PUBLICATION

Health Care Providers: President's Emergency Declaration Paves Way for Additional Regulatory Flexibility

March 14, 2020

With the emergency declaration under the National Emergencies Act related to the coronavirus (COVID-19) on March 13, 2020, President Trump paved the way for CMS to temporarily waive certain Medicare, Medicaid, and Children's Health Insurance Program (CHIP) requirements. The President's declaration is intended to provide much needed regulatory relief to our nation's hospitals and other care providers who treat government program beneficiaries. These actions are authorized under Section 1135 of the Social Security Act, which allows the Centers for Medicare & Medicaid Services (CMS) to temporarily waive or modify certain requirements to ensure that sufficient health care items and services are available to meet the needs of government program beneficiaries (Section 1135 Waivers).

Following the press conference announcing the President's actions, CMS issued a COVID-19 Emergency Declaration Health Care Providers Fact Sheet setting forth certain regulatory flexibilities that CMS is authorizing, including blanket waivers of requirements discussed in this article. Notably, however, the industry is still waiting on an official Section 1135 Waiver document issued by Health and Human Services (HHS) Secretary Alex Azar setting forth precise actions and potential additional waivers. For example, in the President's press conference, he suggested that CMS would be relaxing requirements related to physician contracting and leases (presumably, Stark law requirements) and the Emergency Medical Treatment and Labor Act (EMTALA), which are not addressed in the guidance issued thus far. ***See update below.**

What are Section 1135 Waivers?

Section 1135 Waivers are authorized related to COVID-19 now that two actions have occurred: (1) the President has declared an emergency under the National Emergencies Act as of March 1, 2020; and (2) HHS Secretary Alex Azar declared a public health emergency as of January 31, 2020. Under this authority, CMS can issue waivers and modifications of program requirements, such as provider conditions of participation, licensure requirements for physicians and other health care professionals, and certain sanctions related to HIPAA privacy, EMTALA, and Stark. In past emergencies, we have seen CMS issue two types of waivers: (1) "blanket" waivers under which all providers in the affected area qualify, and (2) individual waivers where providers must proactively apply for relief from the particular regulatory requirement. These waivers typically are available until the end of the emergency period, or 60 days from the date the waiver of modification is first published, unless the Secretary extends them. With respect to the COVID-19 emergency, we are still awaiting more concrete information regarding the duration of the waivers, but we expect they will last at least through the period of the emergency declaration.

There are several important things to note with respect to the waivers. First, Section 1135 Waiver authority extends only to federal health care program requirements and does not apply to state law requirements. In the past, the waivers have applied only to program requirements for providers in the discrete affected areas (i.e., hurricane or earthquake area), but the current COVID-19 actions seemingly have nationwide effect. In addition, while the 1135 Waivers provide specific regulatory flexibility, the waivers do not add additional covered services or extend coverage to individuals not otherwise eligible for Medicare, Medicaid, or CHIP.

What is Currently Covered under the Section 1135 Waiver Guidance?

1. Flexibility for Out-of-State Providers

In order to support staffing needs of hospitals and other medical facilities in response to the emergency, CMS is temporarily waiving Medicare requirements that out-of-state providers be licensed in the state where they are providing services when they are licensed in another state. While this supports practitioners providing care where it is most needed, it is important to note that this applies to federal licensure requirements, and all state-level requirements will need to be met or addressed via a requested Medicaid waiver as discussed below.

2. Provider Enrollment

CMS is taking a number of actions from a Provider Enrollment perspective to relax certain requirements and make it easier for new and potential suppliers to obtain billing privileges, including the following:

- Waiving the Medicare enrollment application fee for institutional providers;
- Temporarily waiving requirements related to fingerprint criminal background checks for "high" risk providers, which are typically required of individuals holding five percent or more ownership (e.g., newly enrolling home health aides (HHAs), suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), opioid treatment programs); and
- Relaxing CMS' on-site review authority that allows CMS to conduct site visits of providers and suppliers to verify compliance with the Medicare enrollment requirements.

In addition, CMS states that it will postpone all revalidation actions, and expedite any new or pending Medicare enrollment applications. CMS will also establish a toll-free hotline for non-certified Part B suppliers, physicians, and non-physician practitioners to enroll and receive temporary Medicare billing privileges during this public health emergency.

3. Suspension of Skilled Nursing Facility (SNF) 3-Day Rule

CMS is waiving the requirement at Section 1812(f) of the Social Security Act for a three-day prior hospitalization for coverage of a SNF stay. This will offer temporary emergency coverage of SNF services without a qualifying hospital stay in instances where the impact of the emergency requires transfer of patients outside this timeline. Additionally, CMS is relaxing the coverage requirements for SNF stays for certain beneficiaries who recently exhausted their SNF benefits. SNF coverage can apply for these beneficiaries even if they have not started a new benefit period as required by the regulations.

The waiver is also addressing some of the administrative burdens for SNFs at 42 CFR § 483.20 and provides relief to SNFs on the timeframe requirements for Minimum Data Set assessments and transmission to support the SNFs focus on providing care to patients during the emergency.

4. Hospital and Health Facility Waivers

Critical Access Hospital (CAH) Bed Limits and Length of Stay

Generally, hospitals with a CAH designation must meet several conditions of participation. The waiver suspends two of those conditions. First, the waiver suspends the rule that a CAH may only have 25 or fewer acute care inpatient beds. This waiver would authorize CAHs to treat Medicare inpatients in beds that would not ordinarily be included in the 25 authorized beds, such as certified rehabilitation or psychiatric distinct part units. Second, CMS has indicated it will waive the rule that a CAH may only maintain an annual average length of stay of 96 hours or less for acute care patients. This change would enable CAHs to avoid transferring patients to an acute care setting if the inpatient's stay is more than 96 hours.

Use of Distinct Part Units

Ordinarily, for a hospital to change the bed capacity of a distinct part unit, CMS must approve the changes in advance. In addition, all residents of the distinct part have to be located in units that are physically separate from those units housing other patients of the institution or institutional complex and vis versa. To enable hospitals to utilize capacity most effectively, the Section 1135 Waivers suspend these rules in several contexts.

Housing Acute Care Patients in Distinct Part Units
CMS is waiving requirements to allow acute care hospitals to house acute care inpatients in excluded distinct part units, where the distinct part unit's beds are appropriate for an acute care inpatient. The 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.

Relocation of Excluded Inpatient Psych Unit and Inpatient Rehab Unit Patients
CMS is also waiving the standard requirement that inpatients treated in distinct parts of the hospital covered under benefits other than Inpatient Prospective Payment System (IPPS) must be treated in a bed certified for that special payment program. Under these waivers, CMS will allow acute care hospitals with excluded distinct part inpatient psychiatric units and excluded distinct part inpatient rehabilitation units to relocate patients in those units to an acute care bed and unit if needed as a result of the COVID-19 emergency. The hospital would continue to bill for either inpatient psychiatric services, or inpatient rehabilitation services, as applicable. The hospital should document the need for the relocation in the patient's medical record.

CMS will also allow inpatient rehabilitation facilities (IRFs) to treat acute care patients without the risk of losing their IRF certification based on the failure to reach applicable thresholds, commonly referred to as the "60 percent rule." The 60 percent rule is a Medicare facility criterion that requires each IRF to discharge at least 60 percent of its patients with one of 13 qualifying conditions. Under the waiver, if an IRF admits a patient solely to respond to the emergency and the patient's medical record properly identifies the patient as such, the IRF may calculate the 60 percent threshold without including the emergency patients in the denominator of the inpatient calculation.

Modification of Long Term Care Hospital (LTCH) Length of Stay Requirements

Typically, to qualify as an LTCH for Medicare payment, a facility must meet Medicare conditions of participation for acute care hospitals and its Medicare patients must have an average inpatient length of stay greater than 25 days. This waiver will allow LTCHs to exclude patient stay admissions and discharges related to the response to the COVID-19 emergency from the 25-day average length of stay requirement.

5. HHA Quality Reporting Requirements

CMS is extending the deadlines related to transmission of Outcome and Assessment Information Set (OASIS) assessments for Medicare and Medicaid patients receiving skilled services from HHAs. In addition, CMS announced it will be extending the auto-cancellation deadlines association with requests for anticipated payment (RAPs) for HHAs during this emergency. Typically, HHA providers are given the greater of 60 days after the end of the episode (day 120) or period (day 90) of care, or 60 days after the paid date of a RAP, to submit the final claim. If the final claim is not submitted within the specified time, the claims processing system automatically cancels the RAP. CMS' waiver will extend this auto-cancellation timeline.

6. Durable Medical Equipment Replacement Requirements

Medicare typically limits when DMEPOS can be replaced when it is lost, stolen, destroyed, irreparably damaged, or otherwise rendered unusable. Under the Section 1135 Waiver, contractors have the flexibility to waive replacement requirements such that the face-to-face requirement, a new physician's order, and new

medical necessity documentation are not required in order to provide replacements in a timelier manner. While some requirements are lessened, it is still necessary for suppliers to include a narrative description on the claim explaining the reason why the equipment must be replaced. CMS guidance states that suppliers must also "maintain documentation indicating that the DMEPOS was lost, destroyed, irreparably damaged or otherwise rendered unusable or unavailable as a result of the emergency."

7. Extensions Related to Medicare Fee-for-Service (FFS), Medicare Advantage (MA), and Part D Appeals

Medicare permits providers and suppliers to appeal claims denials. There are typically stringent time limits applicable to filing and pursuing these claims. The waiver offers extension on appeals for FFS claims and MA and Part D appeals. In addition, it provides flexibilities related to timeliness of responding to information requests, and the ability to process appeals even if some information may be incomplete.

Notably, the currently available government guidance does not specifically reference inpatient claims appeals. Also, it does not specify whether the waiver will apply only to claims filed going forward or whether it will apply to claims already denied or in the process of adjudication.

8. Medicaid and CHIP Waivers

In order to support the provision of services during the declared emergency period, the Secretary is authorized to waive not only Medicare requirements, but also certain Medicaid and CHIP requirements as well. These waivers are not automatic and must be requested by the applicable state or territory.

The types of waivers that can be requested through the 1135 process for Medicaid and CHIP include:

- Waive prior authorization requirements in FFS programs;
- Permit providers located out of state/territory to provide care to another state's Medicaid enrollees impacted by the emergency;
- Temporarily suspend certain provider enrollment and revalidation requirements to increase access to care;
- Temporarily waive requirements that physicians and other health care professionals be licensed in the state in which they are providing services, so long as they have an equivalent licensing in another state; and
- Temporarily suspend requirements for certain pre-admission and annual screenings for nursing home residents.

The available flexibilities under such a waiver, as well as how to request such a waiver, are detailed by CMS in the Medicaid and CHIP Disaster Response Toolkit.

What's Next?

As with everything associated with the COVID-19 response, CMS' guidance is being supplemented not just daily, but hour-by-hour. While the above Section 1135 Waiver guidance is a start to providing much needed regulatory flexibility for hospitals and other frontline providers, we expect additional flexibility and waivers to be announced in the coming days. If you have any questions regarding the above guidance, please do not hesitate to reach out to the authors or your trusted Baker Donelson attorney.

***Update as of March 15, 2020:** HHS Secretary Alex Azar issued the official document invoking the Section 1135 Waiver authority as of 6:00 p.m. Eastern on March 15, 2020, with retroactive effect to March 1, 2020. This document indicates that waivers are being provided for, among other things, sanctions under EMTALA, Stark, and certain HIPAA privacy requirements. Notably, the Stark law waiver allows CMS to determine the

conditions and circumstances under which sanctions will be waived. In past Section 1135 Waivers, CMS has required providers to request waivers in writing in advance. We will continue to monitor this issue and provide updates once CMS issues further guidance.

Helpful Resources

CMS Current Emergencies Website

CMS Section 1135 Waiver Website