

AUTHORITY TO WAIVE REQUIREMENTS DURING NATIONAL EMERGENCIES

Sec. 1135. [42 U.S.C. 1320b–5] (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 titles 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 titles XVIII, XIX, or XXI, or any regulation thereunder (and the requirements of this title other than this section, and regulations thereunder, insofar as they relate to such titles), 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 <u>1867</u> (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 arises out of the circumstances of the emergency;
- (B)^[74] 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 <u>1877(g)</u> (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; [75]
- (6) limitations on payments under section 1851(i) 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; and [76]
- (7)^[77] sanctions and penalties that arise from the noncompliance with the following requirements (as promulgated under the authority of section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S. C. 1320d-2 note)—
- (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.

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 title 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 [78] a 72-hour period beginning upon implementation of a hospital disaster protocal. 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. [79] 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. [80]

- (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).
- (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.—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^[81] or the Robert T. Stafford Disaster Relief and Emergency Assistance Act^[82]; and
- (B) a public health emergency declared by the Secretary pursuant to section 319 of the Public Health Service Act.
- (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.
- P.L. 109-417, §302(b)(1)(A), amended subparagraph (B) in its entirety, effective December 12, 2006, and applicable 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.

For subparagraph (B) as it formerly read, see Vol. II, Appendix J, Superseded Provisions, P.L. 109-417.

- [75] P.L. 108-276, §9(2), struck out "and".
- P.L. 108-276, §9(3), struck out the period and substituted a semicolon and "and".
- P.L. 108-276, §9(4), added paragraph (7), effective July 21, 2004.
- P.L. 109-417, §302(b)(1)(B), struck out "and shall be limited to" and substituted "and, except in the case of a waiver or modification to which the fifth sentence of this subsection applies, shall be limited to", effective December 19, 2006, and applicable 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.

- [79] P.L. 108-276, §9(5), added this sentence, effective July 21, 2004.
- P.L. 109-417, §302(b)(1)(C), added this sentence, effective December 19, 2006, and applicable 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.
- [81] P.L. 94-412.
- [82] P.L. 93-288.