tion 2194 of Pub. L. 97–35, set out as a note under section 701 of this title.

EFFECTIVE DATE

Pub. L. 96–499, title IX, § 901(b), Dec. 5, 1980, 94 Stat. 2611, provided that: ''The amendment made by subsection (a) [enacting this section] shall apply to grants, gifts, and endowments, and income therefrom, made or established after the date of the enactment of this Act [Dec. 5, 1980].''

§ 1320b–5. Authority to waive requirements during national emergencies

(a) Purpose

The purpose of this section is to enable the Secretary to ensure to the maximum extent feasible, in any emergency area and during an emergency period (as defined in subsection (g)(1))—

(1) that sufficient health care items and services are available to meet the needs of individuals in such area enrolled in the programs under subchapters XVIII, XIX, and XXI; and

(2) that health care providers (as defined in subsection (g)(2)) that furnish such items and services in good faith, but that are unable to comply with one or more requirements described in subsection (b), may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse.

(b) Secretarial authority

To the extent necessary to accomplish the purpose specified in subsection (a), the Secretary is authorized, subject to the provisions of this section, to temporarily waive or modify the application of, with respect to health care items and services furnished by a health care provider (or classes of health care providers) in any emergency area (or portion of such an area) during any portion of an emergency period, the requirements of subchapters XVIII, XIX, or XXI, or any regulation thereunder (and the requirements of this subchapter other than this section, and regulations thereunder, insofar as they relate to such subchapters), pertaining to—

(1)(A) conditions of participation or other certification requirements for an individual health care provider or types of providers,

(B) program participation and similar requirements for an individual health care provider or types of providers, and

(C) pre-approval requirements;

(2) requirements that physicians and other health care professionals be licensed in the State in which they provide such services, if they have equivalent licensing in another State and are not affirmatively excluded from practice in that State or in any State a part of which is included in the emergency area;

(3) actions under section 1395dd of this title (relating to examination and treatment for emergency medical conditions and women in labor) for—

(A) a transfer of an individual who has not been stabilized in violation of subsection (c) of such section if the transfer is necessitated by the circumstances of the declared emergency in the emergency area during the emergency period; or

(B) the direction or relocation of an individual to receive medical screening in an alternative location—

(i) pursuant to an appropriate State emergency preparedness plan; or

(ii) in the case of a public health emergency described in subsection (g)(1)(B) that involves a pandemic infectious disease, pursuant to a State pandemic preparedness plan or a plan referred to in clause (i), whichever is applicable in the State;

(4) sanctions under section 1395nn(g) of this title (relating to limitations on physician referral);

(5) deadlines and timetables for performance of required activities, except that such deadlines and timetables may only be modified, not waived;

(6) limitations on payments under section 1395w–21(i) of this title for health care items and services furnished to individuals enrolled in a Medicare+Choice plan by health care professionals or facilities not included under such plan;

(7) sanctions and penalties that arise from noncompliance with the following requirements (as promulgateid under the authority of section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note)—[1]

(A) section 164.510 of title 45, Code of Federal Regulations, relating to—

(i) requirements to obtain a patient's agreement to speak with family members or friends; and

(ii) the requirement to honor a request to opt out of the facility directory;

(B) section 164.520 of such title, relating to the requirement to distribute a notice; or

(C) section 164.522 of such title, relating to—

(i) the patient's right to request privacy restrictions; and

(ii) the patient's right to request confidential communications;

(8) in the case of a telehealth service (as defined in paragraph (4)(F) of section 1395m(m) of this title) furnished in any emergency area (or portion of such an area) during any portion of any emergency period, the requirements of section 1395m(m) of this title; and

(9) any requirement under section 1395x(s)(7) of this title or section 1395m(*l*) of this title that an ambulance service include the transport of an individual to the extent necessary to allow payment for ground ambulance services furnished in response to a 911 call (or the equivalent in areas without a 911 call system) in cases in which an individual would have been transported to a destination permitted under Medicare regulations (as described in section 410.40 to title 42, Code of Federal Regulations (or successor regulations)) but such transport did not occur as a result of community-wide emergency medical service (EMS) protocols due to the public health emergency described in subsection (g)(1)(B).

[1] So in original. A second closing parenthesis probably should precede the dash.

Insofar as the Secretary exercises authority under paragraph (6) with respect to individuals enrolled in a Medicare+Choice plan, to the extent possible given the circumstances, the Secretary shall reconcile payments made on behalf of such enrollees to ensure that the enrollees do not pay more than would be required had they received services from providers within the network of the plan and may reconcile payments to the organization offering the plan to ensure that such organization pays for services for which payment is included in the capitation payment it receives under part C of subchapter XVIII. A waiver or modification provided for under paragraph (3) or (7) shall only be in effect if such actions are taken in a manner that does not discriminate among individuals on the basis of their source of payment or of their ability to pay, and, except in the case of a waiver or modification to which the fifth sentence of this subsection applies, shall be limited to a 72-hour period beginning upon implementation of a hospital disaster protocol. A waiver or modification under such paragraph (7) shall be withdrawn after such period and the provider shall comply with the requirements under such paragraph for any patient still under the care of the provider. If a public health emergency described in subsection (g)(1)(B) involves a pandemic infectious disease (such as pandemic influenza), the duration of a waiver or modification under paragraph (3) shall be determined in accordance with subsection (e) as such subsection applies to public health emergencies. Ground ambulance services for which payment is made pursuant to paragraph (9) shall be paid at the base rate that would have been paid under the fee schedule established under[2] 1395m(*l*) of this title (excluding any mileage payment) if the individual had been so transported and, with respect to ambulance services furnished by a critical access hospital or an entity described in paragraph (8) of such section, at the amount that otherwise would be paid under such paragraph.

(c) Authority for retroactive waiver

A waiver or modification of requirements pursuant to this section may, at the Secretary's discretion, be made retroactive to the beginning of the emergency period or any subsequent date in such period specified by the Secretary.

(d) Certification to Congress

The Secretary shall provide a certification and advance written notice to the Congress at least two days before exercising the authority under this section with respect to an emergency area. Such a certification and notice shall include—

(1) a description of—

(A) the specific provisions that will be waived or modified;

(B) the health care providers to whom the waiver or modification will apply;

(C) the geographic area in which the waiver or modification will apply; and

(D) the period of time for which the waiver or modification will be in effect; and

(2) a certification that the waiver or modification is necessary to carry out the purpose specified in subsection (a).

[2] So in original. The word ''section'' probably should appear.

(e) Duration of waiver

(1) In general

A waiver or modification of requirements pursuant to this section terminates upon—

(A) the termination of the applicable declaration of emergency or disaster described in subsection (g)(1)(A);

(B) the termination of the applicable declaration of public health emergency described in subsection (g)(1)(B); or

(C) subject to paragraph (2), the termination of a period of 60 days from the date the waiver or modification is first published (or, if applicable, the date of extension of the waiver or modification under paragraph (2)).

(2) Extension of 60-day periods

The Secretary may, by notice, provide for an extension of a 60-day period described in paragraph (1)(C) (or an additional period provided under this paragraph) for additional period or periods (not to exceed, except as subsequently provided under this paragraph, 60 days each), but any such extension shall not affect or prevent the termination of a waiver or modification under subparagraph (A) or (B) of paragraph (1).

(f) Report to Congress

Within one year after the end of the emergency period in an emergency area in which the Secretary exercised the authority provided under this section, the Secretary shall report to the Congress regarding the approaches used to accomplish the purposes described in subsection (a), including an evaluation of such approaches and recommendations for improved approaches should the need for such emergency authority arise in the future.

(g) Definitions

For purposes of this section:

(1) Emergency area; emergency period

(A) In general

Subject to subparagraph (B), an ''emergency area'' is a geographical area in which, and an ''emergency period'' is the period during which, there exists—

(i) an emergency or disaster declared by the President pursuant to the National Emergencies Act [50 U.S.C. 1601 et seq.] or the Robert T. Stafford Disaster Relief and Emergency Assistance Act [42 U.S.C. 5121 et seq.]; and

(ii) a public health emergency declared by the Secretary pursuant to section 247d of this title.

(B) Exception

For purposes of paragraphs (8) and (9) of subsection (b), an ''emergency area'' is a geographical area in which, and an ''emergency period'' is the period during which, there exists—

(i) the public health emergency declared by the Secretary pursuant to section 247d of this title on January 31, 2020, entitled ''Determination that a Public Health Emergency Exists Nationwide as the Result of the 2019 Novel Coronavirus''; and

(ii) any renewal of such declaration pursuant to such section 247d of this title.

(2) Health care provider

The term ''health care provider'' means any entity that furnishes health care items or services, and includes a hospital or other provider of services, a physician or other health care practitioner or professional, a health care facility, or a supplier of health care items or services.

(Aug. 14, 1935, ch. 531, title XI, § 1135, as added Pub. L. 107–188, title I, § 143(a), June 12, 2002, 116 Stat. 627; amended Pub. L. 108–276, § 9, July 21, 2004, 118 Stat. 863; Pub. L. 109–417, title III, § 302(b)(1), Dec. 19, 2006, 120 Stat. 2855; Pub. L. 116–123, div. B, § 102(a)(1), (2), (b), Mar. 6, 2020, 134 Stat. 156; Pub. L. 116–127, div. F, § 6010, Mar. 18, 2020, 134 Stat. 210; Pub. L. 116–136, div. A, title III, § 3703, Mar. 27, 2020, 134 Stat. 416; Pub. L. 117–2, title IX, § 9832, Mar. 11, 2021, 135 Stat. 222.)

Editorial Notes

REFERENCES IN TEXT

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (b)(7), is section 264(c) of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

The National Emergencies Act, referred to in subsec. (g)(1)(A)(i), is Pub. L. 94–412, Sept. 14, 1976, 90 Stat. 1255, which is classified principally to chapter 34 (§ 1601 et seq.) of Title 50, War and National Defense. For complete classification of this Act to the Code, see Short Title note set out under section 1601 of Title 50 and Tables.

The Robert T. Stafford Disaster Relief and Emergency Assistance Act, referred to in subsec. (g)(1)(A)(i), is Pub. L. 93–288, May 22, 1974, 88 Stat. 143, which is classified principally to chapter 68 (§ 5121 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 5121 of this title and Tables.

PRIOR PROVISIONS

A prior section 1320b–5, act Aug. 14, 1935, ch. 531, title XI, § 1135, as added Pub. L. 97–35, title XXI, § 2173(c), Aug. 13, 1981, 95 Stat. 809; amended Pub. L. 97–248, title I, § 101(b)(3), Sept. 3, 1982, 96 Stat. 335; Pub. L. 99–509, title IX, § 9343(f), Oct. 21, 1986, 100 Stat. 2041; Pub. L. 100–203, title IV, § 4068(b), Dec. 22, 1987, 101 Stat. 1330–114; Pub. L. 100–360, title IV, § 411(g)(6), July 1, 1988, 102 Stat. 785; Pub. L. 103–432, title I, § 147(c)(2), Oct. 31, 1994, 108 Stat. 4429, related to development of model prospective rate methodology, prior to repeal by Pub. L. 106–113, div. B, § 1000(a)(6) [title III, § 321(*l*)], Nov. 29, 1999, 113 Stat. 1536, 1501A–368, effective Nov. 29, 1999.

AMENDMENTS

2021—Subsec. (b). Pub. L. 117–2, § 9832(a)(2), inserted at end of concluding provisions ''Ground ambulance services for which payment is made pursuant to paragraph (9) shall be paid at the base rate that would have been paid under the fee schedule established under 1395m(*l*) of this title (excluding any mileage payment) if the individual had been so transported and, with respect to ambulance services furnished by a critical access hospital or an entity described in paragraph (8) of such section, at the amount that otherwise would be paid under such paragraph.''

Subsec. (b)(9). Pub. L. 117–2, § 9832(a)(1), added par. (9).

Subsec. (g)(1)(B). Pub. L. 117–2, § 9832(b), substituted ''paragraphs (8) and (9) of subsection (b)'' for ''subsection (b)(8)'' in introductory provisions.

2020—Subsec. (b)(8). Pub. L. 116–136, § 3703(1), substituted '', the requirements of section 1395m(m) of this title.'' for ''to an individual by a qualified provider (as defined in subsection (g)(3))—

''(A) the requirements of paragraph (4)(C) of such section, except that a facility fee under paragraph (2)(B)(i) of such section may only be paid to an originating site that is a site described in any of subclauses (I) through (IX) of paragraph (4)(C)(ii) of such section; and

''(B) the restriction on use of a telephone described in the second sentence of section 410.78(a)(3) of title 42, Code of Federal Regulations (or a successor regulation), but only if such telephone has audio and video capabilities that are used for two-way, real-time interactive communication.''

Pub. L. 116–123, § 102(a)(1), added par. (8).

Subsec. (g)(1). Pub. L. 116–123, § 102(b), amended par. (1) generally. Prior to amendment, text read as follows: ''An 'emergency area' is a geographical area in which, and an 'emergency period' is the period during which, there exists—

''(A) an emergency or disaster declared by the President pursuant to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act; and

''(B) a public health emergency declared by the Secretary pursuant to section 247d of this title.''

Subsec. (g)(3). Pub. L. 116–136, § 3703(2), struck out par. (3) which defined the term ''qualified provider''.

Pub. L. 116–123, § 102(a)(2), added par. (3).

Subsec. (g)(3)(A). Pub. L. 116–127 amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: ''furnished to such individual an item or service for which payment was made under subchapter XVIII during the 3-year period ending on the date such telehealth service was furnished; or''.

2006—Subsec. (b). Pub. L. 109–417, § 302(b)(1)(B), (C), in concluding provisions, substituted ''and, except in the case of a waiver or modification to which the fifth sentence of this subsection applies, shall be limited to'' for ''and shall be limited to'' and inserted at end ''If a public health emergency described in subsection (g)(1)(B) involves a pandemic infectious disease (such as pandemic influenza), the duration of a waiver or modification under paragraph (3) shall be determined in accordance with subsection (e) as such subsection applies to public health emergencies.''

Subsec. (b)(3)(B). Pub. L. 109–417, § 302(b)(1)(A), added subpar. (B) and struck out former subpar. (B) which read as follows: ''the direction or relocation of an individual to receive medical screening in an alternate location pursuant to an appropriate State emergency preparedness plan;''.

2004—Subsec. (b). Pub. L. 108–276, § 9(5), inserted at end of concluding provisions: ''A waiver or modification provided for under paragraph (3) or (7) shall only be in effect if such actions are taken in a manner that does not discriminate among individuals on the basis of their source of payment or of their ability to pay, and shall be limited to a 72-hour period beginning upon implementation of a hospital disaster protocol. A waiver or modification under such paragraph (7) shall be withdrawn after such period and the provider shall comply with the requirements under such paragraph for any patient still under the care of the provider.''

Subsec. (b)(3). Pub. L. 108–276, § 9(1), added par. (3) and struck out former par. (3) which read as follows: ''sanctions under section 1395dd of this title (relating to examination and treatment for emergency medical conditions and women in labor) for a transfer of an individual who has not been stabilized in violation of subsection (c) of this section of such section if the transfer arises out of the circumstances of the emergency;''.

Subsec. (b)(7). Pub. L. 108–276, § 9(2)–(4), added par. (7).

Statutory Notes and Related Subsidiaries

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 201 of Pub. L. 108–173, set out as a note under section 1395w–21 of this title.

EFFECTIVE DATE OF 2006 AMENDMENT

Pub. L. 109–417, title III, §302(b)(2), Dec. 19, 2006, 120 Stat. 2856, provided that: ''The amendments made by paragraph (1) [amending this section] shall take effect on the date of the enactment of this Act [Dec. 19, 2006] and shall apply to public health emergencies declared pursuant to section 319 of the Public Health Service Act (42 U.S.C. 247d) on or after such date.''

EFFECTIVE DATE

Pub. L. 107–188, title I, §143(b), June 12, 2002, 116 Stat. 629, provided that: ''The amendment made by subsection (a) [enacting this section] shall be effective on and after September 11, 2001.''

COVERAGE OF TESTING FOR COVID–19

Pub. L. 116–127, div. F, §6001, Mar. 18, 2020, 134 Stat. 201, as amended by Pub. L. 116–136, div. A, title III, §3201, Mar. 27, 2020, 134 Stat. 366, provided that:

''(a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage (including a grandfathered health plan (as defined in section 1251(e) of the Patient Protection and Affordable Care Act [42 U.S.C. 18011(e)])) shall provide coverage, and shall not impose any cost sharing (including deductibles, copayments, and coinsurance) requirements or prior authorization or other medical management requirements, for the following items and services furnished during any portion of the emergency period defined in paragraph (1)(B) of section 1135(g) of the Social Security Act (42 U.S.C. 1320b–5(g)) beginning on or after the date of the enactment of this Act [Mar. 18, 2020]:

''(1) An in vitro diagnostic test defined in section 809.3 of title 21, Code of Federal Regulations (or successor regulations) for the detection of SARS–CoV–2 or the diagnosis of the virus that causes COVID–19, and the administration of such a test, that—

''(A) is approved, cleared, or authorized under section 510(k), 513, 515, or 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 360c, 360e, 360bbb–3);

''(B) the developer has requested, or intends to request, emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3), unless and until the emergency use authorization request under such section 564 has been denied or the developer of such test does not submit a request under such section within a reasonable timeframe;

''(C) is developed in and authorized by a State that has notified the Secretary of Health and Human Services of its intention to review tests intended to diagnose COVID–19; or

''(D) other test that the Secretary determines appropriate in guidance.

''(2) Items and services furnished to an individual during health care provider office visits (which term in this paragraph includes in-person visits and telehealth visits), urgent care center visits, and emergency room visits that result in an order for or administration of an in vitro diagnostic product described in paragraph (1), but only to the extent such items and services relate to the furnishing or administration of such product or to the evaluation of such individual for purposes of determining the need of such individual for such product.

''(b) ENFORCEMENT.—The provisions of subsection (a) shall be applied by the Secretary of Health and Human Services, Secretary of Labor, and Secretary of the Treasury to group health plans and health insurance issuers offering group or individual health insurance coverage as if included in the provisions of part A of title XXVII of the Public Health Service Act [42 U.S.C. 300gg et seq.], part 7 of the Employee Retirement Income Security Act of 1974 [probably means part 7 of subtitle B of title I of Pub. L. 93–406, 29 U.S.C. 1181 et seq.], and subchapter B of chapter 100 of the Internal Revenue Code of 1986 [26 U.S.C. 9811 et seq.], as applicable.

''(c) IMPLEMENTATION.—The Secretary of Health and Human Services, Secretary of Labor, and Secretary of the Treasury may implement the provisions of this section through sub-regulatory guidance, program instruction or otherwise.

''(d) TERMS.—The terms 'group health plan'; 'health insurance issuer'; 'group health insurance coverage', and 'individual health insurance coverage' have the meanings given such terms in section 2791 of the Public Health Service Act (42 U.S.C. 300gg–91), section 733 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191b), and section 9832 of the Internal Revenue Code of 1986 [26 U.S.C. 9832], as applicable.''

IMPLEMENTATION OF 2020 AMENDMENT

Pub. L. 116–123, div. B, §102(a)(3), Mar. 6, 2020, 134 Stat. 156, provided that: ''The Secretary of Health and Human Services may implement the amendments made by this subsection [amending this section] by program instruction or otherwise.''

§ 1320b–6. Exclusion of representatives and health care providers convicted of violations from participation in social security programs

(a) In general

The Commissioner of Social Security shall exclude from participation in the social security programs any representative or health care provider—

(1) who is convicted of a violation of section 408 or 1383a of this title;

(2) who is convicted of any violation under title 18 relating to an initial application for or continuing entitlement to, or amount of, benefits under subchapter II of this chapter, or an initial application for or continuing eligibility for, or amount of, benefits under subchapter XVI of this chapter; or

(3) who the Commissioner determines has committed an offense described in section 1320a–8(a)(1) of this title.

(b) Notice, effective date, and period of exclusion

(1) An exclusion under this section shall be effective at such time, for such period, and upon such reasonable notice to the public and to the individual excluded as may be specified in regulations consistent with paragraph (2).

(2) Such an exclusion shall be effective with respect to services furnished to any individual on or after the effective date of the exclusion. Nothing in this section may be construed to preclude, in determining disability under subchapter II or subchapter XVI, consideration of any medical evidence derived from services provided by a health care provider before the effective date of the exclusion of the health care provider under this section.

(3)(A) The Commissioner shall specify, in the notice of exclusion under paragraph (1), the period of the exclusion.

(B) Subject to subparagraph (C), in the case of an exclusion under subsection (a), the minimum period of exclusion shall be 5 years, except that the Commissioner may waive the exclusion in the case of an individual who is the sole source of essential services in a community. The Commissioner's decision whether to waive the exclusion shall not be reviewable.

(C) In the case of an exclusion of an individual under subsection (a) based on a conviction or a determination described in subsection (a)(3) oc-