(Added Pub. L. 102–190, div. A, title VII, §715(a), Dec. 5, 1991, 105 Stat. 1403; amended Pub. L. 103–160, div. A, title VII, §716(a)(1), Nov. 30, 1993, 107 Stat. 1691; Pub. L. 104–106, div. A, title VII, §706, Feb. 10, 1996, 110 Stat. 373.)

AMENDMENTS

1996—Subsec. (h). Pub. L. 104–106 struck out subsec. (h) which read as follows: ''EXPIRATION OF PROGRAM.—The Secretary may not carry out the specialized treatment facility program authorized by this section after September 30, 1995.''

1993—Pub. L. 103–160 substituted ''Specialized treatment facility program'' for ''Issuance of nonavailability of health care statements'' as section catchline and amended text generally. Prior to amendment, text read as follows: ''In determining whether to issue a nonavailability of health care statement for any person entitled to health care in facilities of the uniformed services under this chapter, the commanding officer of such a facility may consider the availability of health care services for such person pursuant to any contract or agreement entered into under this chapter for the provision of health care services within the area served by that facility.''

§1106. Submittal of claims: standard form; time limits

(a) STANDARD FORM.—The Secretary of Defense, after consultation with the other administering Secretaries, shall prescribe by regulation a standard form for the submission of claims for the payment of health care services provided under this chapter.

(b) TIME FOR SUBMISSION.—A claim for payment for services provided under this chapter shall be submitted as provided in such regulations as follows:

(1) In the case of services provided outside the United States, the Commonwealth of Puerto Rico, or the possessions of the United States, by not later than three years after the services are provided.

(2) In the case of any other services, by not later than one year after the services are provided.

(Added Pub. L. 102–190, div. A, title VII, §716(a)(1), Dec. 5, 1991, 105 Stat. 1403; amended Pub. L. 105–85, div. A, title VII, §738(a), Nov. 18, 1997, 111 Stat. 1815; Pub. L. 112–81, div. A, title VII, §712, Dec. 31, 2011, 125 Stat. 1476.)

AMENDMENTS

2011—Subsec. (b). Pub. L. 112–81 substituted ''as follows:'' for ''not later than one year after the services are provided.'' and added pars. (1) and (2).

1997—Pub. L. 105–85 substituted '': standard form; time limits'' for ''under CHAMPUS'' in section catchline and amended text generally. Prior to amendment, text read as follows:

''(a) SUBMITTAL TO CLAIMS PROCESSING OFFICE.—Each provider of services under the Civilian Health and Medical Program of the Uniformed Services shall submit claims for payment for such services directly to the claims processing office designated pursuant to regulations prescribed under subsection (b). A claim for payment for services shall be submitted in a standard form (as prescribed in the regulations) not later than one year after the services are provided.

''(b) REGULATIONS.—The regulations required by subsection (a) shall be prescribed by the Secretary of Defense after consultation with the other administering Secretaries.

''(c) WAIVER.—The Secretary of Defense may waive the requirements of subsection (a) if the Secretary determines that the waiver is necessary in order to ensure adequate access for covered beneficiaries to health care services under this chapter.''

REGULATIONS

Pub. L. 102–190, div. A, title VII, §716(b), Dec. 5, 1991, 105 Stat. 1404, provided that: ''The regulations required by section 1106 of title 10, United States Code (as added by subsection (a)), shall be prescribed to take effect not later than 180 days after the date of the enactment of this Act [Dec. 5, 1991].''

ESTABLISHMENT OF APPEALS PROCESS FOR CLAIMCHECK DENIALS

Pub. L. 105–261, div. A, title VII, §714, Oct. 17, 1998, 112 Stat. 2060, provided that:

''(a) ESTABLISHMENT OF APPEALS PROCESS.—Not later than January 1, 1999, the Secretary of Defense shall establish an appeals process in cases of denials through the ClaimCheck computer software system (or any other claims processing system that may be used by the Secretary) of claims by civilian providers for payment for health care services provided under the TRICARE program.

''(b) REPORT.—Not later than March 1, 1999, the Secretary shall submit to Congress a report on the implementation of this section.''

NATIONAL CLAIMS PROCESSING SYSTEM FOR CHAMPUS

Pub. L. 102–484, div. A, title VII, §711, Oct. 23, 1992, 106 Stat. 2433, provided that:

''(a) CLAIMS PROCESSING SYSTEM REQUIRED.—(1) The Secretary of Defense, in consultation with the other administering Secretaries, shall provide by contract for the operation of a claims processing system to be known as the 'National Claims Processing System for CHAMPUS'. The Secretary may procure the system in installments, including the use of incremental modules. The system, including completion and integration of all modules, shall be in full operation not later than seven years after the date of the enactment of this Act [Oct. 23, 1992].

''(2) The Secretary shall use competitive procedures for entering into any contract or contracts under paragraph (1).

''(b) SYSTEM FUNCTIONS.—The claims processing system shall include at least the following functions:

''(1) The maintenance in electronic or written form, or both, of appropriate information on health care services provided to covered beneficiaries by or through third parties under CHAMPUS or any alternative CHAMPUS program or demonstration project. Such information shall include—

''(A) the services to which such beneficiaries are entitled or eligible under an insurance plan, medical service plan, or health plan under CHAMPUS;

''(B) the insurers, medical services, or health plans that provide such services; and

''(C) the services available to beneficiaries under each insurance plan, medical service plan, or health plan, and the payment required of the beneficiaries and the insurer, medical service, or health plan for such services under the plan.

''(2) The ability to receive in electronic or written form claims submitted by insurers, medical services, and health plans for services provided to covered beneficiaries.

''(3) The ability to process, adjudicate, and pay (by electronic or other means) such claims.

''(4) The provision of the information described in paragraphs (1) and (2) and information on the matters referred to in paragraph (3) by telephone, electronic, or other means to covered beneficiaries, insurers, medical services, and health plans.

''(c) CONSISTENCY WITH MEDICARE CLAIMS REQUIREMENTS.—The Secretary of Defense shall ensure, to the maximum extent practicable, that claims submitted to the claims processing system conform to the requirements applicable to claims submitted to the Secretary

of Health and Human Services with respect to medical care provided under part A of title XVIII of the Social Security Act (42 U.S.C. 1395c et seq.).

''(d) IDENTIFICATION CARD.—The Secretary of Defense shall take appropriate actions to determine whether the use by covered beneficiaries of a standard identification card containing electronically readable information will enhance the capability of the claims processing center to carry out the activities set forth in subsection (b).

''(e) TRANSITION TO SYSTEM.—After January 1, 1996, any modification or acquisition related to claims processing systems operations in the Office of the Civilian Health and Medical Program of the Uniformed Services shall contain provisions to transfer such operations to the claims processing system required by subsection (a). After January 1, 1999, any renewal or acquisition for fiscal intermediary services (including coordinated care implementations in military hospitals and clinics) shall contain provisions to transfer claims processing systems operations related to such fiscal intermediary services to the claims processing system required by subsection (a).

''(f) DEFINITIONS.—For purposes of this section:

''(1) The term 'administering Secretaries' has the meaning given that term in paragraph (3) of section 1072 of title 10, United States Code.

''(2) The term 'CHAMPUS' means the Civilian Health and Medical Program of the Uniformed Services, as defined in paragraph (4) of such section.

''(3) The term 'covered beneficiary' has the meaning given that term in paragraph (5) of such section.''

§ 1107. Notice of use of an investigational new drug or a drug unapproved for its applied use

(a) NOTICE REQUIRED.—(1) Whenever the Secretary of Defense requests or requires a member of the armed forces to receive an investigational new drug or a drug unapproved for its applied use, the Secretary shall provide the member with notice containing the information specified in subsection (d).

(2) The Secretary shall also ensure that health care providers who administer an investigational new drug or a drug unapproved for its applied use, or who are likely to treat members who receive such a drug, receive the information required to be provided under paragraphs (3) and (4) of subsection (d).

(b) TIME OF NOTICE.—The notice required to be provided to a member under subsection (a)(1) shall be provided before the investigational new drug or drug unapproved for its applied use is first administered to the member.

(c) FORM OF NOTICE.—The notice required under subsection (a)(1) shall be provided in writing.

(d) CONTENT OF NOTICE.—The notice required under subsection (a)(1) shall include the following:

(1) Clear notice that the drug being administered is an investigational new drug or a drug unapproved for its applied use.

(2) The reasons why the investigational new drug or drug unapproved for its applied use is being administered.

(3) Information regarding the possible side effects of the investigational new drug or drug unapproved for its applied use, including any known side effects possible as a result of the interaction of such drug with other drugs or treatments being administered to the members receiving such drug.

(4) Such other information that, as a condition of authorizing the use of the investigational new drug or drug unapproved for its applied use, the Secretary of Health and Human Services may require to be disclosed.

(e) RECORDS OF USE.—The Secretary of Defense shall ensure that the medical records of members accurately document—

(1) the receipt by members of any investigational new drug or drug unapproved for its applied use; and

(2) the notice required by subsection (a)(1).

(f) LIMITATION AND WAIVER.—(1) In the case of the administration of an investigational new drug or a drug unapproved for its applied use to a member of the armed forces in connection with the member's participation in a particular military operation, the requirement that the member provide prior consent to receive the drug in accordance with the prior consent requirement imposed under section 505(i)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)) may be waived only by the President. The President may grant such a waiver only if the President determines, in writing, that obtaining consent 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 prior consent for administration of a particular drug is required by reason of a determination by the Secretary of Health and Human Services that such drug is subject to the investigational new drug requirements of section 505(i) of the Federal Food, Drug, and Cosmetic Act.

(3) The Secretary of Defense may request the President to waive the prior consent requirement with respect to the administration of an investigational new drug or a drug unapproved for its applied use to a member of the armed forces in connection with the member's participation in a particular military operation. With respect to any such administration—

(A) the Secretary may not delegate to any other official the authority to request the President to waive the prior consent requirement for the Department of Defense; and

(B) if the President grants the requested waiver, the Secretary shall submit to the chairman and ranking minority member of each congressional defense committee a notification of the waiver, together with the written determination of the President under paragraph (1) and the Secretary's justification for the request or requirement under subsection (a) for the member to receive the drug covered by the waiver.

(4) In this subsection:

(A) The term ''relevant FDA regulations'' means the regulations promulgated under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)).

(B) The term ''prior consent requirement'' means the requirement included in the relevant FDA regulations pursuant to section 505(i)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)).

(g) DEFINITIONS.—In this section: