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For more information, contact:

Mark Polston
+1 202 626 5540
mpolston@kslaw.com

James Boswell
+1 404 572 3534
jboswell@kslaw.com

Christopher Kenny
+1 202 626 9253
ckenny@kslaw.com

Catherine Greaves
+1 512 457 2005
cgreaves@kslaw.com

Jennifer Siegel
+1 213 443 4389
jsiegel@kslaw.com

Marcia Augsburger
+1 916 321 4803
maugsburger@kslaw.com

King & Spalding

Washington, D.C.
1700 Pennsylvania Avenue, NW
Washington, D.C. 20006-4707
Tel: +1 202 737 0500

CMS Releases Section 1135 Waiver in Response to the Novel Coronavirus Pandemic

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On March 13, 2020, President Trump declared the coronavirus pandemic a national emergency, invoking powers under the National Emergency Act and the Stafford Act. The President's declaration, coupled with Secretary Azar's earlier declaration of a public health emergency under Section 319 of the Public Health Service Act[1], authorized the Secretary to waive certain Medicare, Medicaid and Children's Health Insurance Program (CHIP) requirements and conditions of participation under Section 1135 of the Social Security Act.

On the same day as the President's declaration, CMS announced that it had used this authority to activate blanket waivers of several Medicare and Medicaid requirements to give healthcare providers more flexibility in responding to the pandemic. For example, CMS's waiver allows hospitals to house acute care patients in distinct parts of the hospital, such as inpatient psychiatric and rehabilitation units, that are excluded from Medicare's inpatient prospective payment system (IPPS). Further, CMS has waived the requirement that Medicare beneficiaries must be hospitalized as an inpatient for three days for their post-acute, skilled nursing facility stays to be covered by Medicare, which allows hospitals to free up beds for more acutely ill patients. Both waivers respond to concerns about a potential shortage in acute care hospital beds as the number of Covid-19 diagnoses grows.

This alert describes these and other provisions of the Secretary's 1135 waiver. Healthcare providers should familiarize themselves now with the scope of the waiver as they prepare for the pandemic. The waiver goes far in assisting providers in responding to the public health emergency, but many questions remain. Further, there is more that can be done. Because the conditions are now in place for Secretary Azar to invoke

Section 1135, healthcare providers have an opportunity to request additional waivers of Medicare, Medicaid and CHIP statutory and regulatory requirements as their need becomes apparent. CMS's announcements on March 13th expressed a willingness to consider additional waiver requests from State authorities and individual healthcare providers.

WHAT IS A SECTION 1135 WAIVER?

Section 1135 of the Social Security Act allows the Secretary of HHS to temporarily waive or modify certain Medicare, Medicaid, and CHIP requirements to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in these programs in an emergency area and to ensure that providers will be reimbursed for the items and services they furnish. The statute gives the Secretary broad authority to waive the following type of requirements under the Medicare, Medicaid and CHIP statutes and regulations:

- All conditions of participation or other provider certification requirements, program participation requirements and pre-approval requirements;
- Requirements that physicians and other health care professionals be licensed in the State in which they are providing services, so long as they have equivalent licensing in another State;
- Emergency Medical Treatment and Active Labor Act (EMTALA) sanctions that otherwise would apply when a provider redirects an individual to receive a medical screening examination so long as the patient is redirected to an alternative location pursuant to a state emergency preparedness plan (or in the case of a public health emergency involving pandemic infectious disease, a state pandemic preparedness plan). EMTALA sanctions can also be waived for transferring an individual who has not been stabilized if the circumstances of the declared emergency require the patient to be transferred;
- Sanctions under the Stark physician self-referral law;
- Deadlines and timetables to perform required activities—for example, the deadline by which to perform skilled nursing care assessments when a patient is admitted to a SNF;
- Limitations on payment to permit Medicare Advantage enrollees to use out of network providers in an emergency situation;
- Sanctions and penalties that arise from noncompliance with certain requirements under 42 C.F.R. §§ 164.510, 164.520 and 164.522, provisions of the HIPAA privacy rule.

At least two days before exercising this authority, the Secretary must certify to Congress the need for a waiver and describe the provisions of law that are waived. He must also describe the areas and healthcare providers to whom the waiver applies and the duration of the waiver.

The Secretary has the option of exercising the waiver for a time-period of sixty (60) days and extending the waiver for subsequent sixty (60) day periods or, alternatively, allowing the waiver to last until the declaration of an emergency, disaster or public health emergency has terminated. EMTALA and HIPAA waivers generally may last no longer than 72-hours after implementation of a hospital's disaster protocol. However, because Secretary Azar's public health emergency declaration involved a "pandemic infectious disease," an EMTALA waiver could last for the duration of the public health crisis or national emergency. 42 U.S.C. § 1320-b-5(b).

CMS has, in past disasters, implemented specific waivers on a "blanket" basis. These are waivers that apply to all healthcare providers in the designated emergency area and do not require a provider-initiated request. When determining whether to implement a "blanket" waiver, CMS looks, in part, at the frequency of requests for specific

waivers in response to the disaster or emergency. Per CMS, providers should still notify the State Survey Agency and CMS Regional Office when operating under a blanket waiver to ensure that they will be properly paid for their services.

A Section 1135 waiver is different than a waiver under Section 1115 of the Social Security Act. The latter type of waiver enables the Secretary and states to implement Medicaid coverage and financing demonstration projects. Though the Secretary so far has not initiated a Section 1115 waiver process, individual states could seek these waivers in order to, among other things, expand Medicaid coverage for Covid-19 services furnished to the uninsured and other populations. Though states must individually apply for Section 1115 waivers, the Secretary has the authority to streamline the process, as he did in deploying a waiver to states affected by Hurricane Katrina.

THE SECRETARY'S 1135 WAIVER IN RESPONSE TO COVID-19

In response to the novel coronavirus pandemic, the Secretary used his authority to adopt a blanket waiver that applies to all healthcare providers in the nation. The CMS fact sheet describing the waiver can be found here. The text of the waiver itself can be found here. The waiver is effective retroactively to March 1st and gives healthcare providers relief from a number of statutory and regulatory requirements.

The Secretary has also used his authority under both 1135 and the Coronavirus Preparedness and Response Supplemental Appropriations Act ("Coronavirus Preparedness Act"), which the President signed March 6, 2020, to waive certain telehealth and HIPAA security requirements. Most significantly, the Secretary waived the telehealth reimbursement requirements under parts A and B that patients be located in certain offices and facilities in rural Health Professional Shortage Areas or counties outside of a Metropolitan Statistical Area; beneficiaries may receive telehealth services in their homes or any other care setting. To avoid a need for new patients to travel to physicians' offices, hospitals, or other facilities, the Secretary also announced that for services furnished under the waiver, HHS will not enforce the established relationship requirement. The Coronavirus Preparedness Act included authority for the Secretary to waive any limitation on the use of telephones with audio and video capabilities for telehealth visits. While such real-time video communications were already generally permissible to the extent they met HIPAA security rule requirements, the Secretary used his section 1135(b) authority to ensure that the HHS Office for Civil Rights (OCR) waives penalties for HIPAA violations against health care providers that use less secure communications technologies, such as FaceTime or Skype, during the public health emergency.

The Covid-19 waiver adopted on March 13th gives healthcare providers significant flexibility in responding to the pandemic. Based upon our reading of both the language of the Secretary's waiver and CMS's March 13th Fact Sheet, the Covid-19 waiver includes:

- **Skilled Nursing Facilities**- CMS has waived the requirement for a 3-day acute care stay for a post-acute SNF stay to be covered. This waiver is designed to increase short-term acute care bed capacity by more quickly moving patients to a lower level of care. To further encourage this movement, CMS has also authorized SNF coverage to certain beneficiaries who have exhausted their SNF benefits, without having to begin a new benefit period. CMS is also relaxing the timeline requirements by which SNFs must conduct a resident assessment. The waiver applies to all such requirements found in 42 C.F.R. § 483.20.
- **Critical Access Hospitals (CAH)**- CAHs receive preferential reimbursement treatment under the Medicare program, which is forfeited if they operate more than 25 inpatient beds or treat patients whose stay exceeds 96 hours. To increase bed capacity during the public health emergency and avoid unnecessary transfers, CMS is waiving these two requirements for CAHs.
- **Housing of Acute Care Patients in Distinct Part Units**- CMS is permitting acute care hospitals to house acute care inpatients in distinct part units that are excluded from IPPS when the beds are appropriate for acute, inpatient care.

CMS is permitting hospitals to bill for the care under acute PPS and recommends that hospitals document in the patient's medical records that the patient is an acute care inpatient who is being housed in an excluded unit due to capacity limitations resulting from the emergency.

- **Care for Inpatient Rehabilitation and Psychiatric Unit Patients**- Similarly, CMS is permitting acute care hospitals to relocate inpatients from an excluded unit—such as a rehabilitation or psychiatric unit—to an acute care bed and unit. Again, CMS recommends the IPPS hospital document in the patient's medical record that the patient is a psychiatric or rehabilitation inpatient who is being cared for in an acute care unit due to capacity or other exigent circumstances resulting from the emergency.
- **Durable Medical Equipment Replacement-** When an item of Durable Medical Equipment (DME) is lost, destroyed or rendered unusable, contractors can now replace the item without a physician's order, new medical necessity documents or by abiding by face-to-face requirements. Suppliers, however, must still document on the claim why the equipment must be replaced and how the item was rendered unavailable by the emergency.
- **Long-Term Care Acute Hospitals (LTCH)**- LTCHs are defined as acute care hospitals with an average length of stay of 25 days or more. They are paid under the LTCH PPS which recognizes the resource intensity of long hospital stays. CMS has waived the average length of stay requirement which will allow LTCHs to discharge patients in order to meet the demands of the emergency without losing their LTCH reimbursement status. This appears to be another effort to increase bed capacity to handle an increase in Covid-19 diagnosed patients.
- **Home Health Agencies**- CMS has waived timeframe requirements pertaining to OASIS Transmission and has allowed Medicare Administrative Contractors to extend the auto-cancellation date for Requests for Anticipated Payments (RAPs).
- **Provider Services Out-of-State-** CMS has waived the requirement that out-of-state providers be licensed in the state where they are providing services, as long as the providers are licensed in another state.
- **Provider Enrollment**- CMS is establishing a hotline for non-certified Part B suppliers, physicians and non-physician practitioners to enroll and receive temporary Medicare billing privileges. CMS is additionally waiving several screening requirements, including certain application fees, fingerprint based criminal background checks and site visits. CMS is postponing revalidation actions, allowing licensed providers to render services outside of their state of enrollment, and expediting pending or new applications from providers.
- **Medicare Appeals for Fee For Service, Medicare Advantage and Part D**- For appeals, CMS is permitting: (1) extensions to file an appeal; (2) a waiver of timeliness requirements for requests for additional information to adjudicate claims; (3) the processing of an appeal with incomplete Appointment of Representation forms; (4) the processing of requests for appeals that don't meet all of the required elements; and the use of all flexibilities available in the appeal process through a showing of good cause.
- **EMTALA-** Sanctions are waived for hospitals directing or relocating an individual to another location to receive medical screening pursuant to an appropriate state emergency plan or for the transfer of an individual who has not been stabilized if the transfer is necessitated by the circumstances of the declared Federal public health emergency for the COVID-19 pandemic.
- **HIPAA**- Penalties and sanctions will not apply for noncompliance with the requirements (i) 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; (ii) distribute notice of privacy practices, and (iii) patient's right to request privacy restrictions or confidential communications, but 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 for up to 72 hours from the time the disaster plan is implemented.

- **Stark-** 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.

ANALYSIS OF THE COVID-19 WAIVER

The Secretary's 1135 waiver grants healthcare providers—particularly hospitals—greater flexibility in addressing the public health emergency created by the novel coronavirus. Most notably, hospitals now have the flexibility to house acute care patients in distinct parts of the hospital that are excluded from Medicare IPPS reimbursement system. This accommodation should now allow providers to increase bed capacity to meet the needs of individuals who require inpatient care as a result of the coronavirus without risking Medicare reimbursement for those services. Similarly, waiving the three-day inpatient stay requirement for coverage of SNF benefits should also encourage hospitals to more quickly move patients to lower levels of care, again hopefully freeing up bed space for more patients with more acute needs. Two provisions of the waiver—relaxing Part B enrollment and waiving in-state licensing requirements—are clearly intended to increase the number of medical professionals available to respond to the crisis, though with every area of the country preparing for an increase in Covid-19 diagnoses, the number of clinicians who are available to travel to provide treatment.

There are also several questions raised by the Covid-19 waiver. While it is helpful for CMS to have waived the in-state licensing requirements for physicians and other practitioners, what about other Medicare conditions of participation that could also prove a barrier for physicians such as providing services pursuant to hospital credentialing and privileges? *See* 42 C.F.R. § 482.22. If the pandemic grows and provider services are strained, hospitals may need to be more creative about the space in which they provide services. To what extent has or will CMS waive or modify the conditions of participation that set minimum standards for the physical environment in which hospitals services are provided and which would allow hospitals to provide services in traditionally non-hospital space? *See* 42 C.F.R. § 482.41. Some of the provisions of the Secretary's waiver give CMS authority to further identify the parameters of the waiver, such as the Secretary's Stark waiver and modifications of "time tables" and "deadlines" that must be met for reimbursement purposes. When will CMS come out with additional information that clarifies the parameters of these waivers?

WHAT SHOULD HOSPITALS AND OTHER PROVIDERS DO NOW?

We encourage healthcare providers to seek assistance in interpreting the Secretary's Section 1135 waiver. CMS's current description of the waiver is sparse, leaving much room for ambiguity and questions. Providers may be contemplating specific actions that may (or may not) be permitted under the current form of the waiver. It is advisable to check with counsel before moving forward. In addition, this is a dynamic situation, and CMS is likely to provide additional guidance on the scope of this waiver. This could come in the form of Frequently Asked Questions or other web-publications that provide further interpretations of the Covid-19 waiver. Providers should continue to monitor CMS's website or regularly check with counsel to determine whether any new pronouncements from CMS expand or clarify the waiver. Finally, to the extent that CMS written guidance is unclear, providers should also consider contacting CMS itself, including its Office of General Counsel, to seek clarification of the waiver.

Most important, we encourage providers to continue to inventory the Medicare, Medicaid and CHIP statutory and regulatory requirements that place unnecessary barriers in responding to the novel coronavirus public health emergency. As the situation develops on the ground, healthcare providers are likely to identify additional obstacles that prevent action from being taken or put providers at risk of legal sanction or lost reimbursement. CMS's policy on Section 1135 waivers allows healthcare providers to request individual Section 1135 waivers if no blanket waiver is available through State Survey Agencies or CMS Regional Offices. Hospitals also may want to be in communication with their state

hospital association and state Medicaid agency to consider requesting a Section 1115 waiver to expand Medicaid coverage – with Federal matching funds – for Covid-19 services.

HOW CAN KING & SPALDING HELP?

King & Spalding has been monitoring all communications and guidance from HHS in order to counsel our clients on the unique legal questions raised by this unique infectious disease public health emergency. We are prepared to assist our clients in understanding the scope and opportunities raised by the Secretary's Covid-19 waiver. The firm enjoys a strong working relationship with the HHS Office of General Counsel which we can leverage to help our clients get clear and quick answers to questions regarding the waiver. We are also prepared to assist our clients with seeking additional waiver relief under Section 1135 that has not yet been authorized by the Secretary.

[1] Department of Health and Human Services (HHS) Secretary Alex M. Azar issued a declaration of public health emergency on January 31, 2020.