Section 1135 Waivers – Flexibilities for States and Providers to Combat COVID-19

by Michael Park, Brian Lee, and Emily Shaw

On March 13, 2020, President Trump declared a national emergency in response to the coronavirus (COVID-19) outbreak under the National Emergencies Act (NEA) and the Robert T. Stafford Disaster Relief and Emergency Assistance Act. This declaration, in conjunction with the January 31, 2020 Public Health Emergency declaration made by the Secretary of the U.S. Department of Health and Human Services (HHS), provided HHS with the authority under Section 1135 of the Social Security Act to waive or modify certain Medicare, Medicaid, Children’s Health Insurance Program (CHIP), and Health Information Portability and Accountability Act (HIPAA) requirements. Thus far, HHS and CMS announced several blanket waivers/modifications of certain restrictions and program requirements and announced additional guidance related to these waivers.

Following the President’s declaration, the Centers for Medicare & Medicaid Services (CMS) announced nationwide (blanket) waivers and modifications of certain federal requirements for hospitals; post-acute care providers; durable medical equipment (DME), prosthetics, orthotics, and supplies (DMEPOS) suppliers; providers; and program integrity and oversight. CMS Administrator Seema Verma announced that these waivers are retroactive to March 1, 2020. On March 17, 2020, CMS announced additional waivers, retroactive to March 6, 2020, that pertain to telehealth and the provision of virtual services. In conjunction with the telehealth waiver, the Office of Inspector General (OIG) and the Office of Civil Rights (OCR) each announced guidance that they would not impose penalties and sanctions associated with certain violations of the Anti-Kickback Statute (AKS) and HIPAA rules, respectively. To date, CMS has not announced waivers of sanctions related to the Emergency Medical Treatment and Labor Act (EMTALA), but has indicated that a blanket waiver is forthcoming.

I. Background on 1135 Waivers

Section 1135 waivers are intended to ensure sufficient health care items and services are available to Medicare, Medicaid, and CHIP beneficiaries while also ensuring health care providers delivering such services in good faith can be reimbursed and not subjected to certain sanctions for noncompliance, absent any fraud or abuse. These waivers apply to federal requirements only (e.g., they do not apply to state licensure requirements or state conditions of participation) and generally end no later than the termination of the emergency period or 60 days from the date of the waiver (absent an extension by the HHS Secretary). Like the CMS waivers announced on March 13, 2020, section 1135 waivers may be retroactive to an earlier date.

Section 1135(b) of the Social Security Act specifies the Secretary’s authority to waive or modify the following:

- Conditions of participation or other certification requirements for an individual health care provider or types of providers.
- Program participation and similar requirements for an individual health care provider or types of providers.
- Pre-approval requirements.
- State licensure requirements.
- Actions under the Emergency Medical Treatment and Labor Act (EMTALA) regarding transfers and direction or relocation of individuals to receive medical screening.
- Sanctions for violations of physician self-referral rules.
- Deadlines and timetables for performance of required activities (may be modified, not waived).
Limitations on the ability to make direct payments to providers for services provided to Medicare Advantage enrollees.

Sanctions and penalties for noncompliance with certain privacy provisions of HIPAA.

CMS has released guidance on implementing additional emergency and disaster-related policies and procedures with and without an 1135 waiver.

a. Applicability

When 1135 waiver authority is invoked, there are various federal health care program policies and procedures as well as requirements waivers or modifications may apply to. However, the 1135 waivers do not provide financial assistance (these generally come from the Small Business Administration disaster assistance loans and the Federal Emergency Management Agency Public Assistance Program). Further, 1135 waivers do not permit a waiver of Medicare coverage or payment rules.

Through the 1135 waiver authority, CMS may issue blanket waivers that apply broadly for certain types of services and facilities, meaning covered health care providers do not need to obtain provider-specific approval from State Survey Agencies or CMS Regional Offices (ROs) for these waivers. CMS recommends, however, that providers notify the State Survey Agency and CMS ROs that they will be operating under the modifications to ensure proper payment. States and individual health care providers also may request additional waivers.

b. Individual waiver requests

States (e.g., state departments of health) and individual health care providers/suppliers can request additional waivers by emailing the State Survey Agencies or CMS ROs. For example, CMS has encouraged states to consider and seek specific waivers for Medicaid that allow providers to care for COVID-19 patients in other states and to reduce licensing requirements. On March 12, 2020, CMS issued a Frequently Asked Questions document for State Medicaid and CHIP Agencies (which was subsequently updated on march 18, 2020) for authorities and flexibilities under an emergency. In this document, CMS describes resources available to respond to COVID-19, including flexibilities related to eligibility and enrollment, benefits, cost-sharing, financing, and the workforce.

According to CMS’s 1135 waiver request guidance, there is no specific form or format for the request, but CMS states that it is helpful if the requester states the scope of the issue and the impact. In addition, the request should include the following basic information:

- Provider name/type
- Full address and Medicare provider number
- Contact person and contact information
- Brief summary of why the waiver is needed
- Type of relief or regulatory reference requested to be waived

CMS recommends that health care provider 1135 waiver requests also be sent to the appropriate state agency to ensure the waiver request does not conflict with any state requirements.

c. Other flexibilities

In addition to the 1135 waivers, HHS also may issue a section 1812(f) waiver to provide for skilled nursing facility (SNF) coverage in the absence of a qualifying hospital stay. CMS activated this authority on March 13, 2020.
II. Blanket Waivers as of March 17, 2020

Below is an overview of the announced regulatory flexibilities as of March 17, 2020. Additional waivers are expected, and states and health care providers continue to have the option of requesting additional waivers if needed.

<table>
<thead>
<tr>
<th>Waiver Category</th>
<th>Overview of Waivers</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hospitals</strong></td>
<td></td>
</tr>
</tbody>
</table>
| **Critical Access Hospitals (CAHs)** | • CMS is waiving the requirements that CAHs limit the number of beds to 25.  
• CMS also is waiving the 96-hour length of stay limit. |
| **Housing Acute Care Patients in Excluded Distinct Part Units** | • CMS is waiving requirements to allow acute care hospitals (ACHs) to house acute care inpatients in excluded distinct part units, where the distinct part unit’s beds are appropriate for acute care inpatients.  
  o The 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. |
| **Care for Excluded Inpatient Psychiatric Unit Patients in the Acute Care Unit of a Hospital** | • CMS is waiving requirements to allow ACHs with excluded distinct part inpatient psychiatric units that, due to the emergency, need to relocate inpatients from the excluded distinct part psychiatric unit to an acute care bed and unit.  
  o The hospital should continue to bill for inpatient psychiatric services under the Inpatient Psychiatric Facility Prospective Payment System (PPS) for impacted 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 emergency.  
  o This waiver may be utilized when the hospital’s acute care beds are appropriate for psychiatric patients and the staff and environment are conducive to safe care. For psychiatric patients, this includes assessment of the acute care bed and unit location to ensure those patients at risk of harm to self and others are safely cared for. |
| **Care for Excluded Inpatient Rehabilitation Unit Patients in the Acute Care Unit of a Hospital** | • CMS is waiving requirements to allow ACHs with excluded distinct part Inpatient Rehabilitation units that, due to the emergency, need to relocate inpatients from the excluded distinct part rehabilitation unit to an acute care bed and unit.  
  o The hospital should continue to bill for inpatient rehabilitation services under the Inpatient Rehabilitation Facility (IRF) PPS for such 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 emergency.  
  o This waiver may be utilized when the hospital’s acute care beds are appropriate for providing care to rehabilitation patients and such patients continue to receive intensive rehabilitation services.  
• CMS also is waiving requirements to allow IRFs to exclude patients from the hospital’s or unit’s inpatient population for purposes of calculating the applicable thresholds associated with the 60 percent rule if the IRF admits a patient solely to
respond to the emergency and the patient’s medical record properly identifies the patient as such.
- This waiver also applies to facilities not yet classified, but are attempting to obtain classification as an IRF.

**Supporting Care for Patients in Long-Term Care Acute Hospitals (LTCHs)**
- CMS is waiving 25-day average length of stay requirement for certain patient stays (admissions or discharges in order to meet the demands of the emergency) so that these facilities can continue to be paid as LTCHs.

### Post-Acute Care

**Skilled Nursing Facilities (SNFs)**
- CMS is waiving the 3-day prior hospitalization stay requirement for coverage of a SNF stay. In addition, for beneficiaries who exhausted their SNF benefits, the waiver authorizes renewed SNF coverage without having to start a new benefit period.
  - According to CMS, the waiver provides SNF eligibility regardless of whether a beneficiary is discharged from a hospital or admitted from the community (e.g., from home or a physician office). This waiver also applies to dates of service beginning on March 1, 2020.
- CMS also is waiving timeframe requirements for Minimum Data Set assessments and transmissions.

**Home Health Agencies (HHAs)**
- CMS is providing HHAs with flexibility with respect to OASIS Transmission timeframes.
- CMS also is allowing Medicare Administrative Contractors to extend the auto-cancellation date of Requests for Anticipated Payment (RAPs).

### Suppliers

**Durable Medical Equipment (DME)**
- CMS is providing flexibility for DME, Prosthetics, Orthotics, and Supplies (DMEPOS) contractors to waive replacement requirements for DMEPOS that are lost, destroyed, irreparably damaged, or otherwise rendered unusable due to the emergency.
  - Suppliers can waive the face-to-face requirement, and the new physician’s order and new medical necessity documentation are not required.
  - Suppliers must still include a narrative description on the claim explaining the reason why the equipment must be replaced and maintain documentation indicating that the DMEPOS was replaced as a result of the emergency.

### Provider Requirements

**Provider Locations**
- CMS is waiving requirements that out-of-state providers be licensed in the state where they are providing services when they are licensed in another state (only applies to Medicare and Medicaid and subject to the State waiving any relevant licensure requirements (see question 1135E-1, here).

**Provider Enrollment**
- CMS is allowing licensed providers to render services outside of their state of enrollment.
- CMS is postponing all revalidation actions and is expediting any pending or new provider applications.
- CMS is establishing a toll-free hotline for non-certified Part B suppliers, physicians, and non-physician practitioners to enroll and receive temporary Medicare billing privileges.
- CMS is waiving the following screening requirements for Medicare enrollment: (1) application fee; (2) criminal background checks associated with fingerprint-based criminal background checks; and (3) site visits to verify accuracy and compliance with Medicare enrollment requirements.
<table>
<thead>
<tr>
<th>Program Integrity and Oversight</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medicare Appeals in Fee-For-Service (FFS), Medicare Advantage (MA), and Part D</strong></td>
</tr>
<tr>
<td>• CMS is providing an extension to file appeals and waiving timelines for requests for additional information to adjudicate an appeal.</td>
</tr>
<tr>
<td>• CMS is processing appeals even with incomplete Appointment of Representation forms and processing requests for appeal that do not meet the required elements using the information that is available.</td>
</tr>
<tr>
<td>• CMS is utilizing all flexibilities available in the appeal process as if good cause requirements have been satisfied.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Telehealth, AKS, and HIPAA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Originating Site</strong></td>
</tr>
<tr>
<td>• CMS is waiving the requirements that telehealth services be provided to beneficiaries in one of the nine eligible originating sites and that the originating site be in a health professional shortage area outside of a Metropolitan Statistical Area (MSA) or a county not included in an MSA.</td>
</tr>
<tr>
<td>o Note, however, that only the listed eligible originating sites may bill for the originating site facility fee.</td>
</tr>
<tr>
<td>• HHS also announced that it will not be auditing the pre-established patient requirement (i.e., the beneficiary was seen by the practitioner or another practitioner within the practice within the last 3 years and billed Medicare for the service) during the public health emergency, effectively nullifying this requirement.</td>
</tr>
</tbody>
</table>

| **Telephone Use** |
| • CMS is waiving the requirement that telehealth be delivered through a two-way, real-time, interactive telecommunication between the patient and the distant site practitioner, which specifically excludes the use of telephones. |
| o Under this waiver, telephones may be used to provide Medicare-reimbursable telehealth services, provided the telephone has real-time audio-video capabilities. |
| o Normally, telehealth services would require a secure, encrypted communications platform and HIPAA-compliant business associate agreement (BAA) with the technology vendor. See below on HIPAA Privacy & Security Rule Enforcement. |

| **State Licensure** |
| • CMS is waiving the requirement that practitioners be licensed in the state or enrolled in Medicare in that jurisdiction so long as the practitioner holds an equivalent license in another state and is enrolled in Medicare where licensed. The practitioner also must not be excluded from practice in any state. |
| o Note, however, that this does not affect state licensing requirements. |

| **Cost-Sharing and AKS** |
| • OIG announced that it will not subject practitioners to sanctions for reductions or waivers of beneficiary cost-sharing obligations for telehealth services. Normally, these could subject practitioners to AKS penalties. This protection is available during the public health emergency. |

| **HIPAA** |
| • OCR announced that it will not impose penalties for noncompliance with certain HIPAA security requirements for telehealth services provided in good faith during the public health emergency. |
| o The telehealth service can be provided for any reason and occur through any number of applications that support video chat (e.g., Apple FaceTime, Facebook Messenger, Google Hangouts, Skype). |
III. Emergency Medical Treatment and Labor Act (EMTALA) Considerations

CMS guidance issued on March 9, 2020 to State Survey Agency Directors reiterated the EMTALA screening obligation for all hospitals and CAHs (referred to collectively as hospitals in this section) with a dedicated emergency department (ED). This memo also provides guidance on alternative screening sites and delivering medical screening exams (MSEs), to alleviate pressure on hospitals and their EDs. Absent an 1135 waiver, hospitals must adhere to current requirements, including that they may not direct an individual coming to the ED to any off-campus location for screening. In addition, the Medicare Conditions of Participation require that hospitals have policies and procedures based on the facility’s emergency preparedness plan as well as their role if an 1135 waiver is declared.

Currently, the EMTALA screening obligation applies to patients suspected of having COVID-19. However, even absent an 1135 waiver, the MSE does not have to occur in an ED. In addition, the content of the MSE is expected to vary based on the individual’s presenting signs and symptoms. According to CMS guidance, the MSE can be “as simple or as complex, as needed, to determine if an [emergency medical condition] exists.” Further, MSEs must be conducted by qualified personnel (e.g., a physician, nurse practitioner, physician’s assistant, or registered nurse) trained to perform MSEs and operating within that individual’s State scope of practice laws. As noted above, CMS has indicated that it plans to issue an EMTALA 1135 waiver in the coming days.

a. Alternative Sites Absent an 1135 Waiver

MSEs may occur at three different types of alternative screening sites. The alternative sites can be in other buildings on a hospital campus or “in tents in the parking lot,” so long as they are determined to be an appropriate setting for medical screening activities and meet the clinical requirements of those individuals referred to the alternative site. The alternative sites also can be non-hospital controlled community screening clinics. These sites also must meet certain requirements, described below.

i. On-Campus Alternative Screening Sites

On-campus sites must be part of the certified hospital. If not, the hospital must take steps to add the location as a new practice location of the hospital. Hospitals can set up log-in and redirection – including outside of the entrance to the ED – to the alternative site, but the person directing should be qualified (e.g., a registered nurse) to recognize individuals “obviously in need of immediate treatment in the ED.” The hospital must stabilize (or appropriately transfer) individuals with an emergency medical condition (EMC), including moving them from the alternative site to another on-campus department.

ii. Off-Campus, Hospital-Controlled Alternative Screening Sites
Hospitals and community officials may encourage the general public to go to these sites for influenza-like illnesses (ILIs); they should not be advertised as a site of care for EMCs. Subsequently, these sites should be staffed by medical personnel trained to evaluate ILIs and, unless the off-campus site is a dedicated ED, EMTALA requirements do not apply. However, if an individual coming to an off-campus site needs emergency care, the hospital must arrange referral or transfer. CMS recommends prior coordination with local emergency medical services for transport arrangements from the off-campus site, if needed. Further, hospitals may not direct individuals coming to the hospital’s ED to go to the off-site location for an MSE.

iii. Community Screening Clinics Not Controlled by the Hospital

Similar to off-campus, hospital-controlled alternative sites, hospitals and community officials may:
- Encourage the general public to go to these sites for ILIs;
- These sites should be staffed by medical personnel trained to evaluate ILIs;
- There is no EMTALA obligation at these sites; and
- Hospitals may not direct individuals coming to the hospital’s ED to go to the off-site location for an MSE.

CMS recommends that the community, hospitals, and emergency medical services plan for referral and transport of individuals needing additional medical attention or who have EMCs.

b. EMTALA 1135 Waiver

1135 EMTALA waivers are limited to waiver of certain EMTALA sanctions and certain prerequisites must be met. These requirements include: (1) President declares an emergency; (2) HHS Secretary declares a public health emergency; (3) CMS issues 1135 waiver for EMTALA sanctions for violations due to the emergency; (4) hospital has implemented its disaster protocol; and (5) CMS determines that sufficient grounds exist for waiving EMTALA sanctions. In terms of duration, because the emergency is related to a pandemic infectious disease, waiver of EMTALA requirements would be in place until the termination of the emergency (waiver of sanctions for non-pandemic disease emergencies are limited to a 72-hour period).

Moreover, CMS is only able to waive sanctions related to two EMTALA provisions:
1. For an inappropriate transfer (if the transfer is necessary due to the circumstances of the emergency); and
2. For the relocation or direction of an individual to receive MSEs in an alternate location pursuant to an appropriate State pandemic/emergency preparedness plan.

In addition, the waiver is applicable only if the hospital’s actions do not discriminate against individuals based on the source of payment or ability to pay (see question 1135N-5, here). Even with an EMTALA waiver, hospitals should follow standard documentation procedures and protocols. Specifically, any change in care delivery permitted under the waiver should be documented, indicating that the transfer and/or relocation was due to the circumstances of the emergency and pursuant to an appropriate State pandemic/emergency preparedness plan. As previously noted, the content of MSEs is expected to vary and can be simple or complex, as needed.

IV. Medicaid and CHIP 1135 waivers

Medicaid and CHIP can play a critical role in helping states and territories respond to public health events. States and territories can seek flexibilities through an 1135 waiver request. There is no specific format for 1135 waiver requests, but the state should clearly state the scope of the issue and the impact. Such requests should be submitted to Jackie Glaze, CMS Acting Director of Medicaid & CHIP Operations Group, by
email (Jackie.Glaze@cms.hhs.gov) or letter. CMS will issue waivers in response to such state requests. Some examples of these flexibilities available under an 1135 waiver include:

- Waiving prior authorization requirements in fee-for-service programs.
- Permitting providers located out of state/territory to provide care to another state’s Medicaid enrollees impacted by the emergency.
- Temporarily suspending certain provider enrollment and revalidation requirements to increase access to care.
- Temporarily waiving requirements that physicians and other health care professionals equivalently licensed in other states be licensed in the state they are providing services.
- Temporarily suspending requirements for certain pre-admission and annual screenings for nursing home residents.
- Extending appeals request timelines and waiving exhaustion requirements.
- Temporarily suspending certain registered nurse supervision requirements for home health agencies and hospice agencies.

Examples of previous CMS state-specific waiver issuances include:

- Louisiana (9/1/2017)
- North Carolina (9/17/2019)

At the time of writing, CMS has approved one state-specific 1135 waiver, Florida (3/16/2020). CMS plans to post additional 1135 waivers as they are issued here.

For a more comprehensive list of 1135 waiver flexibilities, see the CMS COVID-19 Health Care Providers Fact Sheet and the Medicaid and CHIP (MAC) Learning Collaborative Inventory of Flexibilities and Authorities in the Event of a Disaster. The latter document includes other authorities, in addition to the 1135 waivers, that are available to states and territories. These include Medicaid State Plan Amendments, CHIP Disaster Relief State Plan Amendments, Verification Plans, 1915(c) waiver (submitted through Appendix K), and 1115 demonstrations. For example, through a 1915(c) waiver, if a Medicaid enrollee already meeting an institutional level of care is quarantined in the community, states could add Live in Caregiver as a service, authorizing family members as providers. Home-delivered meals, such as Meals on Wheels, could be added to provide one meal per day to the individual. A State Plan Amendment could be submitted to stop charging copayments for particular items or services in Medicaid. For further details relating to operationalization of Medicaid flexibilities, see the CMS COVID-19 Frequently Asked Questions for State Medicaid and CHIP Agencies.

V. Next Steps for Health Care Providers and Suppliers

As states and the Federal government continue to work to combat COVID-19, additional 1135 waivers are expected, especially related to EMTALA. While there are blanket waivers, states and health care providers should communicate with the appropriate CMS ROs (in coordination with the relevant State agency) to notify them of the intent to utilize the waivers and modifications for payment purposes. In addition, certain states, territories, and local areas may have unique needs not covered by the current 1135 waivers, and they should make additional 1135 waiver requests.

a. Documentation and Coding Considerations

When providing services under an 1135 waiver, health care providers should, to the greatest extent possible comply with normal documentation requirements. In addition, pursuant to Chapter 38 of the Medicare Claims Processing Manual, institutional and non-institutional providers should add certain condition codes and modifiers to emergency-related claims for which Medicare payment is conditioned.
i. **Documentation Guidance**

The 1135 waivers may permit new flexibilities, but coverage and payment requirements are not changed. Subsequently, the most important documentation guidance is to follow standard procedures for the service delivered. In addition, when HHS or CMS provides an 1135 waiver, the agency “will usually tailor its response to specific, identified needs that are communicated by or through State officials or health industry representatives” (see question A-3, here).

In addition, health care providers should clearly annotate in the patient’s medical record (i.e., include a narrative description) that the service was delivered in whatever modified way authorized by the 1135 waiver due to issues related to the emergency. For example, acute care hospitals housing inpatients in excluded distinct part units should annotate the patient’s medical record to indicate the patient is an acute care inpatient housed in the excluded unit because of capacity issues related to the emergency. In addition, health care providers should be sure to maintain adequate documentation of the services furnished pursuant to the waiver to support the provision of care and payment. Similarly, if an EMTALA waiver is provided, newly permissible transfers should include clear documentation that they occurred due to the circumstances of the emergency.

ii. **General Billing Procedures**

On March 16, 2020, CMS released guidance on Medicare fee-for-service (FFS) billing during the COVID-19 national emergency. Specifically, the guidance states that providers should apply the following to Medicare FFS claims delivered under a blanket waiver:

- The “DR” (disaster related) condition code for institutional billing (i.e., claims submitted using the ASC X12 837 institutional claims format or paper Form CMS-1450).
- The “CR” (catastrophe/disaster related) modifier for Part B billing, both institutional and non-institutional (i.e., claims submitted using the ASC X12 837 professional claim format or paper Form CMS-1500 or, for pharmacies, in the NCPDP format).

In practice, institutional providers (e.g., hospitals, skilled nursing facilities) should use the “DR” condition code in all billing situations related to a declared emergency. Specifically, the DR code is mandatory for any claim for which Medicare payment is conditioned. Non-institutional providers (e.g., physicians, non-physician practitioners, suppliers) must use the “CR” modifier for applicable HCPCS codes on any claim for which Medicare Part B payment is conditioned.

Note that the requirement or authorization to use either the DR condition code or the CR modifier does not constitute a waiver of a Medicare requirement; it merely reflects that a waiver or other special condition may apply to the item or service delivered during the emergency. When the DR condition code or the CR modifier is required, Medicare contractors will notify providers and suppliers of the appropriate use of the DR code and CR modifier (see question 1135D-2, here).

* * *

In addition to advising clients on how obtaining and appropriately operating under an 1135 waiver, Alston & Bird has established a multidisciplinary task force to aid clients in answering the wide array of questions arising from the COVID-19 outbreak.