

§ 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 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.

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(3) The pharmacy benefits program shall assure the availability of clinically appropriate pharmaceutical agents to members of the armed forces, including, where appropriate, agents not included on the uniform formulary described in paragraph (2).

(4) The pharmacy benefits program may provide that prior authorization be required for certain pharmaceutical agents to assure that the use of such agents is clinically appropriate.

(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), 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

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shall function under procedures established by the Secretary under the regulations prescribed under subsection (g).

(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 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.—(1) Concurrent with the establishment of the Pharmacy and Therapeutics Committee under subsection (b), the Secretary shall establish a Uniform Formulary Beneficiary Advisory Panel to review and comment on the development of the uniform formulary. The Secretary shall consider the comments of the panel before implementing the uniform formulary or implementing changes to the uniform formulary.

(2) The Secretary shall determine the size and membership of the panel established under paragraph (1), which shall include members that represent—

(A) nongovernmental organizations and associations that represent the views and interests of a large number of eligible covered beneficiaries;

(B) contractors responsible for the TRICARE retail pharmacy program;

(C) contractors responsible for the national mail-order pharmacy program; and

(D) TRICARE network providers.

(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 Secretary shall use a modification to the bid price adjustment methodology in the current managed care support contracts 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.

(e) Pharmacy Data Transaction Service.—The Secretary of Defense shall implement the use of the Pharmacy Data Transaction Service in all fixed facilities of the uniformed services under the jurisdiction of the Secretary, in the TRICARE retail pharmacy program, and in the national mail-order pharmacy program.

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(f) 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.

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

NOTES

Source

(Added Pub. L. 106-65, div. A, title VII, Sec. 701(a)(1), Oct. 5, 1999, 113 Stat. 677; amended Pub. L. 106-398, Sec. 1 [[div. A], title X, Sec. 1087(a)(5)], Oct. 30, 2000, 114 Stat. 1654, 1654A-290; Pub. L. 107-107, div. A, title X, Sec. 1048(c)(4), Dec. 28, 2001, 115 Stat. 1226; Pub. L. 108-136, div. A, title VII, Sec. 725, Nov. 24, 2003, 117 Stat. 1535; Pub. L. 108-375, div. A, title VII, Sec. 714, Oct. 28, 2004, 118 Stat. 1985.)

Amendments

2004—Subsec. (a)(2)(E)(i). Pub. L. 108-375, Sec. 714(b), inserted before semicolon at end “and additional determinations by the Pharmacy and Therapeutics Committee of the relative clinical and cost effectiveness of the agents”.

Subsec. (a)(6). Pub. L. 108-375, Sec. 714(a), designated existing provisions as subpar. (A) and added subpar. (B).

2003—Subsec. (b)(1). Pub. L. 108-136, Sec. 725(1), substituted “facilities and representatives of providers in facilities of the uniformed services” for “facilities, contractors responsible for the TRICARE retail pharmacy program, contractors responsible for the national mail-order pharmacy program, providers in facilities of the uniformed services, and TRICARE network providers” in second sentence.

Subsec. (c)(2). Pub. L. 108-136, Sec. 725(2), substituted “represent—” for “represent nongovernmental”, inserted “(A) nongovernmental” before “organizations”, substituted “beneficiaries;” for “beneficiaries.”, and added subpars. (B) to (D).

2001—Subsec. (a)(8). Pub. L. 107-107 substituted “October 5, 1999,” for “the date of the enactment of this section”.

2000—Subsec. (a)(6). Pub. L. 106-398, Sec. 1 [[div. A], title X, Sec. 1087(a)(5)(A)], substituted “in the regulations prescribed” for “as part of the regulations established”.

Subsec. (a)(7). Pub. L. 106-398, Sec. 1 [[div. A], title X, Sec. 1087(a)(5)(B)], substituted “that are not included on the uniform formulary but that are” for “not included on the uniform formulary, but;”.

Subsec. (b)(1). Pub. L. 106-398, Sec. 1 [[div. A], title X, Sec. 1087(a)(5)(C)], substituted “prescribed under” for “required by” in last sentence.

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Subsec. (d)(2). Pub. L. 106-398, Sec. 1 [[div. A], title X, Sec. 1087(a)(5)(D)], substituted “Effective not later than April 5, 2000, the Secretary shall use” for “Not later than 6 months after the date of the enactment of this section, the Secretary shall utilize”.

Subsec. (e). Pub. L. 106-398, Sec. 1 [[div. A], title X, Sec. 1087(a)(5)(E)], substituted “The” for “Not later than April 1, 2000, the” and inserted “in” before “the TRICARE” and before “the national”.

Subsec. (f). Pub. L. 106-398, Sec. 1 [[div. A], title X, Sec. 1087(a)(5)(F)], substituted “In this section:” for “As used in this section—” in introductory provisions, “The term” for “the term” in pars. (1) and (2), and a period for “; and” at end of par. (1).

Subsec. (g). Pub. L. 106-398, Sec. 1 [[div. A], title X, Sec. 1087(a)(5)(G)], substituted “prescribe” for “promulgate”.

Termination Of Advisory Panels

Advisory panels established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a panel established by the President or an officer of the Federal Government, such panel is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a panel established by Congress, its duration is otherwise provided for by law. See sections 3(2) and 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 770, 776, set out in the Appendix to Title 5, Government Organization and Employees.

Demonstration Project On Coverage Of Selected Over-The-Counter Drugs Under The Pharmacy Benefits Program

Pub. L. 109-364, div. A, title VII, Sec. 705, Oct. 17, 2006, 120 Stat. 2280, provided that:

“(a) Requirement to Conduct Demonstration.—The Secretary of Defense shall conduct a demonstration project under section 1092 of title 10, United States Code, to allow particular over-the-counter drugs to be included on the uniform formulary under section 1074g of such title.

“(b) Elements of Demonstration Project.—

“(1) Inclusion of certain over-the-counter drugs.—(A) As part of the demonstration project, the Secretary shall modify uniform formulary specifications under section 1074g(a) of such title to include an over-the-counter drug (referred to in this section as an ‘OTC drug’) on the uniform formulary if the Pharmacy and Therapeutics Committee finds that the OTC drug is cost-effective and therapeutically equivalent to a prescription drug. If the Pharmacy and Therapeutics Committee makes such a finding, the OTC drug shall be considered to be in the same therapeutic class of pharmaceutical agents as the prescription drug.

“(B) An OTC drug shall be made available to a beneficiary through the demonstration project, but only if—

“(i) the beneficiary has a prescription for a drug requiring a prescription; and

“(ii) pursuant to subparagraph (A), the OTC drug—

“(I) is on the uniform formulary; and

“(II) has been determined to be therapeutically equivalent to the prescription drug.

“(2) Conduct through military facilities, retail pharmacies, or mail order program.—The Secretary shall conduct the demonstration project through at least two of the means described in subparagraph (E) of section 1074g(a)(2)(E) [sic] of such title through which OTC drugs are provided and may conduct the demonstration project throughout the entire pharmacy benefits program or at a limited number of sites. If the project is conducted at a limited number of sites, the number of sites shall be not less than five in each TRICARE region for each of the two means described in such subparagraph.

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“(3) Period of demonstration.—The Secretary shall provide for conducting the demonstration project for a period of time necessary to evaluate the feasibility and cost effectiveness of the demonstration. Such period shall be at least as long as the period covered by pharmacy contracts in existence on the date of the enactment of this Act [Oct. 17, 2006] (including any extensions of the contracts), or five years, whichever is shorter.

“(4) Implementation deadline.—Implementation of the demonstration project shall begin not later than May 1, 2007.

“(c) Evaluation of Demonstration Project.—The Secretary shall evaluate the demonstration project for the following:

“(1) The costs and benefits of providing OTC drugs under the pharmacy benefits program in each of the means chosen by the Secretary to conduct the demonstration project.

“(2) The clinical effectiveness of providing OTC drugs under the pharmacy benefits program.

“(3) Customer satisfaction with the demonstration project.

“(d) Report.—Not later than two years after implementation of the demonstration project begins, the Secretary shall submit to the Committees on Armed Services of the Senate and House of Representatives a report on the demonstration project. The report shall contain—

“(1) the evaluation required by subsection (c);

“(2) recommendations for improving the provision of OTC drugs under the pharmacy benefits program; and

“(3) recommendations on whether permanent authority should be provided to cover OTC drugs under the pharmacy benefits program.

“(e) Continuation of Demonstration Project.—If the Secretary recommends in the report under subsection (d) that permanent authority should be provided, the Secretary may continue the demonstration project for up to one year after submitting the report.

“(f) Definitions.—In this section:

“(1) The term ‘drug’ means a drug, including a biological product, within the meaning of section 1074g(f)(2) of title 10, United States Code.

“(2) The term ‘OTC drug’ has the meaning indicated for such term in subsection (b)(1)(A).

“(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.”

Interoperability Of Department Of Veterans Affairs And Department Of Defense Pharmacy Data Systems

Pub. L. 107-314, div. A, title VII, Sec. 724, Dec. 2, 2002, 116 Stat. 2598, provided that:

“(a) Interoperability.—The Secretary of Veterans Affairs and the Secretary of Defense shall seek to ensure that on or before October 1, 2004, the Department of Veterans Affairs pharmacy data system and the Department of Defense pharmacy data system (known as the ‘Pharmacy Data Transaction System’) are interoperable for both Department of Defense beneficiaries and Department of Veterans Affairs beneficiaries by achieving real-time interface, data exchange, and checking of prescription drug data of outpatients, and using national standards for the exchange of outpatient medication information.

“(b) Alternative Requirement.—If the interoperability specified in subsection (a) is not achieved by October 1, 2004, as determined jointly by the Secretary of Defense and the Secretary of Veterans Affairs, the Secretary of Veterans Affairs shall adopt the Department of Defense Pharmacy Data Transaction System for use by the Department of Veterans Affairs health care system. Such system shall be fully operational not later than October 1, 2005.

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“(c) Implementation Funding for Alternative Requirement.—The Secretary of Defense shall transfer to the Secretary of Veterans Affairs, or shall otherwise bear the cost of, an amount sufficient to cover three-fourths of the cost to the Department of Veterans Affairs for computer programming activities and relevant staff training expenses related to implementation of subsection (b). Such amount shall be determined in such manner as agreed to by the two Secretaries.”

Deadline For Establishment Of Committee

Pub. L. 106-65, div. A, title VII, Sec. 701(b), Oct. 5, 1999, 113 Stat. 680, directed the Secretary of Defense to establish the Pharmacy and Therapeutics Committee required by subsec. (b) of this section not later than 30 days after Oct. 5, 1999.

Reports Required

Pub. L. 106-65, div. A, title VII, Sec. 701(c), Oct. 5, 1999, 113 Stat. 680, directed the Secretary of Defense to submit reports to Congress, not later than Apr. 1 and Oct. 1 of fiscal years 2000 and 2001, on the implementation of the uniform formulary required under subsec. (a) of this section, the results of a survey conducted by the Secretary of prescribers for military medical treatment facilities and TRICARE contractors, the operation of the Pharmacy Data Transaction Service required by subsec. (e) of this section, and any other actions taken by the Secretary to improve management of the pharmacy benefits program under this section.

Study For Design Of Pharmacy Benefit For Certain Covered Beneficiaries

Pub. L. 106-65, div. A, title VII, Sec. 701(d), Oct. 5, 1999, 113 Stat. 680, required the Secretary of Defense to prepare and submit to Congress, by Apr. 15, 2001, a study on a design for a comprehensive pharmacy benefit for covered beneficiaries under chapter 55 of title 10, who are entitled to benefits under part A, and enrolled under part B, of title XVIII of the Social Security Act, and to provide an estimate of the costs of implementing and operating such design, prior to repeal by Pub. L. 107-107, div. A, title VII, Sec. 723, Dec. 28, 2001, 115 Stat. 1168.

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