

Compliance Topics

Background

CMS has released waivers that address topics that otherwise might be considered compliance issues. Full discussions of these and other waivers may be found at the following:

<https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf>

<https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers>



Waivers have an issue date of March 30, 2020, but will be **retroactive to March 1, 2020**, nationwide, and shall terminate as set forth in section 1135(e) of the Act. Parties may not use the blanket waivers after the expiration of the Secretary's authority to grant waivers for the COVID-19 outbreak in the United States.¹

Compliance topics impacted by recently released waivers include the following.



Emergency Medical Treatment & Labor Act (EMTALA)

CMS is waiving the enforcement of section 1867(a) of the Act. This will allow hospitals, psychiatric hospitals, and critical access hospitals (CAHs) to **screen patients at a location offsite from the hospital's campus** to prevent the spread of COVID-19, so long as it is not inconsistent with a state's emergency preparedness or pandemic plan. Greater detail regarding the following may be found at:

<https://www.cms.gov/files/document/qso-20-15-emtala-requirements-and-coronavirus-0311-updated-003pdf.pdf-1>

- ✓ Hospitals may set up alternative screening sites on campus.
 - The medical screening examination (MSE) does not have to take place in the ED.
 - A hospital may set up alternative sites on its campus to perform the MSE.
- ✓ Hospitals may set up screening at off-campus, hospital-controlled sites.
 - Hospitals and community officials may encourage the public to go to these sites instead of the hospital for screening for influenza-like illness (ILI).
 - A hospital may not tell individuals who have already come to its ED to go to the off-site location for the MSE. Unless the off-campus site is already a dedicated ED (DED) of the hospital, as defined under EMTALA regulations, EMTALA requirements do not apply.
- ✓ Communities may set up screening clinics at sites not under the control of a hospital.
 - There is no EMTALA obligation at these sites.

Every hospital or CAH with a dedicated emergency department (ED) is required to conduct an appropriate MSE of all individuals who come to the ED, including individuals who are suspected of having COVID-19, regardless of whether they arrive by ambulance or are walk-ins. Every ED is expected to have the capability to apply appropriate COVID-19 screening criteria when applicable, to immediately identify and isolate individuals who meet the screening criteria to be a potential COVID-19 patient and to contact their state or local public health officials to determine next steps when an individual meeting the screening criteria is found.²

In the case of individuals with suspected or confirmed COVID-19, hospitals and CAHs are expected to consider the current guidance of CDC and public health officials in determining whether they have the capability to provide appropriate isolation required for stabilizing treatment and/or to accept appropriate transfers. In the event of any EMTALA complaints alleging inappropriate transfers or refusal to accept appropriate transfers, CMS will take into consideration the public health guidance in effect at the time.

Additional details and scenarios are discussed at:

<https://www.cms.gov/files/document/qso-20-15-hospital-cah-emtala-revised.pdf>

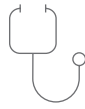


Verbal Orders

CMS is waiving the requirements of 42 CFR §482.23, §482.24 and §485.635(d)(3) to provide additional flexibility related to verbal orders where readback verification is required, but authentication may occur later than 48 hours.

- ✓ If verbal orders are used for the use of drugs and biologicals (except immunizations), they are to be used infrequently.

- ✓ All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner or by another practitioner who is responsible for the care of the patient.
- ✓ Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders.
- ✓ Although the regulation requires that medication administration be based on a written, signed order, this does not preclude the CAH from using verbal orders. A practitioner responsible for the care of the patient must authenticate the order in writing as soon as possible after the fact.



Medicare Physician Supervision

The physician can enter a contractual arrangement that meets the definition of auxiliary personnel at 42 CFR 410.26.

- ✓ Including with staff of another provider/supplier type, such as a home health agency or a qualified home infusion therapy supplier, or entities that furnish ambulance services, that can provide the staff and technology necessary to provide care that would ordinarily be provided incident to a physicians' service (including services that can be performed via telehealth).
- ✓ In such instances, the provider/supplier would seek payment for any services provided by auxiliary personnel from the billing practitioner and would not submit claims to Medicare for such services.

Direct physician supervision is no longer required for non-surgical extended duration therapeutic services provided in hospital outpatient departments and critical access hospitals. Instead, a physician can provide a general level of supervision for these services so that a physician is no longer required to be immediately available in the office suite.

CMS is waiving 482.12(c)(1-2) and (4), which requires that Medicare patients in the hospital be under the care of a physician. This allows hospitals to use other practitioners, such as physician's assistant and nurse practitioners, fully possible. This waiver should be implemented in accordance with a state's emergency preparedness or pandemic plan.

Under current rules, Medicare payment is made for services by a teaching physician involving residents only if the physician is physically present for the service or procedure.

- ✓ Teaching physicians can provide services with medical residents virtually through audio/video real-time communications technology.
- ✓ This does not apply in the case of surgical, high risk, interventional, or other complex procedures, services performed through an endoscope, and anesthesia services.
- ✓ This allows teaching hospitals to maximize their workforce to safely take care of patients.³



Restraint Reporting Requirements

CMS is waiving the requirements which require that hospitals report patients in an intensive care unit whose death is caused by their disease, but who required soft wrist restraints to prevent pulling tubes/IVs, no later than the close of business on the next business day.

Due to current hospital surge, CMS is waiving this requirement to ensure that hospitals are focusing on increased patient care demands and increased patient census, provided any death where the restraint may have contributed is still reported within standard time limits (i.e., close of business on the next business day following knowledge of the patient's death).



Patient Rights

CMS is waiving requirements only for hospitals that are impacted by a widespread outbreak of COVID-19. Hospitals that are in a state which has widespread confirmed cases (i.e., 51 or more confirmed cases*) as updated on the CDC website, CDC States Reporting Cases of COVID-19, would not be required to meet the following requirements.

- ✓ With respect to timeframes in providing a copy of a medical record.
- ✓ Related to patient visitation, including the requirement to have written policies and procedures on visitation of patients who are in COVID-19 isolation and quarantine processes.
- ✓ Regarding seclusion.



Provider Enrollment

CMS is temporarily waiving requirements that out-of-state practitioners be licensed in the state where they are providing services when they are licensed in another state. CMS will waive the physician or non-physician practitioner licensing requirements when the following four conditions are met.

- ✓ Must be enrolled as such in the Medicare program.
- ✓ Must possess a valid license to practice in the state which relates to his or her Medicare enrollment.
- ✓ Is furnishing services – whether in person or via telehealth – in a state in which the emergency is occurring to contribute to relief efforts in his or her professional capacity.
- ✓ Is not affirmatively excluded from practice in the state or any other state that is part of the 1135 emergency area.

For the physician or non-physician practitioner to avail him or herself of the 1135 waiver under the conditions described above, the state also would have to waive its licensure requirements, either individually or categorically, for the type of practice for which the physician or non-physician practitioner is licensed in his or her home state.

CMS has established toll-free hotlines for physicians, non-physician practitioners and Part A certified providers and suppliers establishing isolation facilities to enroll and receive temporary Medicare billing privileges. CMS is providing the following flexibilities for provider enrollment.

- ✓ Waive certain screening requirements.
- ✓ Postpone all revalidation actions.
- ✓ Allow licensed physicians and other practitioners to bill Medicare for services provided outside of their state of enrollment.
- ✓ Expedite any pending or new applications from providers.
- ✓ Allow practitioners to render telehealth services from their home without reporting their home address on their Medicare enrollment while continuing to bill from your currently enrolled location.
- ✓ Allow opted-out practitioners to terminate their opt-out status early and enroll in Medicare to provide care to more patients.



“Stark Law” Waivers

The physician self-referral law (also known as the “Stark Law”) prohibits a physician from making referrals for certain healthcare services payable by Medicare if the physician (or an immediate family member) has a financial relationship with the entity performing the service. There are statutory and regulatory exceptions, but in short, a physician cannot refer a patient to any entity with which he or she has a financial relationship.

CMS will permit certain referrals and the submission of related claims that would otherwise violate the Stark Law. The following is a summary of issues addressed however **numerous details** surrounding these waivers may be found at: <https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf>.

- ✓ Hospitals and other health care providers can pay above or below fair market value to rent equipment or receive services from physicians (or vice versa).
 - For example, a physician practice may be willing to rent or sell needed equipment to a hospital at a price that is below what the practice could charge another party; or,
 - A hospital may provide space on hospital grounds at no charge to a physician who is willing to treat patients who seek care at the hospital but are not appropriate for emergency department or inpatient care.
- ✓ Health care providers can support each other financially to ensure continuity of health care operations.
 - For example, a physician owner of a hospital may make a personal loan to the hospital without charging interest at a fair market rate so that the hospital can make payroll or pay its vendors.
- ✓ Hospitals can provide benefits to their medical staffs, such as multiple daily meals, laundry service to launder soiled personal clothing, or childcare services while the physicians are at the hospital and engaging in activities that benefit the hospital and its patients.
- ✓ Allowing the provision of certain items and services that are solely related to COVID-19 purposes (as defined in the waivers), even when the provision of the items or services would exceed the annual non-monetary compensation cap.
 - For example, a home health agency may provide continuing medical education to physicians in the community on the latest care protocols for homebound patients with COVID-19, or a hospital may provide isolation shelter or meals to the family of a physician who was exposed to the novel coronavirus while working in the hospital’s emergency department.

- ✓ Physician-owned hospitals can temporarily increase the number of their licensed beds, operating rooms, and procedure rooms, even though such expansion would otherwise be prohibited under the Stark Law.
 - For example, a physician-owned hospital may temporarily convert observation beds to inpatient beds to accommodate patient surge during the COVID-19 pandemic in the United States.
- ✓ Loosen some of the restrictions when a group practice can furnish medically necessary designated health services (DHS) in a patient's home.
 - For example, any physician in the group may order medically necessary DHS that is furnished to a patient by a technician or nurse in the patient's home contemporaneously with a physician service that is furnished via telehealth by the physician who ordered the DHS.
- ✓ Group practices can furnish medically necessary MRIs, CT scans or clinical laboratory services from locations like mobile vans in parking lots that the group practice rents on a part-time basis.



Signature Requirements

CMS is waiving signature and proof of delivery requirements for Part B drugs and Durable Medical Equipment when a signature cannot be obtained because of the inability to collect signatures. Suppliers should document in the medical record the appropriate date of delivery and that a signature was not able to be obtained because of COVID-19.

Guidance

- ✓ Review, implement and monitor revised EMTALA guidelines to ensure compliance in all settings.
- ✓ Review waiver for delayed signature and use of verbal orders. Determine if terms of the waiver will be implemented and educate all applicable staff.
- ✓ Review guidelines regarding deaths related to restraint use and ensure compliance with reporting guidelines.
- ✓ Ensure patient rights are waived only in the circumstances outlined and monitor for compliance.
- ✓ Review guidelines for physician supervision and use of alternative providers. Determine the elements that will be implemented at the hospital and ensure the medical staff and other key staff are involved and conversant with the provisions put in place.
- ✓ Allow waiver of Stark guidelines in conjunction with the hospital's Compliance Officer and committee when appropriate to facilitate care and safety of patient and staff.
- ✓ In those settings where it is applicable educate staff impacted by the signature requirement changes for delivery of Part B or DME.



Sources

1. <https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf>
2. <https://www.cms.gov/files/document/qso-20-15-hospital-cah-emtala-revised.pdf>
3. <https://www.cms.gov/files/document/covid-teaching-hospitals.pdf> ■