Updates
March 25, 2020
Guide to Federal Health Program Waivers Concerning the COVID-19 Crisis

The federal Department of Health and Human Services (HHS) on March 13, 2020, invoked its authority under section 1135 of the Social Security Act (the act) to waive certain requirements that providers normally must meet to receive reimbursement for services to Medicare, Medicaid, and Children's Hospital Insurance Program (CHIP) beneficiaries. This action is intended to help general acute care hospitals, Critical Access Hospitals (CAHs), skilled nursing facilities (SNFs), physicians, and other providers address an impending healthcare crisis due to the transmission of the novel coronavirus and the spread of COVID-19 disease.

HHS is empowered to issue section 1135 waivers to ensure—to the maximum extent feasible—that sufficient healthcare items and services are available to Medicare, Medicaid, and CHIP enrollees during a declared emergency. Section 1135 waivers are designed to allow providers to receive reimbursement under these federal healthcare programs when in good faith they must rely on the privileges and relaxed requirements the waivers afford in addressing the declared emergency.

Section 1135 allows HHS to waive the following:

1. Conditions of participation, pre-approval requirements, and other requirements that healthcare providers must meet to participate in Medicare
2. Requirements that physicians or other healthcare professionals hold licenses in the state in which they provide services, if they have an equivalent license from another state (and are not affirmatively barred from practice in that or any state which is included in the emergency area)
3. Sanctions under the Emergency Medical Treatment and Labor Act (EMTALA) for violating certain EMTALA obligations related to medical screening and transfer of patients who present at a facility that must comply with EMTALA
4. Sanctions under the Physician Self-Referral Law (the "Stark" law)
5. Limitations on payments for healthcare items and services furnished to Medicare+Choice beneficiaries by out-of-network providers
6. Sanctions and penalties for noncompliance with certain, specified requirements imposed by the Health Insurance Portability and Accountability Act (HIPAA) for a limited duration of 72 hours after the implementation of a hospital disaster protocol

In addition, the waiver allows HHS to modify deadlines and timetables for performance of activities required under the Medicare, Medicaid, or CHIP programs.

In some prior uses of its section 1135 authority, HHS authorized the waiver or modification of such requirements once both preconditions for doing so were met: (1) the president's declaration of an emergency or disaster under the National Emergencies Act and/or the Stafford Disaster Relief and Emergency Assistance Act; and (2) the Secretary of HHS declaration of a public health emergency under the Public Health Service Act. Thereafter, states, local governments, and industry groups, such as state hospital associations, healthcare systems, or individual providers, made written requests to the appropriate regional office of the Centers for Medicare and Medicaid Services (CMS) or the relevant state survey agency to operate under one of the 1135 waivers that HHS had authorized. The requesting party typically was required to explain why a particular 1135 waiver was needed to operate under the circumstances created by the emergency, including a description of the pertinent facts and how it would operate under the particular 1135 waiver it was seeking. CMS has also issued "blanket waivers" that apply to all similarly situated providers located in the area covered by an emergency declaration.

On March 13, 2020, CMS issued several blanket 1135 waivers related to COVID-19 without first reviewing specific requests (the blanket waivers). Providers need not obtain additional approval or authorization from CMS to operate under a blanket waiver. HHS also authorized CMS to issue all other allowed 1135 waivers (the authorized waivers). To obtain an authorized waiver, a written request should be made to the applicable CMS regional office and, if applicable, the relevant state survey agency to receive approval to operate under any authorized waiver.

The blanket waivers take effect beginning March 1, 2020, (the effective date of the president's declaration of a national emergency) and apply to all providers in the United States. The March 1, 2020, effective date also applies to any authorized waiver approved by CMS.

Section 1135 waivers expire either 60 days after their publication (noting a March 13, 2020, publication date for the blanket waivers) or upon the termination of the emergency as declared by the president or the HHS secretary. HHS may renew the terms of any 1135 waiver for additional 60-day periods (assuming that the emergency declarations remain in place).

The COVID-19 1135 Blanket Waivers

In issuing nation-wide COVID-19 blanket waivers, CMS recognized the enormous public health crisis the nation is facing. Providers can now operate under these relaxed regulations while still billing and receiving reimbursement under the Medicare, Medicaid, and CHIP programs for services rendered on or after March 1, 2020, that fall under the terms of the blanket waivers.

To date, HHS has issued the following blanket waivers:

General Acute Care Hospitals

- Acute care hospitals may house acute care inpatients in excluded distinct part units, provided the unit's beds are appropriate for acute care inpatients. Hospitals should bill for the care under the Inpatient Prospective Payment System (IPPS) 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.
- Acute care hospitals with excluded distinct part inpatient psychiatric units or with excluded distinct part inpatient rehabilitation units may relocate inpatients from the excluded distinct part unit to an acute care bed and unit. The hospital should continue to bill under the applicable Prospective Payment System as it previously did. The hospital should also annotate the medical record to indicate the patient is a psychiatric or rehabilitation inpatient being cared for in an acute care bed because of capacity or other exigent circumstances related to COVID-19. This 1135 waiver may be used only if the hospital's acute care beds are appropriate for psychiatric or rehabilitation patients. For psychiatric inpatients, the staff and environment must be conducive to safe care, including the safety of patients at risk of harm to themselves and other patients in the acute care beds. For rehabilitation inpatients, the patients must continue to receive intensive rehabilitation services.
- CMS has temporarily waived requirements under Medicare and Medicaid that out-of-state physicians and other providers be licensed in the state where they are providing services, provided they are duly licensed in another state.
- Acute care hospitals with distinct part inpatient rehabilitation units can exclude patients admitted solely to respond to the COVID-19 emergency from the unit's inpatient population for purposes of meeting the "60% rule" to receive reimbursement as an Inpatient Rehabilitation Facility. To avail itself of this

allowance, the hospital must ensure that the patient's medical record accurately identifies the patient as admitted to the rehabilitation unit solely due to the COVID-19 emergency.

Inpatient Rehabilitation Facilities (IRF)

- Like the 1135 waiver applicable to distinct part inpatient rehabilitation units, an IRF can exclude patients admitted solely to respond to the COVID-19 emergency from its inpatient population for purposes of meeting the 60% rule. The hospital must ensure that the patient's medical record properly identifies the patient as admitted to the IRF solely due to the COVID-19 emergency.

Critical Access Hospitals (CAH)

- CMS has provided a blanket waiver for the requirement that a CAH limit the number of its beds to 25, and the length of patient stays to 96 hours. CAH patients would not be counted toward the determination of the 25-bed limit or considered for the 96-hour average length of stay limit if their stays are clearly identified in the medical record as relating to the COVID-19 emergency. CAHs must also annotate all Medicare fee-for-service claims for such admissions or length-of-stay extensions with the "DR" condition code or the "CR" modifier, as applicable, for the period that the CAH remains affected by the COVID-19 emergency.

Skilled Nursing Facilities (SNF)

- CMS is waiving the requirement at section 1812(f) of the act that requires at least a three-day hospitalization before Medicare will cover SNF services provided to those people who need to be transferred **to or from** an SNF as a result of COVID-19. This includes persons evacuated from a nursing home, persons discharged from a hospital and transferred to an SNF so the hospital can provide care to patients experiencing COVID-19, and patients who need SNF care due to COVID-19.
- For beneficiaries who recently exhausted their 100-day SNF benefits and are no longer admitted at an SNF, the 1135 waiver renews SNF coverage for an additional 100 days without first waiting 60 days for the start of a new benefit period, as is typically required.
- CMS is waiving 42 CFR section 483.20 timing requirements for Minimum Data Set assessments and transmission.

Long-Term Care Hospitals (LTCH)

- LTCHs may exclude from the 25-day average length of stay requirement those patient stays resulting from an the admission **or** discharge necessitated by COVID-19 response. The medical record must clearly reflect when an admission or discharge is made to meet the demands of the COVID-19 emergency, and associated Medicare fee-for-service claims must contain the "DR" condition code or the "CR" modifier, as applicable, for the period that the LTCH is affected by the COVD-19 emergency.

Suppliers of Durable Medical Equipment Prosthetics, Orthotics, and Supplies (DMEPOS)

- DMEPOS suppliers may waive replacement requirements when the equipment is lost, destroyed, irreparably damaged, or otherwise rendered unusable as result of the COVID-19 emergency. Such requirements include the face-to-face requirement, a new physician order, and new medical necessity documentation. Suppliers must include a narrative description on the claim explaining the reason why the equipment must be replaced and must maintain documentation indicating that the DMEPOS was lost, destroyed, irreparably damaged, or otherwise rendered unusable or unavailable as a result of the COVID-19 emergency.

Home Health Agencies

- CMS is relieving home health agencies of the timeframes for Outcome and Assessment Information Set (OASIS) reporting.
- CMS is allowing Medicare Administrative Contractors (MAC) to extend the auto-cancellation date of Requests for Anticipated Payment (RAP) during emergencies.

Licensed Practitioners (physicians, physician assistants, CRNAs, RNs, etc.)

- CMS has temporarily waived Medicare and Medicaid requirements that out-of-state providers be licensed in the state where they are providing services if they have an equivalent license from another state and are not affirmatively barred from practice in any other state. It is important to keep in mind, however, that CMS typically requires that the following three conditions be met:

    1. The practitioner must be enrolled in the Medicare program
    2. The practitioner must have a valid license to practice in the state which relates to the practitioner's Medicare enrollment
    3. The practitioner traveled to the state in order to contribute to emergency relief efforts in a professional capacity
- The practitioner should enroll with the MAC that covers the state in which the emergency work is performed and should bill that MAC. CMS has implemented streamlined provider enrollment processes under the blanker waivers that would apply for these purposes (see immediately below).

Provider Enrollment

- CMS is taking the following steps to expedite enrollment of providers in Medicare:
    - Establishing a toll-free hotline for non-certified Part B suppliers, physicians, and non-physician practitioners to enroll and receive temporary Medicare billing privileges
    - Waiving the following screening requirements: application fee (42 C.F.R § 424.514); criminal background checks associated with fingerprint-based criminal background checks (FCBC) (42 C.F.R § 424.518); and site visits (42 C.F.R § 424.517)
    - Postponing revalidation actions
    - Expediting pending or new applications from providers

Medicare Coverage and Benefits Appeals for Beneficiaries Enrolled in the Fee-for-Service Program, Medicare Advantage, or Medicare Part D

- CMS is relaxing the Medicare appeals process to do the following:
    - Extend the time to file an appeal
    - Waive timeliness for requests for additional information to adjudicate the appeal
    - Process the appeal even with incomplete Appointment of Representation forms but communicating only with the beneficiary
    - Process requests for appeal that don't meet all the required elements
    - Offer other flexibility if good cause is shown

Physician Self-Referral Law (Stark Law)

- CMS initially announced on March 13, 2020, that sanctions under the Stark Law will be waived on a case-by-case basis as determined appropriate by CMS. But CMS recently announced that in the imminent future it will issue "blanket waivers" with respect to Stark law requirements, which would be effective nationwide as of March 1, 2020. These waivers will not apply to any action taken that discriminates among individuals based on their source of payment or ability to pay. The Stark Law in general prohibits

physicians from billing Medicare or Medicaid for services rendered to patients referred to certain providers (designated health services) with which the physician or the physician's family has a financial relationship unless an exception prescribed in federal law applies.

The COVID-19 1135 Authorized Waivers

HHS has authorized CMS to issue any of the other 1135 waivers listed above that can be implemented under the act. As discussed below, states, providers, or other stakeholders must receive specific approval from CMS to operate under these 1135 waivers (*see* Guideline 6 below).

Emergency Medical Treatment and Labor Act (EMTALA)

- Without incurring sanctions under EMTALA, providers may direct or relocate an individual to another location to receive medical screening pursuant to an appropriate state emergency preparedness plan or transfer an individual who has not been stabilized if the transfer is necessitated by the COVID-19 pandemic. This 1135 waiver does not apply to any action that discriminates among individuals on the basis of their source of payment or ability to pay.
- Although HHS' public notice indicates that the EMTALA 1135 waiver is available for providers to request but is not a blanket waiver, CMS informed the Texas Hospital Association that it indeed is a blanket waiver that providers may rely upon without further action. Despite this, stakeholders should confirm the Texas advice in writing to their CMS regional office.

Health Insurance Portability and Accountability Act (HIPAA)

- HIPAA sanctions and penalties are waived for noncompliance with the following provisions of the HIPAA privacy regulations: (1) obtaining 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;[1] (2) distributing a notice of privacy practices;[2] and (3) the patient's right to request privacy restrictions or confidential communications.[3] In order for the waiver to apply, the following conditions must be met:
    - Hospitals must have hospital disaster protocols in operation during the time the 1135 waivers are in effect
    - The 1135 waivers are only in effect after the implementation of a hospital disaster protocol, and no longer than the duration of the 1135 waiver emergency period
    - This waiver does not apply to any action taken that discriminates among individuals based on their ability to pay or the source of payment

Additional Guidelines for Providers

1. Operation under the blanket waivers or authorized waivers is limited to allowing providers to address the public health emergency brought on by COVID-19. Providers should rely on these waivers only to the extent reasonably necessary to address the novel coronavirus pandemic.
2. To ensure proper reimbursement, providers and suppliers should routinize recording in the medical record and on claim forms that the services are waiver-exempt as necessitated by the COVID-19 emergency.
3. With the exception of the HIPAA authorized waiver discussed above, the blanket waivers and any approved authorized waiver will be in effect from March 1, 2020. These waivers will terminate at the end of the declared emergency period and will in general need to be renewed every 60 days from the date of their initial publication (in the case of the blanket waivers) or approval (in the case of the authorized waivers). That said, CMS guidance includes the directive that providers should resume compliance with

applicable Medicare, Medicaid, and CHIP requirements and regulations when they are able to comply with the waived requirements based on their particular facts and circumstances. If providers are in doubt about whether they can rely on a waiver, they should consult counsel or directly contact CMS, their state survey agency, or their MAC.

4. Institutional providers (hospitals, SNFs, home health agencies, etc.) should use the "DR" condition code when billing Medicare for any claim that is conditioned on the existence of an 1135 waiver. Providers should also be on the alert for notices in which CMS or their MAC requires the "DR" code in other circumstances.
5. Non-institutional providers (e.g., physicians) should use the "CR" modifier for any applicable HCPCS codes for any claim for which Medicare Part B payment is conditioned on the existence of an 1135 waiver. CMS or MACs may require non-institutional providers to use the "CR" modifier in other circumstances, and providers should be attuned to any announcements to that effect.
6. Stakeholders should consider requesting COVID-19 1135 waivers if doing so will assist them in treating patients infected with the novel coronavirus or otherwise providing adequate care in light of the challenges and stresses wrought by the pandemic. CMS typically responds to these requests within three business days. States, local governments, state hospital associations or other provider associations, healthcare systems, individual providers, or other stakeholders can request an authorized waiver by emailing the appropriate CMS regional office or, if appropriate, contacting the state survey agency. The requests should explain the need for the 1135 waiver requested and provide the pertinent facts that support the request. As of March 24, 2020, CMS has approved certain 1135 waivers among the possible options for 1135 authorized waivers for the following states: Alabama, Arizona, California, Florida, Illinois, Louisiana, Mississippi, New Hampshire, New Jersey, New Mexico, North Carolina, Virginia, and Washington.
7. An 1135 waiver does not waive or affect state law requirements, such as those relating to licensure or conditions of participation in state-operated programs. For example, the blanket waiver pertaining to practitioners licensed in a state other than the state in which they provide services does not waive state-imposed licensure requirements. Providers should determine what steps their state has taken to waive or modify licensure requirements.
8. The contact information for the regional CMS offices is as follows:
    - ROATLHSQ@cms.hhs.gov (Atlanta RO): Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee
    - RODALDSC@cms.hhs.gov (Dallas RO): Arkansas, Louisiana, New Mexico, Oklahoma, Texas
    - ROPHIDSC@cms.hhs.gov (Northeast Consortium): Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia, New York, New Jersey, Puerto Rico, Virgin Islands, Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
    - ROCHISC@cms.hhs.gov (Midwest Consortium): Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin, Iowa, Kansas, Missouri, Nebraska
    - ROSFOSO@cms.hhs.gov (Western Consortium): Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming, Alaska, Idaho, Oregon, Washington, Arizona, California, Hawaii, Nevada, Pacific Territories

Endnotes

[1] *See* 45 C.F.R. § 164.510.

[2] *See* 45 C.F.R. § 164.520.

[3] *See* 45 C.F.R. § 164.522.

Authors

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