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Legal and compliance developments and the coronavirus

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On January 31, 2020, in response to the COVID-19 crisis, the Secretary of Health and Human Services (HHS) Alex Azar declared a public health emergency.[1] Following President Donald Trump's declaration of a national emergency under the National Emergencies Act and emergency determination under the Stafford Act, the Secretary of HHS was allowed to issue waivers of certain Medicare, Medicaid, and Children's Health Insurance Program requirements pursuant to Section 1135 of the Social Security Act.[2] As a result, on March 13, 2020, the Secretary of HHS authorized the Centers for Medicare & Medicaid Services (CMS) to take waivers and modifications.[3] The purpose of these Section 1135 waivers is to ensure that sufficient healthcare items and services are available to meet the needs of Medicare, Medicaid, and Children's Health Insurance Program beneficiaries in case of emergency and that providers who furnish such services in good faith can be reimbursed and exempted from sanctions.[4]

Section 1135 waivers are usually issued to respond to specific concerns in a given emergency area. Once a waiver is authorized, healthcare providers must submit requests to operate under that authority to the State Survey Agency or CMS Regional Office. The requests generally include a justification for the waiver and expected duration of the modification requested. The State Survey Agency and CMS Regional Office will then review the provider's request and make appropriate decisions, usually on a case-by-case basis. However, due to the gravity of the current crisis, and in order to avoid a case-by-case determination, on March 13, 2020, CMS has made the decision to issue certain blanket waivers.[5] Blanket waivers are issued when a determination has been made that all similarly situated providers need such a waiver.[6] Providers may conduct their operations subject to these blanket waivers immediately and with no further action required. These blanket waivers include coverage for the following:

- **Skilled nursing facilities (SNF):** Waiver of the three-day prior hospitalization requirement for coverage of an SNF stay provides temporary emergency coverage of SNF services without a qualifying hospital stay for those people who are evacuated, transferred, or otherwise dislocated as a result of the effect of disaster or emergency. "In addition, for certain beneficiaries who recently exhausted their SNF benefits, it authorizes renewed SNF coverage without first having to start a new benefit period." This waiver provides relief to SNFs on the time frame requirements for Minimum Data Set assessments and transmission.[7]
- **Critical access hospitals**: CMS is waiving the requirements that critical access hospitals limit the number of beds to 25, and that the length of stay be limited to 96 hours.
- **Housing acute care patients in excluded distinct part units**: Acute care hospitals may house acute care inpatients in excluded distinct part units where the beds are appropriate for acute care inpatients. "The

Inpatient Prospective Payment System (IPPS) hospital should bill for the care and annotate the patient's medical record to indicate the patient is an acute care inpatient being housed in the excluded unit because of capacity issues related to the disaster or emergency."

- **Durable medical equipment:** Contractors may waive replacement requirements such as the face-to-face visit, a new physician's order, or medical necessity documentation when the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) is lost, destroyed, irreparably damaged, or otherwise rendered unusable or unavailable as a result of the emergency.
- **Care for excluded inpatient psychiatric unit patients in the acute care unit of a hospital:** Acute care hospitals may relocate inpatients from the excluded distinct part psychiatric unit to an acute care bed and unit. "The hospital should continue to bill for inpatient psychiatric services under the Inpatient Psychiatric Facility Prospective Payment System for these patients and annotate the medical record to indicate the patient is a psychiatric inpatient being cared for in an acute care bed because of capacity or other exigent circumstances related to the COVID-19 emergency."
- **Care for excluded inpatient rehabilitation unit patients in the acute care unit of a hospital:** Acute care hospitals with excluded distinct part inpatient rehabilitation units may relocate inpatients from the excluded distinct part rehabilitation unit to an acute care bed and unit. "The hospital should continue to bill for inpatient rehabilitation services under the inpatient rehabilitation facility prospective payment system for these patients and annotate the medical record to indicate the patient is a rehabilitation inpatient being cared for in an acute care bed because of capacity or other exigent circumstances related to the disaster or emergency."
- **Supporting care for patients in long-term care hospitals (LTCHs):** LTCHs may "exclude patient stays where an LTCH admits or discharges patients in order to meet the demands of the emergency from the 25-day average length of stay requirement, which allows these facilities to be paid as LTCHs."
- **Home health agencies (HHAs):** HHAs are entitled to relief on the time frames related to OASIS Transmission. Medicare administrative contractors (MACs) may extend the auto-cancellation date of requests for anticipated payment during emergencies.
- **Provider locations:** Temporarily waives requirements that out-of-state providers be licensed in the state where they are providing services when they are licensed in another state. This applies to Medicare and Medicaid.
- **Provider enrollment**: Toll-free hotline for "physicians and non-physician practitioners and Part A certified providers and suppliers establishing isolation facilities" to enroll and receive temporary Medicare billing privileges. The application fee, finger-based criminal background checks, and site visits are waived; all revalidation actions are postponed; licensed providers are allowed to render services outside of their state of enrollment; and any pending or new applications from providers are expedited. Despite this waiver, the provider must still comply with the licensure and other laws of each state in which they propose to render services.
- **Medicare appeals in fee-for-service, Medicare Advantage, and Part D:** For MACs and qualified independent contractors in the fee-for-service program, as well as the Medicare Advantage and Part D independent review entities, it provides extension to file an appeal; waives timeliness for requests for additional information to adjudicate the appeal; allows processing of the appeal even with incomplete appointment of representation forms but communicating only to the beneficiary; allows processing of requests for appeal that do not meet the required elements using information that is available; and allows use of all flexibilities

available in the appeal process as if good cause requirements are satisfied.