SEC. 708. INCLUSION OF CERTAIN OVER-THE-COUNTER DRUGS IN TRICARE UNIFORM FORMULARY.

(a) INCLUSION.—Subsection (a)(2) of section 1074g of title 10, United States Code, is amended—

(1) in subparagraph (D), by striking "No pharmaceutical agent may be excluded" and inserting "Except as provided in subparagraph (F), no pharmaceutical agent may be excluded"; and

(2) by adding at the end the following new subparagraph:

"(F)(i) The Secretary may implement procedures to place selected over-the-counter drugs on the uniform formulary and to make such drugs available to eligible covered beneficiaries. An over-the-counter drug may be included on the uniform formulary only if the Pharmacy and Therapeutics Committee established under subsection (b) finds that the over-the-counter drug is cost-effective and clinically effective. If the Pharmacy and Therapeutics Committee recommends an over-the-counter drug for inclusion on the uniform formulary, the drug shall be considered to be in the same therapeutic class of pharmaceutical agents, as determined by the Committee, as similar prescription drugs.

"(ii) Regulations prescribed by the Secretary to carry out clause (i) shall include the following with respect to over-the-counter drugs included on the uniform formulary:

"(I) A determination of the means and conditions under paragraphs (5) and (6) of this section through which over-the-counter drugs will be available to eligible covered beneficiaries and the amount of cost share that such beneficiaries will be required to pay for over-the-counter drugs, except that no such cost share may be required for a member of a uniformed service on active duty.

"(II) Any terms and conditions for the dispensing of over-the-counter drugs to eligible covered beneficiaries.".

(b) DEFINITIONS.—Subsection (g) of such section is amended by adding at the end the following new paragraphs:

"(3) The term 'over-the-counter drug' means a drug that is not subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)).

"(4) The term 'prescription drug' means a drug that is subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)).".

(c) TECHNICAL AMENDMENTS.—

(1) CROSS-REFERENCE AMENDMENTS.—Subsections (a)(6)(A) and (b)(1) of such section are amended by striking "subsection (g)" and inserting "subsection (h)".

(2) REPEAL OF OBSOLETE PROVISIONS.—

(A) Subsection (a)(2)(D) of such section is amended by striking the last sentence.

(B) Subsection (b)(2) of such section is amended by striking "Not later than" and all the follows through "such 90-day period, the committee" and inserting "The committee".

(C) Subsection (d)(2) of such section is amended—

(i) by striking "Effective not later than April 5, 2000, the Secretary" and inserting "The Secretary"; and

(ii) by striking "the current managed care support contracts" and inserting "the managed care support contracts current as of October 5, 1999,".

Section-by-Section Analysis

This proposal would authorize the Department of Defense (DoD) to place selected over-the-counter (OTC) drugs on the uniform formulary and make such drugs available to eligible covered beneficiaries. Such drugs could be included on the uniform formulary if the DoD Pharmacy and Therapeutics Committee finds that the OTC drug is cost-effective, clinically effective, and in the same therapeutic class of pharmaceutical agents as a prescription drug.

This proposal builds directly from DoD's experience with covering selected OTC drugs under demonstration authority. Under this continuing demonstration, which is national in scope, mail-order coverage of selected OTC drugs began in May 2007 and retail coverage began in October 2007. . One difference between the demonstration and this proposal is that under the demonstration, no co-pay has been required for the covered OTC drugs. This proposal allows the Secretary to establish the amount of the co-pay, including a zero co-pay, if appropriate. This proposal assumes that OTC drugs will be subject to the same co-pay as generic drugs since they will be considered for inclusion on the formulary with other drugs in the same therapeutic class of pharmaceutical agents.

The OTC drugs identified for coverage by the DoD Pharmacy and Therapeutics Committee are expected to have a lower net cost to DoD than the likely mix of legacy brand and/or generic drugs that would otherwise be dispensed in that drug class. The basic criteria regarding cost-effectiveness in this context means that DoD would only approve an OTC drug for inclusion under this proposal if it expected DoD to save money relative to the alternative, legacy drugs that would otherwise be consumed. This cost-effectiveness standard would be reinforced by the requirement for a prescription even for the OTC drug and by the $5 co-pay ($0 co-pay through the TRICARE Mail Order Pharmacy (TMOP)).

Budget Implications: The savings associated with this proposal are reflected in the following table:

SAVINGS WITH $5.00 CO-PAY ($0 CO-PAY for TMOP)($ MILLIONS)								
	FY 2013	**FY 2014**	**FY 2015**	**FY 2016**	**FY 2017**	**Appropriation**	**Budget Activity**	**Dash-1 Line Item**
DHP	($3.41)	($3.44)	($3.47)	($3.49)	($3.51)	DHP O&M	BA 01	010
MERCHF	($3.496)	($3.94)	($3.90)	($3.85)	($3.79)	MERCHF O&M	BA 01	010
Total	($7.37)	($7.38)	($7.37)	($7.35)	($7.30)	-		

Cost Methodology: To project this analysis of the current OTC demonstration experience to the five-year period from fiscal year (FY) 2013 through FY 2017, and to reflect DoD's plan under this legislation to charge a $5 OTC co-pay (excluding active duty Service members), the following adjustments were made:

1) $5 co-pay impacts: Drawing on the health economics literature, estimated that the $5 co-

pay would cause a 12.5 percent drop in OTC utilization relative to the utilization that would occur with no co-pay. For the remaining OTC utilization, we lowered the government cost per prescription for non-active duty prescriptions to account for the $5 co-pay.

2) Assumed an underlying utilization trend of 3.5 percent per year.

3) Assumed annual price inflation of 3.5 percent for the OTC drugs. For the legacy drugs, assumed no net price inflation over the forecast period on the assumption that manufacturers would forego price increases on the legacy drugs given the competition from the OTC drugs. All else equal, this differential in the price inflation assumptions between OTC and legacy drugs causes a very slight reduction in the savings over time.

4) Assumed annual administrative costs of approximately $250,000 per year for the OTC program (e.g., to educate beneficiaries, physicians and network pharmacies, to respond to OTC-related phone calls, etc.).

Changes to Existing Law: This proposal would make the following changes to section 1074g of title 10, United States Code:

§ 1074g. Pharmacy benefits program

(a) PHARMACY BENEFITS.—(1) The Secretary of Defense, after consulting with the other administering Secretaries, shall establish an effective, efficient, integrated pharmacy benefits program under this chapter (hereinafter in this section referred to as the "pharmacy benefits program").

(2)(A) The pharmacy benefits program shall include a uniform formulary of pharmaceutical agents, which shall assure the availability of pharmaceutical agents in the complete range of therapeutic classes. The selection for inclusion on the uniform formulary of particular pharmaceutical agents in each therapeutic class shall be based on the relative clinical and cost effectiveness of the agents in such class.

(B) In considering the relative clinical effectiveness of agents under subparagraph (A), the Secretary shall presume inclusion in a therapeutic class of a pharmaceutical agent, unless the Pharmacy and Therapeutics Committee established under subsection (b) finds that a pharmaceutical agent does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome over the other drugs included on the uniform formulary.

(C) In considering the relative cost effectiveness of agents under subparagraph (A), the Secretary shall rely on the evaluation by the Pharmacy and Therapeutics Committee of the costs of agents in a therapeutic class in relation to the safety, effectiveness, and clinical outcomes of such agents.

(D) The Secretary shall establish procedures for the selection of particular pharmaceutical agents for the uniform formulary. Such procedures shall be established so as best to accomplish, in the judgment of the Secretary, the objectives set forth in paragraph (1). ~~No~~ Except as provided in subparagraph (F), no pharmaceutical agent may be excluded from the uniform formulary except upon the recommendation of the Pharmacy and Therapeutics Committee. ~~The Secretary shall begin to implement the uniform formulary not later than October 1, 2000.~~

(E) Pharmaceutical agents included on the uniform formulary shall be available to eligible covered beneficiaries through—

(i) facilities of the uniformed services, consistent with the scope of health care services offered in such facilities and additional determinations by the Pharmacy and Therapeutics Committee of the relative clinical and cost effectiveness of the agents;

(ii) retail pharmacies designated or eligible under the TRICARE program or the Civilian Health and Medical Program of the Uniformed Services to provide pharmaceutical agents to covered beneficiaries; or

(iii) the national mail-order pharmacy program.

(F)(i) The Secretary may implement procedures to place selected over-the-counter drugs on the uniform formulary and to make such drugs available to eligible covered beneficiaries. An over-the-counter drug may be included on the uniform formulary only if the Pharmacy and Therapeutics Committee established under subsection (b) finds that the over-the-counter drug is cost-effective and clinically effective. If the Pharmacy and Therapeutics Committee recommends an over-the-counter drug for inclusion on the uniform formulary, the drug shall be considered to be in the same therapeutic class of pharmaceutical agents, as determined by the Committee, as similar prescription drugs.

(ii) Regulations prescribed by the Secretary to carry out subparagraph (F)(i) shall include the following with respect to over-the-counter drugs included on the uniform formulary:

(I) A determination of the means and conditions under paragraphs (5) and (6) of this section through which over-the-counter drugs will be available to eligible covered beneficiaries and the amount of cost share that such beneficiaries will be required to pay for over-the-counter drugs, except that no such cost share may be required for a member of a uniformed service on active duty.

(II) Any terms and conditions for the dispensing of over-the-counter drugs to eligible covered beneficiaries.

(3) * * *

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(5) The pharmacy benefits program shall assure the availability to eligible covered beneficiaries of pharmaceutical agents not included on the uniform formulary. Such pharmaceutical agents shall be available through at least one of the means described in paragraph (2)(E) under terms and conditions that may include cost sharing by the eligible covered beneficiary in addition to any such cost sharing applicable to agents on the uniform formulary.

(6)(A) The Secretary, in the regulations prescribed under subsection ~~(g)~~ (h), may establish cost sharing requirements (which may be established as a percentage or fixed dollar amount) under the pharmacy benefits program for generic, formulary, and nonformulary agents. For nonformulary agents, cost sharing shall be consistent with common industry practice and not in excess of amounts generally comparable to 20 percent for beneficiaries covered by section 1079 of this title or 25 percent for beneficiaries covered by section 1086 of this title.

(B) For a medicare-eligible beneficiary, the cost-sharing requirements may not be in excess of the cost-sharing requirements applicable to all other beneficiaries covered by section 1086 of this title. For purposes of the preceding sentence, a medicare-eligible beneficiary is a beneficiary eligible for health benefits under section 1086 of this title pursuant to subsection (d)(2) of such section.

(7) The Secretary shall establish procedures for eligible covered beneficiaries to receive pharmaceutical agents that are not included on the uniform formulary but that are considered to be clinically necessary. Such procedures shall include peer review procedures under which the Secretary may determine that there is a clinical justification for the use of a pharmaceutical agent that is not on the uniform formulary, in which case the pharmaceutical agent shall be provided under the same terms and conditions as an agent on the uniform formulary. Such procedures shall also include an expeditious appeals process for an eligible covered beneficiary, or a network or uniformed provider on behalf of the beneficiary, to establish clinical justification for the use of a pharmaceutical agent that is not on the uniform formulary.

(8) In carrying out this subsection, the Secretary shall ensure that an eligible covered beneficiary may continue to receive coverage for any maintenance pharmaceutical that is not on the uniform formulary and that was prescribed for the beneficiary before October 5, 1999, and stabilized the medical condition of the beneficiary.

(b) ESTABLISHMENT OF COMMITTEE.—(1) The Secretary of Defense shall, in consultation with the Secretaries of the military departments, establish a Pharmacy and Therapeutics Committee for the purpose of developing the uniform formulary of pharmaceutical agents required by subsection (a), reviewing such formulary on a periodic basis, and making additional recommendations regarding the formulary as the committee determines necessary and appropriate. The committee shall include representatives of pharmacies of the uniformed services facilities and representatives of providers in facilities of the uniformed services. Committee members shall have expertise in treating the medical needs of the populations served through such entities and in the range of pharmaceutical and biological medicines available for treating such populations. The committee shall function under procedures established by the Secretary under the regulations prescribed under subsection ~~(g)~~(h).

(2) ~~Not later than 90 days after the establishment of the Pharmacy and Therapeutics Committee by the Secretary, the committee shall convene to design a proposed uniform formulary for submission to the Secretary. After such 90-day period, the~~ The committee shall meet at least quarterly and shall, during meetings, consider for inclusion on the uniform formulary under the standards established in subsection (a) any drugs newly approved by the Food and Drug Administration.

(c) ADVISORY PANEL.—

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(d) PROCEDURES.—(1) In the operation of the pharmacy benefits program under subsection (a), the Secretary of Defense shall assure through management and new contractual arrangements that financial resources are aligned such that the cost of prescriptions is borne by the organization that is financially responsible for the health care of the eligible covered beneficiary.

(2) ~~Effective not later than April 5, 2000, the~~ The Secretary shall use a modification to the bid price adjustment methodology in the ~~current~~ managed care support contracts current as of October 5, 1999, to ensure equitable and timely reimbursement to the TRICARE managed care support contractors for pharmaceutical products delivered in the nonmilitary environments. The methodology shall take into account the "at-risk" nature of the contracts as well as managed care support contractor pharmacy costs attributable to changes to pharmacy service or formulary management at military medical treatment facilities, and other military activities and policies that

affect costs of pharmacy benefits provided through the Civilian Health and Medical Program of the Uniformed Services. The methodology shall also account for military treatment facility costs attributable to the delivery of pharmaceutical products in the military facility environment which were prescribed by a network provider.

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(g) DEFINITIONS.—In this section:

(1) The term "eligible covered beneficiary" means a covered beneficiary for whom eligibility to receive pharmacy benefits through the means described in subsection (a)(2)(E) is established under this chapter or another provision of law.

(2) The term "pharmaceutical agent" means drugs, biological products, and medical devices under the regulatory authority of the Food and Drug Administration.

(3) The term "over-the-counter drug" means a drug that is not subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)).

(4) The term "prescription drug" means a drug that is subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)).

(h) REGULATIONS.—The Secretary of Defense shall, after consultation with the other administering Secretaries, prescribe regulations to carry out this section.