department determine whether these drugs can be treated in the same manner as the other OTC drugs which moved from prescription to non-prescription status.

Modification of the Demonstration Project:

(1) Inclusion of the Over-the-Counter Plan B One-Step Emergency Contraceptive (levonorgestrel).

(2) OTC availability of Plan B One-Step Emergency Contraceptive (levonorgestrel) through the demonstration project will be at retail dispensing venue. Eligibility includes all active duty service women and female beneficiaries of child-bearing potential, without age restrictions. All military treatment facility (MTF) pharmacies carry OTC Plan B One-Step, and provide it to all active duty service women and female beneficiaries of child-bearing potential, without age restrictions, at no cost. The OTC Plan B One-Step Emergency Contraceptive (levonorgestrel) will not be available through the demonstration project at the TRICARE mail order program because it would be clinically inappropriate to take OTC Plan B One-Step Emergency Contraceptive (levonorgestrel) after 72 hours (3 days).

(3) Eligible beneficiaries will not require a written prescription for Plan B One-Step Emergency Contraceptive (levonorgestrel). The beneficiary simply presents to the retail pharmacy and which will process the request identically to all other pharmacy claims.

(4) Cost sharing requirements. The cost sharing will be zero copay.

(5) Period of demonstration. The demonstration project will continue until November 30, 2016.

Dated: September 16, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

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