WAIVER OR MODIFICATION OF REQUIREMENTS UNDER SECTION 1135 OF THE SOCIAL SECURITY ACT

October 27, 2009

1. Pursuant to Section 1135(b) of the Social Security Act (the Act) (42 U.S.C. § 1320b-5), I hereby waive or modify the following requirements of titles XVIII, XIX, or XXI of the Act or regulations thereunder, and the following requirements of Title XI of the Act, and regulations thereunder, insofar as they relate to Titles XVIII, XIX, or XXI of the Act, but in each case, only to the extent necessary, as determined by the Centers for Medicare & Medicaid Services, to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the Medicare, Medicaid and CHIP programs and to ensure that health care providers that furnish such items and services in good faith, but are unable to comply with one or more of these requirements as a result of the 2009-H1N1 influenza pandemic, may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse:

   a. Certain conditions of participation, certification requirements, program participation or similar requirements for individual health care providers or types of health care providers, including as applicable, 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, and pre-approval requirements.

   b. Requirements that physicians or other health care professionals hold licenses in the State in which they provide services, if they have an equivalent license from another State (and are not affirmatively barred from practice in that State or any State a part of which is included in the emergency area).

   c. Actions under section 1867 of the Act (the Emergency Medical Treatment and Labor Act, or EMTALA) for the direction or relocation of an individual to another location to receive medical screening pursuant to an appropriate state emergency preparedness plan or a state pandemic preparedness plan or for the transfer of an individual who has not been stabilized if the transfer is necessitated by the circumstances of the declared public health emergency for the 2009-H1N1 influenza pandemic.

d. Sanctions under section 1877(g) (relating to limitations on physician referral) under such conditions and in such circumstances as the Centers for Medicare & Medicaid Services determines appropriate.

e. Limitations on payments under section 1851(i) of the Act for health care items and services furnished to individuals enrolled in a Medicare Advantage plan by health care professionals or facilities not included in the plan's network.

2. Pursuant to Section 1135(b)(7) of the Act, I hereby waive sanctions and penalties arising from noncompliance with the following provisions of the HIPAA privacy regulations: (a) the requirements to obtain a patient's agreement to speak with family members or friends or to honor a patient's request to opt out of the facility directory (as set forth in 45 C.F.R. § 164.510); (b) the requirement to distribute a notice of privacy practices (as set forth in 45 C.F.R. § 164.520); and (c) the patient's right to request privacy restrictions or confidential communications (as set forth in 45 C.F.R. § 164.522); but in each case, only with respect to hospitals in the designated geographic area that have hospital disaster protocols in operation during the time the waiver is in effect.

3. Pursuant to Section 1135(b)(5), I also hereby modify deadlines and timetables and for the performance of required activities, but only to the extent necessary, as determined by the Centers for Medicare & Medicaid Services, to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the Medicare, Medicaid and CHIP programs and to ensure that health care providers that furnish such items and services in good faith, but are unable to comply with one or more of these requirements as a result of the 2009-H1N1 influenza pandemic, may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse.

These waivers and modifications will become effective at 5:00 P.M. Eastern Standard Time on October 29, 2009, but will have retroactive effect to October 23, 2009, nationwide, and continue through the period described in Section 1135(e). Notwithstanding the foregoing, the waivers described in paragraph 2 above are in effect for a period of time not to exceed 72 hours from implementation of a hospital disaster protocol but not beyond the period described in Section 1135(e). The waivers described in paragraphs 1(c) and 2 above are not effective with respect to any action taken thereunder that discriminates among individuals on the basis of their source of payment or their ability to pay.

The waivers and modifications described herein apply in the geographic area covered by the President's proclamation, pursuant to the National Emergencies Act, on October 23, 2009, that the 2009-H1N1 influenza pandemic constitutes a national emergency; and former Acting Secretary Charles E. Johnson's April 26, 2009, determination, pursuant to section 319 of the Public Health Service Act, that a public health emergency exists nationwide involving Swine Influenza A (now called 2009 – H1N1 flu), renewed by me on July 24, 2009 and October 1, 2009.

Date:
10/27/09

Kathleen Sebelius
Secretary
Department of Health and Human Services

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

OCT 27 2009

The Honorable Nancy Pelosi
Speaker of the House
United States House of Representatives
Washington, D.C. 20515

Re: Waiver and/or Modification of Certain HIPAA, and Medicare, Medicaid, and Children's Health Insurance Program Requirements

Dear Madam Speaker:

As required under Section 1135(d) of the Social Security Act (the Act) (42 U.S.C. § 1320b-5), I hereby notify you that as a consequence of the 2009-H1N1 influenza pandemic, on October 29, 2009, I intend to waive or modify certain HIPAA and Medicare, Medicaid, or Children's Health Insurance Program requirements as indicated on the enclosed document. I certify that these waivers and/or modifications are necessary to carry out the purposes of Section 1135 of the Act.

Sincerely,

Kathleen Sebelius

Kathleen Sebelius

Enclosure