Section 1135 Waivers and COVID-19: An Overview

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In response to the novel Coronavirus (COVID-19) outbreak in the United States, both Congress and the Trump Administration have acted to confront the challenges of providing health care to sick patients. These efforts have included the provision of certain regulatory flexibilities for health care entities under Section 1135 of the Social Security Act (42 U.S.C. § 1320b-5). To address the difficulties of providing health care in exigent circumstances, Section 1135 generally authorizes the Secretary of Health and Human Services (HHS Secretary) to waive or modify specified statutory and regulatory requirements related to the provision of health care services under the Medicare, Medicaid, and State Children’s Health Insurance (CHIP) programs (so-called “Section 1135 waivers”). In recent years, the HHS Secretary has issued Section 1135 waivers several times, most commonly for natural disasters. This Legal Sidebar summarizes Section 1135 and recent legislative and administrative developments relating to this authority.

Legal Framework

The general purpose of Section 1135 is to help ensure that in an emergency or disaster, health care program enrollees have sufficient access to health care, and health care providers can continue to furnish care, despite noncompliance with certain federal requirements. To the extent necessary to carry out this purpose, Section 1135 permits the HHS Secretary to waive or modify the following federal requirements when the President has declared an emergency or major disaster under either the National Emergencies Act or the Stafford Act, and the HHS Secretary has declared a public health emergency:

- conditions of participation, certification requirements, program participation, and pre-approval requirements under Medicare, Medicaid, or CHIP;
- licensing requirements for health care professionals in each state in which they provide services, assuming they are not excluded from practicing in the relevant state or emergency area;
- sanctions under the Emergency Medical Treatment and Active Labor Act (EMTALA) for certain transfers or redirections of patients away from hospital emergency rooms;
- deadlines and timetables for performance of required activities;

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sanctions under the Stark Law, which prohibits certain physician self-referrals for designated health services paid for by Medicare or Medicaid;

- limitations on payment under Medicare Advantage plans for health care providers that are out-of-network; and

- sanctions and penalties that arise from noncompliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rules.

Pursuant to Section 1135 waivers, health care entities may be reimbursed for the care they provide to health care program enrollees and are exempt from sanctions associated with noncompliance, absent any determination of fraud or abuse.

The HHS Secretary has broad discretion over Section 1135 waiver implementation. The Secretary may generally determine which provisions to waive or modify within the categories listed above, and which health care providers may be subject to these waivers or modifications. In past emergencies, the Centers for Medicare and Medicaid Services (CMS), an agency within the HHS Department, has issued certain automatically applicable Section 1135 “blanket waivers,” based on a determination that similarly situated providers in an emergency area needed such waivers. CMS has also implemented waivers on a case-by-case basis, which compelled health care providers within an emergency area to obtain approval for section 1135 relief.

Additionally, the HHS Secretary has discretion over the duration of Section 1135 waivers. The HHS Secretary’s Section 1135 authority may be retroactively applied to the beginning of the period during which the concurrent emergency declarations were in effect. Waivers and modifications can generally remain in effect until the underlying emergency declarations end, or sixty days have elapsed since notice of the waivers or modifications was published, unless the HHS Secretary extends the waiver period.

**Section 1135 and COVID-19: Recent Developments**

To address the COVID-19 outbreak, Congress recently passed the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, which, during the period of the COVID-19 public health emergency, expands the types of waivable provisions under Section 1135 to include certain telehealth benefits under the Medicare program. Under current law, Medicare Part B generally pays for physicians or other practitioners to furnish services through a telecommunications system, but beneficiaries may have to travel to a specified “originating site” and/or use specific telecommunications equipment for the service to be covered under the program. The new legislation allows the HHS Secretary to waive these requirements so that beneficiaries may receive telehealth services from locations other than an originating site, such as their homes, and without otherwise required telecommunications equipment. The new waivable provisions are not expressly limited to diagnosis or treatment of COVID-19, and expanded telehealth capabilities may apply in an emergency area, regardless of a particular patient’s needs. As amended by the Families First Coronavirus Response Act, the COVID-19 Section 1135 telehealth waiver generally applies to physicians and other practitioners (and their group practices) who previously furnished Medicare-covered services to a specific beneficiary during the three-year period prior to telehealth service.

Additionally, following the President’s March 13, 2020 declaration that the COVID-19 pandemic constitutes a national emergency, HHS Secretary Alex Azar invoked his Section 1135 authority to allow waivers and modifications of certain health care laws and regulations. Under this authority, the HHS Secretary has approved blanket waivers for many provisions related to, among other things, hospital and nursing facility standards, certain provider enrollment requirements, and Medicare telehealth services. Additionally, waivers of other federal provisions, including provisions related to EMTALA, the Stark Law, and certain Medicaid requirements (see, e.g., here), appear to be available on a case-by-case basis. The COVID-19 Section 1135 waivers apply nationwide, and applicability is retroactive to March 1, 2020.
As the federal government’s response to the COVID-19 outbreak continues, Congress may choose to amend Section 1135 to expand or otherwise alter the HHS Secretary’s authority to waive the applicability of health care program requirements. Congress could also consider additional waivers related to COVID-19 specifically, such as waivers of federal health care fraud and abuse provisions that can, in some cases, limit a health care entity’s ability to waive cost-sharing obligations, or provide reduced price services to federal health care program beneficiaries.

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