

col execution and their role, with the support of medical personnel, in ensuring successful execution of the protocol.

SEC. 6. *Scope.* (a) This order applies to the consideration and Presidential approval of a waiver of informed consent under 10 U.S.C. 1107 and does not apply to other FDA regulations.

(b) This order is intended only to improve the internal management of the Federal Government. Nothing contained in this order shall create any right or benefit, substantive or procedural, enforceable by any party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

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### § 1107a. Emergency use products

(a) **WAIVER BY THE PRESIDENT.**—(1) In the case of the administration of a product authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act to members of the armed forces, the condition described in section 564(e)(1)(A)(ii)(III) of such Act and required under paragraph (1)(A) or (2)(A) of such section 564(e), designed to ensure that individuals are informed of an option to accept or refuse administration of a product, may be waived only by the President only if the President determines, in writing, that complying with such requirement is not in the interests of national security.

(2) The waiver authority provided in paragraph (1) shall not be construed to apply to any case other than a case in which an individual is required to be informed of an option to accept or refuse administration of a particular product by reason of a determination by the Secretary of Health and Human Services that emergency use of such product is authorized under section 564 of the Federal Food, Drug, and Cosmetic Act.

(b) **PROVISION OF INFORMATION.**—If the President, under subsection (a), waives the condition described in section 564(e)(1)(A)(ii)(III) of the Federal Food, Drug, and Cosmetic Act, and if the Secretary of Defense, in consultation with the Secretary of Health and Human Services, makes a determination that it is not feasible based on time limitations for the information described in section 564(e)(1)(A)(ii)(I) or (II) of such Act and required under paragraph (1)(A) or (2)(A) of such section 564(e), to be provided to a member of the armed forces prior to the administration of the product, such information shall be provided to such member of the armed forces (or next-of-kin in the case of the death of a member) to whom the product was administered as soon as possible, but not later than 30 days, after such administration. The authority provided for in this subsection may not be delegated. Information concerning the administration of the product shall be recorded in the medical record of the member.

(c) **APPLICABILITY OF OTHER PROVISIONS.**—In the case of an authorization by the Secretary of Health and Human Services under section 564(a)(1) of the Federal Food, Drug, and Cosmetic Act based on a determination by the Secretary of Defense under section 564(b)(1)(B) of such Act, subsections (a) through (f) of section 1107 shall not apply to the use of a product that is the subject of such authorization, within the scope of such authorization and while such authorization is effective.

(Added Pub. L. 108–136, div. A, title XVI, §1603(b)(1), Nov. 24, 2003, 117 Stat. 1689; amended Pub. L. 108–375, div. A, title VII, §726(b), Oct. 28, 2004, 118 Stat. 1992; Pub. L. 109–364, div. A, title X, §1071(a)(5), (g)(7), Oct. 17, 2006, 120 Stat. 2398, 2402; Pub. L. 115–91, div. A, title VII, §716, Dec. 12, 2017, 131 Stat. 1438; Pub. L. 115–92, §1(c), Dec. 12, 2017, 131 Stat. 2025.)

#### REFERENCES IN TEXT

Section 564 of the Federal Food, Drug, and Cosmetic Act, referred to in text, is classified to section 360bbb-3 of Title 21, Food and Drugs.

#### AMENDMENTS

2017—Subsec. (d). Pub. L. 115–92 struck out subsec. (d) which related to additional authority to reduce deaths and severity of injuries caused by agents of war.

Pub. L. 115–91 added subsec. (d).

2006—Subsec. (a). Pub. L. 109–364, §1071(g)(7), made technical correction to directory language of Pub. L. 108–375, §726(b)(1). See 2004 Amendment note below.

Pub. L. 109–364, §1071(a)(5), redesignated subpars. (A) and (B) as pars. (1) and (2), respectively, and, in par. (2), substituted “paragraph (1)” for “subparagraph (A)”.

2004—Subsec. (a). Pub. L. 108–375, §726(b)(1), as amended by Pub. L. 109–364, §1071(g)(7), inserted “(A)” after “PRESIDENT.—”.

Subsec. (a)(A). Pub. L. 108–375, §726(b)(2), struck out “is not feasible, is contrary to the best interests of the members affected, or” after “such requirement”.

Subsec. (a)(B). Pub. L. 108–375, §726(b)(3), added subpar. (B).

#### EFFECTIVE DATE OF 2017 AMENDMENT

Pub. L. 115–92, §1(c), Dec. 12, 2017, 131 Stat. 2025, provided that the amendment made by section 1(c) is effective as of the enactment of the National Defense Authorization Act for Fiscal Year 2018 [Pub. L. 115–91].

#### EFFECTIVE DATE OF 2006 AMENDMENT

Pub. L. 109–364, div. A, title X, §1071(g), Oct. 17, 2006, 120 Stat. 2402, provided that the amendment made by section 1071(g)(7) is effective as of Oct. 28, 2004, and as if included in Pub. L. 108–375 as enacted.

#### TERMINATION DATE

Pub. L. 108–136, div. A, title XVI, §1603(d), Nov. 24, 2003, 117 Stat. 1690, which provided that section 1603 of Pub. L. 108–136 (enacting this section and section 360bbb-3 of Title 21, Food and Drugs, and amending section 331 of Title 21) would not be in effect (and the law was to read as if that section had never been enacted) as of the date on which, following enactment of the Project Bioshield Act of 2003, the President submits to Congress a notification that the Project Bioshield Act of 2003 provides an effective emergency use authority with respect to members of the Armed Forces, was repealed by Pub. L. 108–276, §4(b), July 21, 2004, 118 Stat. 859. [The Project Bioshield Act of 2003 was not enacted.]

### § 1108. Health care coverage through Federal Employees Health Benefits program: demonstration project

(a) **FEHBP OPTION DEMONSTRATION.**—The Secretary of Defense, after consulting with the other administering Secretaries, shall enter into an agreement with the Office of Personnel Management to conduct a demonstration project (in this section referred to as the “demonstration project”) under which eligible beneficiaries described in subsection (b) and residing within one of the areas covered by the demonstration project may enroll in health benefits plans offered through the Federal Employees Health

Benefits program under chapter 89 of title 5. The number of eligible beneficiaries and family members of such beneficiaries under subsection (b)(2) who may be enrolled in health benefits plans during the enrollment period under subsection (d)(2) may not exceed 66,000.

(b) ELIGIBLE BENEFICIARIES; COVERAGE.—(1) An eligible beneficiary under this subsection is—

(A) a member or former member of the uniformed services described in section 1074(b) of this title who is entitled to hospital insurance benefits under part A of title XVIII of the Social Security Act (42 U.S.C. 1395c et seq.);

(B) an individual who is an unremarried former spouse of a member or former member described in section 1072(2)(F) or 1072(2)(G);

(C) an individual who is—

(i) a dependent of a deceased member or former member described in section 1076(b) or 1076(a)(2)(B) of this title or of a member who died while on active duty for a period of more than 30 days; and

(ii) a member of family as defined in section 8901(5) of title 5; or

(D) an individual who is—

(i) a dependent of a living member or former member described in section 1076(b)(1) of this title who is entitled to hospital insurance benefits under part A of title XVIII of the Social Security Act, regardless of the member's or former member's eligibility for such hospital insurance benefits; and

(ii) a member of family as defined in section 8901(5) of title 5.

(2) Eligible beneficiaries may enroll in a Federal Employees Health Benefit plan under chapter 89 of title 5 under this section for self-only coverage or for self and family coverage which includes any dependent of the member or former member who is a family member for purposes of such chapter.

(3) A person eligible for coverage under this subsection shall not be required to satisfy any eligibility criteria specified in chapter 89 of title 5 (except as provided in paragraph (1)(C) or (1)(D)) as a condition for enrollment in health benefits plans offered through the Federal Employees Health Benefits program under the demonstration project.

(4) For purposes of determining whether an individual is a member of family under paragraph (5) of section 8901 of title 5 for purposes of paragraph (1)(C) or (1)(D), a member or former member described in section 1076(b) or 1076(a)(2)(B) of this title shall be deemed to be an employee under such section.

(5) An eligible beneficiary who is eligible to enroll in the Federal Employees Health Benefits program as an employee under chapter 89 of title 5 is not eligible to enroll in a Federal Employees Health Benefits plan under this section.

(c) AREA OF DEMONSTRATION PROJECT.—The Secretary of Defense and the Director of the Office of Personnel Management shall jointly identify and select the geographic areas in which the demonstration project will be conducted. The Secretary and the Director shall establish at least six, but not more than ten, such demonstration areas. In establishing the areas, the Secretary and Director shall include—

(1) an area that includes the catchment area of one or more military medical treatment facilities;

(2) an area that is not located in the catchment area of a military medical treatment facility;

(3) an area in which there is a Medicare Subvention Demonstration project area under section 1896<sup>1</sup> of title XVIII of the Social Security Act (42 U.S.C. 1395ggg); and

(4) not more than one area for each TRICARE region.

(d) DURATION OF DEMONSTRATION PROJECT.—(1) The Secretary of Defense shall conduct the demonstration project during three contract years under the Federal Employees Health Benefits program.

(2) Eligible beneficiaries shall, as provided under the agreement pursuant to subsection (a), be permitted to enroll in the demonstration project during an open enrollment period for the year 2000 (conducted in the fall of 1999). The demonstration project shall terminate on December 31, 2002.

(e) PROHIBITION AGAINST USE OF MTFs AND ENROLLMENT UNDER TRICARE.—Covered beneficiaries under this chapter who are provided coverage under the demonstration project shall not be eligible to receive care at a military medical treatment facility or to enroll in a health care plan under the TRICARE program.

(f) TERM OF ENROLLMENT IN PROJECT.—(1) Subject to paragraphs (2) and (3), the period of enrollment of an eligible beneficiary who enrolls in the demonstration project during the open enrollment period for the year 2000 shall be three years unless the beneficiary disenrolls before the termination of the project.

(2) A beneficiary who elects to enroll in the project, and who subsequently discontinues enrollment in the project before the end of the period described in paragraph (1), shall not be eligible to reenroll in the project.

(3) An eligible beneficiary enrolled in a Federal Employees Health Benefits plan under this section may change health benefits plans and coverage in the same manner as any other Federal Employees Health Benefits program beneficiary may change such plans.

(g) EFFECT OF CANCELLATION.—The cancellation by an eligible beneficiary of coverage under the Federal Employee Health Benefits program shall be irrevocable during the term of the demonstration project.

(h) SEPARATE RISK POOLS; CHARGES.—(1) The Director of the Office of Personnel Management shall require health benefits plans under chapter 89 of title 5 that participate in the demonstration project to maintain a separate risk pool for purposes of establishing premium rates for eligible beneficiaries who enroll in such a plan in accordance with this section.

(2) The Director shall determine total subscription charges for self only or for family coverage for eligible beneficiaries who enroll in a health benefits plan under chapter 89 of title 5 in accordance with this section. The subscription charges shall include premium charges paid to

<sup>1</sup> See References in Text note below.

the plan and amounts described in section 8906(c) of title 5 for administrative expenses and contingency reserves.

(i) **GOVERNMENT CONTRIBUTIONS.**—The Secretary of Defense shall be responsible for the Government contribution for an eligible beneficiary who enrolls in a health benefits plan under chapter 89 of title 5 in accordance with this section, except that the amount of the contribution may not exceed the amount of the Government contribution which would be payable if the electing beneficiary were an employee (as defined for purposes of such chapter) enrolled in the same health benefits plan and level of benefits.

(j) **APPLICATION OF MEDIGAP PROTECTIONS TO DEMONSTRATION PROJECT ENROLLEES.**—(1) Subject to paragraph (2), the provisions of section 1882(s)(3) (other than clauses (i) through (iv) of subparagraph (B)) and 1882(s)(4) of the Social Security Act shall apply to enrollment (and termination of enrollment) in the demonstration project under this section, in the same manner as they apply to enrollment (and termination of enrollment) with a Medicare+Choice<sup>2</sup> organization in a Medicare+Choice<sup>2</sup> plan.

(2) In applying paragraph (1)—

(A) any reference in clause (v) or (vi) of section 1882(s)(3)(B) of such Act to 12 months is deemed a reference to 36 months; and

(B) the notification required under section 1882(s)(3)(D) of such Act shall be provided in a manner specified by the Secretary of Defense in consultation with the Director of the Office of Personnel Management.

(Added Pub. L. 105-261, div. A, title VII, § 721(a)(1), Oct. 17, 1998, 112 Stat. 2061; amended Pub. L. 108-375, div. A, title X, § 1084(d)(8), Oct. 28, 2004, 118 Stat. 2061; Pub. L. 112-239, div. A, title X, § 1076(g)(1), Jan. 2, 2013, 126 Stat. 1955.)

#### REFERENCES IN TEXT

The Social Security Act, referred to in subsecs. (b)(1)(A), (D)(i), and (j)(1), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended. Part A of title XVIII of the Act is classified generally to Part A (§ 1395c et seq.) of subchapter XVIII of chapter 7 of Title 42, The Public Health and Welfare. Section 1882 of the Act is classified to section 1395ss of Title 42. For complete classification of this Act to the Code, see section 1305 of Title 42 and Tables.

Section 1896 of the Social Security Act, referred to in subsec. (c)(3), was classified to section 1395ggg of Title 42, The Public Health and Welfare, and was omitted from the Code.

#### AMENDMENTS

2013—Subsecs. (j) to (l). Pub. L. 112-239 redesignated subsec. (l) as (j) and struck out former subsecs. (j) and (k) which required reports regarding the demonstration project by the Secretary of Defense and the Director of the Office of Personnel Management and by the Comptroller General.

2004—Subsec. (e). Pub. L. 108-375 substituted “health” for “heath”.

#### CHANGE OF NAME

References to Medicare+Choice deemed to refer to Medicare Advantage or MA, subject to an appropriate transition provided by the Secretary of Health and Human Services in the use of those terms, see section

<sup>2</sup> See Change of Name note below.

201(b) of Pub. L. 108-173, set out as a note under section 1395w-21 of Title 42, The Public Health and Welfare.

#### COMPREHENSIVE EVALUATION OF IMPLEMENTATION OF DEMONSTRATION PROJECTS AND TRICARE PHARMACY REDESIGN

Pub. L. 105-261, div. A, title VII, § 724, Oct. 17, 1998, 112 Stat. 2069, as amended by Pub. L. 106-65, div. A, title X, § 1067(3), Oct. 5, 1999, 113 Stat. 774, required the Comptroller General, not later than Mar. 31, 2003, to submit to committees of Congress a report containing a comprehensive comparative analysis of the FEHBP demonstration project conducted under this section, the TRICARE Senior Supplement under Pub. L. 105-261, § 722, formerly set out as a note under section 1073 of this title, and the redesign of the TRICARE pharmacy system under section Pub. L. 105-261, § 723, set out as a note under section 1073 of this title.

#### § 1109. Organ and tissue donor program

(a) **RESPONSIBILITIES OF THE SECRETARY OF DEFENSE.**—The Secretary of Defense shall ensure that the advanced systems developed for recording armed forces members’ personal data and information (such as the SMARTCARD, MEDITAG, and Personal Information Carrier) include the capability to record organ and tissue donation elections.

(b) **RESPONSIBILITIES OF THE SECRETARIES OF THE MILITARY DEPARTMENTS.**—The Secretaries of the military departments shall ensure that—

(1) appropriate information about organ and tissue donation is provided—

(A) to each officer candidate during initial training; and

(B) to each recruit—

(i) after completion by the recruit of basic training; and

(ii) before arrival of the recruit at the first duty assignment of the recruit;

(2) members of the armed forces are given recurring, specific opportunities to elect to be organ or tissue donors during service in the armed forces and upon retirement; and

(3) members of the armed forces electing to be organ or tissue donors are encouraged to advise their next of kin concerning the donation decision and any subsequent change of that decision.

(c) **RESPONSIBILITIES OF THE SURGEONS GENERAL OF THE MILITARY DEPARTMENTS.**—The Surgeons General of the military departments shall ensure that—

(1) appropriate training is provided to enlisted and officer medical personnel to facilitate the effective operation of organ and tissue donation activities under garrison conditions and, to the extent possible, under operational conditions; and

(2) medical logistical activities can, to the extent possible without jeopardizing operational requirements, support an effective organ and tissue donation program.

(Added Pub. L. 105-261, div. A, title VII, § 741(b)(1), Oct. 17, 1998, 112 Stat. 2073; amended Pub. L. 106-398, § 1 [[div. A], title X, § 1087(a)(8)], Oct. 30, 2000, 114 Stat. 1654, 1654A-290.)

#### AMENDMENTS

2000—Subsec. (b). Pub. L. 106-398 struck out “(1)” before “The Secretaries” in introductory provisions.