



To: Ambulatory Surgery Centers
From: IEHP – Provider Relations
Date: April 6, 2020
Subject: **COVID-19 – Ambulatory Surgery Centers (ASCs) Temporarily Enrolling as Hospitals**

The Centers for Medicare & Medicaid Services (CMS) has published **Guidance for Processing Attestation Statements from Ambulatory Surgical Centers (ASCs) Temporarily Enrolling as Hospitals** due to COVID-19 (<https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/guidance-processing-attestations-ambulatory-surgical-centers-asc-temporarily-enrolling-hospitals>).

CMS is allowing all Medicare-enrolled ASCs to enroll as hospitals and provide inpatient and outpatient hospital services to help address the urgent need to increase hospital capacity to take care of patients.

- Providers cannot be certified/enrolled as both an ASC and hospital simultaneously.
- ASCs that enroll as a hospital must meet the hospital Conditions of Participation.
- Onsite survey is not required for approval; however, the CMS Regional Office may survey at a later date to ensure quality and safety.

Any Medicare-certified ASC wishing to enroll as a hospital during the COVID-19 Public Health Emergency (PHE) should notify the Medicare Administrative Contractor (MAC) that serves their jurisdiction of its intent by calling the MAC's provider enrollment hotline.

CMS MEMORANDUM & ATTESTATION (please complete pages 4-5):
<https://www.cms.gov/files/document/qso-20-24-asc.pdf>

As a reminder, all communications sent by IEHP can also be found on our Provider portal at: www.iehp.org > For Providers > Plan Updates > Correspondence **or** www.iehp.org > For Providers > Plan Updates > Coronavirus (COVID-19) Advisory.

If you have any questions, please do not hesitate to contact the IEHP Provider Relations Team at (909) 890-2054.

Enclosures: COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers
Guidance for Processing Attestation Statements from Ambulatory Surgical Centers (ASCs)
Temporarily Enrolling as Hospitals during the COVID-19 Public Health Emergency
Medicare Administrative Contractors (MACs)

COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers

The Trump Administration is taking aggressive actions and exercising regulatory flexibilities to help healthcare providers contain the spread of 2019 Novel Coronavirus Disease (COVID-19). CMS is empowered to take proactive steps through 1135 waivers as well as, where applicable, authority granted under section 1812(f) of the Social Security Act (the Act) and rapidly expand the Administration's aggressive efforts against COVID-19. As a result, the following blanket waivers are in effect, with a retroactive effective date of March 1, 2020 through the end of the emergency declaration. For general information about waivers, see Attachment A to this document. **These waivers DO NOT require a request to be sent to the 1135waiver@cms.hhs.gov mailbox or that notification be made to any of CMS's regional offices.**

Hospitals, Psychiatric Hospitals, and Critical Access Hospitals (CAHs), including Cancer Centers and Long-Term Care Hospitals (LTCHs)

- **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.
- **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 read-back verification is required, but authentication may occur later than 48 hours. This will allow more efficient treatment of patients in surge situations. Specifically, the following requirements are waived:
 - §482.23(c)(3)(i) - If verbal orders are used for the use of drugs and biologicals (except immunizations), they are to be used infrequently.
 - §482.24(c)(2) - 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.
 - §482.24(c)(3) - Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders. This would include all subparts at §482.24(c)(3).
 - §485.635(d)(3) - 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.

- **Reporting Requirements.** CMS is waiving the requirements at 42 CFR §482.13(g) (1)(i)-(ii), 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 under 42 CFR §482.13 **only for hospitals that are considered to be impacted by a widespread outbreak of COVID-19.** Hospitals that are located 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, at <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html>, would not be required to meet the following requirements:
 - §482.13(d)(2) - With respect to timeframes in providing a copy of a medical record.
 - §482.13(h) - 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.
 - §482.13(e)(1)(ii) - Regarding seclusion.

*The waiver flexibility is based on the number of confirmed cases as reported by CDC and will be assessed accordingly when COVID-19 confirmed cases decrease.

- **Sterile Compounding.** CMS is waiving requirements (also outlined in USP797) at 42 CFR §482.25(b)(1) and §485.635(a)(3) in order to allow used face masks to be removed and retained in the compounding area to be re-donned and reused during the same work shift in the compounding area only. This will conserve scarce face mask supplies. CMS will not review the use and storage of face masks under these requirements.
- **Detailed Information Sharing for Discharge Planning for Hospitals and CAHs.** CMS is waiving the requirement 42 CFR §482.43(a)(8), §482.61(e), and §485.642(a)(8) to provide detailed information regarding discharge planning, described below:
 - The hospital, psychiatric hospital, and CAH must assist patients, their families, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, home health agency (HHA), skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), and long-term care hospital (LTCH) quality measures and resource use measures. The hospital must ensure that the post-acute care data on quality measures and resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.
 - CMS is maintaining the discharge planning requirements that ensure a patient is discharged to an appropriate setting with the necessary medical information and goals of care as described in 42 CFR §482.43(a)(1)-(7) and (b).

- **Limiting Detailed Discharge Planning for Hospitals.** CMS is waiving all the requirements and subparts at 42 CFR §482.43(c) related to post-acute care services so as to expedite the safe discharge and movement of patients among care settings, and to be responsive to fluid situations in various areas of the country. CMS is maintaining the discharge planning requirements that ensure a patient is discharged to an appropriate setting with the necessary medical information and goals of care as described in 42 CFR §482.43(a)(1)-(7) and (b). CMS is waiving the more detailed requirement that hospitals ensure those patients discharged home and referred for HHA services, or transferred to a SNF for post-hospital extended care services, or transferred to an IRF or LTCH for specialized hospital services, must:
 - §482.43(c)(1): Include in the discharge plan a list of HHAs, SNFs, IRFs, or LTCHs that are available to the patient.
 - §482.43(c)(2): Inform the patient or the patient’s representative of their freedom to choose among participating Medicare providers and suppliers of post-discharge services.
 - §482.43(c)(3): Identify in the discharge plan any HHA or SNF to which the patient is referred in which the hospital has a disclosable financial interest, as specified by the Secretary, and any HHA or SNF that has a disclosable financial interest in a hospital under Medicare.
- **Medical Staff.** CMS is waiving requirements under 42 CFR §482.22(a)(1)-(4) to allow for physicians whose privileges will expire to continue practicing at the hospital and for new physicians to be able to practice before full medical staff/governing body review and approval to address workforce concerns related to COVID-19. CMS is waiving §482.22(a)(1)-(4) regarding details of the credentialing and privileging process. **(Please also refer to Practitioner Locations Blanket Waiver listed below.)**
- **Medical Records.** CMS is waiving requirements under 42 CFR §482.24(a) through (c), which cover the subjects of the organization and staffing of the medical records department, requirements for the form and content of the medical record, and record retention requirements, and these flexibilities may be implemented so long as they are not inconsistent with a state’s emergency preparedness or pandemic plan. CMS is waiving §482.24(c)(4)(viii) related to medical records to allow flexibility in completion of medical records within 30 days following discharge from a hospital. This flexibility will allow clinicians to focus on the patient care at the bedside during the pandemic.
- **Flexibility in Patient Self Determination Act Requirements (Advance Directives).** CMS is waiving the requirements at sections 1902(a)(58) and 1902(w)(1)(A) of the Act (for Medicaid); 1852(i) of the Act (for Medicare Advantage); and 1866(f) of the Act and 42 CFR §489.102 (for Medicare), which require hospitals and CAHs to provide information about their advance directive policies to patients. CMS is waiving this requirement to allow for staff to more efficiently deliver care to a larger number of patients.

- **Physical Environment.** CMS is waiving certain requirements under the Medicare conditions of participation at 42 CFR §482.41 and §485.623 to allow for flexibilities during hospital, psychiatric hospital, and CAH surges. CMS will permit non-hospital buildings/space to be used for patient care and quarantine sites, provided that the location is approved by the state (ensuring that safety and comfort for patients and staff are sufficiently addressed) and so long as it is not inconsistent with a state's emergency preparedness or pandemic plan. This allows for increased capacity and promotes appropriate cohorting of COVID-19 patients.
- **Telemedicine.** CMS is waiving the provisions related to telemedicine at 42 CFR §482.12(a)(8)–(9) for hospitals and §485.616(c) for CAHs, making it easier for telemedicine services to be furnished to the hospital's patients through an agreement with an off-site hospital. This allows for increased access to necessary care for hospital and CAH patients, including access to specialty care.
- **Physician Services.** CMS is waiving requirements under 42 CFR §482.12(c)(1)–(2) and §482.12(c)(4), which requires that Medicare patients be under the care of a physician. This waiver may be implemented so long as it is not inconsistent with a state's emergency preparedness or pandemic plan. This allows hospitals to use other practitioners to the fullest extent possible.
- **Anesthesia Services.** CMS is waiving requirements under 42 CFR §482.52(a)(5), §485.639(c)(2), and §416.42 (b)(2) that a certified registered nurse anesthetist (CRNA) is under the supervision of a physician in paragraphs §482.52(a)(5) and §485.639(c)(2). CRNA supervision will be at the discretion of the hospital and state law. This waiver applies to hospitals, CAHs, and Ambulatory Surgical Centers (ASCs). These waivers will allow CRNAs to function to the fullest extent of their licensure, and may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.
- **Utilization Review.** CMS is waiving certain requirements under 42 CFR §482.1(a)(3) and 42 CFR §482.30 which address the statutory basis for hospitals and includes the requirement that hospitals participating in Medicare and Medicaid must have a utilization review plan that meets specified requirements.
 - CMS is waiving the entire utilization review condition of participation Utilization Review (UR) at §482.30, which requires that a hospital must have a UR plan with a UR committee that provides for a review of services furnished to Medicare and Medicaid beneficiaries to evaluate the medical necessity of the admission, duration of stay, and services provided. These flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan. Removing these administrative requirements will allow hospitals to focus more resources on providing direct patient care.

- **Written Policies and Procedures for Appraisal of Emergencies at Off Campus Hospital Departments.** CMS is waiving 42 CFR §482.12(f)(3), emergency services, with respect to surge facilities **only**, such that written policies and procedures for staff to use when evaluating emergencies are not required for surge facilities. This removes the burden on facilities to develop and establish additional policies and procedures at their surge facilities or surge sites related to the assessment, initial treatment and referral of patients. These flexibilities may be implemented so long as they are not inconsistent with a state’s emergency preparedness or pandemic plan.
- **Emergency Preparedness Policies and Procedures.** CMS is waiving 42 CFR §482.15(b) and §485.625(b), which requires the hospital and CAH to develop and implement emergency preparedness policies and procedures, and §482.15(c)(1)–(5) and §485.625(c)(1)–(5) which requires that the emergency preparedness communication plans for hospitals and CAHs to contain specified elements with respect to the surge site. The requirement under the communication plan requires hospitals and CAHs to have specific contact information for staff, entities providing services under arrangement, patients’ physicians, other hospitals and CAHs, and volunteers. This would not be an expectation for the surge site. This waiver applies to both hospitals and CAHs, and removes the burden on facilities to establish these policies and procedures for their surge facilities or surge sites.
- **Quality Assessment and Performance Improvement Program.** CMS is waiving 42 CFR §482.21(a)–(d) and (f), and §485.641(a), (b), and (d), which provide details on the scope of the program, the incorporation, and setting priorities for the program’s performance improvement activities, and integrated Quality Assurance & Performance Improvement programs (for hospitals that are part of a hospital system). These flexibilities, which apply to both hospitals and CAHs, may be implemented so long as they are not inconsistent with a state’s emergency preparedness or pandemic plan. We expect any improvements to the plan to focus on the Public Health Emergency (PHE). While this waiver decreases burden associated with the development of a hospital or CAH QAPI program, the requirement that hospitals and CAHs maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program will remain. This waiver applies to both hospitals and CAHs.
- **Nursing Services.** CMS is waiving the requirements at 42 CFR §482.23(b)(4), which requires the nursing staff to develop and keep current a nursing care plan for each patient, and §482.23(b)(7), which requires the hospital to have policies and procedures in place establishing which outpatient departments are not required to have a registered nurse present. These waivers allow nurses increased time to meet the clinical care needs of each patient and allows for the provision of nursing care to an increased number of patients. In addition, we expect that hospitals will need relief for the provision of inpatient services and as a result, the requirement to establish nursing-related policies and procedures for outpatient departments is likely of lower priority. These flexibilities apply to both hospitals and CAHs §485.635(d)(4), and may be implemented so long as they are not inconsistent with a state’s emergency preparedness or pandemic plan.

- **Food and Dietetic Services.** CMS is waiving the requirement at paragraph 42 CFR §482.28(b)(3), which requires providers to have a current therapeutic diet manual approved by the dietitian and medical staff readily available to all medical, nursing, and food service personnel. Such manuals would not need to be maintained at surge capacity sites. These flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan. Removing these administrative requirements will allow hospitals to focus more resources on providing direct patient care.
- **Respiratory Care Services.** CMS is waiving the requirements at 42 CFR §482.57(b)(1) that require hospitals to designate in writing the personnel qualified to perform specific respiratory care procedures and the amount of supervision required for personnel to carry out specific procedures. These flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan. Not being required to designate these professionals in writing will allow qualified professionals to operate to the fullest extent of their licensure and training in providing patient care.
- **CAH Personnel Qualifications.** CMS is waiving the minimum personnel qualifications for clinical nurse specialists at paragraph 42 CFR §485.604(a)(2), nurse practitioners at paragraph §485.604(b)(1)–(3), and physician assistants at paragraph §485.604(c)(1)–(3). Removing these Federal personnel requirements will allow CAHs to employ individuals in these roles who meet state licensure requirements and provide maximum staffing flexibility. These flexibilities should be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.
- **CAH Staff Licensure.** CMS is deferring to staff licensure, certification, or registration to state law by waiving 42 CFR §485.608(d) regarding the requirement that staff of the CAH be licensed, certified, or registered in accordance with applicable federal, state, and local laws and regulations. This waiver will provide maximum flexibility for CAHs to use all available clinicians. These flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.
- **CAH Status and Location.** CMS is waiving the requirement at 42 CFR §485.610(b) that the CAH be located in a rural area or an area being treated as being rural, allowing the CAH flexibility in the establishment of surge site locations. CMS is also waiving the requirement at §485.610(e) regarding the CAH's off-campus and co-location requirements, allowing the CAH flexibility in establishing temporary off-site locations. In an effort to facilitate the establishment of CAHs without walls, these waivers will suspend restrictions on CAHs regarding their rural location and their location relative to other hospitals and CAHs. These flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.

- **CAH Length of Stay.** CMS is waiving the requirements that CAHs limit the number of beds to 25, and that the length of stay be limited to 96 hours under the Medicare conditions of participation for number of beds and length of stay at 42 CFR §485.620.
- **Temporary Expansion Locations:** For the duration of the PHE related to COVID-19, CMS is waiving certain requirements under the Medicare conditions of participation at 42 CFR §482.41 and §485.623 (as noted elsewhere in this waiver document) and the provider-based department requirements at §413.65 to allow hospitals to establish and operate as part of the hospital any location meeting those conditions of participation for hospitals that continue to apply during the PHE. This waiver also allows hospitals to change the status of their current provider-based department locations to the extent necessary to address the needs of hospital patients as part of the state or local pandemic plan. This extends to any entity operating as a hospital (whether a current hospital establishing a new location or an Ambulatory Surgical Center (ASC) enrolling as a hospital during the PHE pursuant to a streamlined enrollment and survey and certification process) so long as the relevant location meets the conditions of participation and other requirements not waived by CMS. This waiver will enable hospitals to meet the needs of Medicare beneficiaries.

Housing Acute Care Patients in the IRF or Inpatient Psychiatric Facility (IPF) Excluded Distinct Part Units

- CMS is waiving requirements to allow acute care hospitals to house acute care inpatients in excluded distinct part units, such as excluded distinct part unit IRFs or IPFs, where the distinct part unit's 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.

Care for Excluded Inpatient Psychiatric Unit Patients in the Acute Care Unit of a Hospital

- CMS is allowing acute care hospitals with excluded distinct part inpatient psychiatric units to relocate inpatients from the excluded distinct part psychiatric unit to an acute care bed and unit as a result of a disaster or emergency. 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. This waiver may be utilized where 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 allowing acute care hospitals with excluded distinct part inpatient rehabilitation units that, as a result of a disaster or emergency, need to relocate inpatients from the excluded distinct part rehabilitation unit to an acute care bed and unit as a result of this PHE. 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. This waiver may be utilized where the hospital's acute care beds are appropriate for providing care to rehabilitation patients and such patients continue to receive intensive rehabilitation services.

Flexibility for Inpatient Rehabilitation Facilities Regarding the “60 Percent Rule”

- CMS is allowing IRFs to exclude patients from the freestanding hospital's or excluded distinct part unit's inpatient population for purposes of calculating the applicable thresholds associated with the requirements to receive payment as an IRF (commonly referred to as the “60 percent rule”) if an IRF admits a patient solely to respond to the emergency and the patient's medical record properly identifies the patient as such. In addition, during the applicable waiver time period, we would also apply the exception to facilities not yet classified as IRFs, but that are attempting to obtain classification as an IRF.

Extension for Inpatient Prospective Payment System (IPPS) Wage Index Occupational Mix Survey Submission

- CMS collects data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. Completed 2019 Occupational Mix Surveys, Hospital Reporting Form CMS-10079, for the Wage Index Beginning FY 2022, are due to the Medicare Administrative Contractors (MACs) on the Excel hospital reporting form available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html> by July 1, 2020. CMS is currently granting an extension for hospitals nationwide affected by COVID-19 until August 3, 2020. If hospitals encounter difficulty meeting this extended deadline date, hospitals should communicate their concerns to CMS via their MAC, and CMS may consider an additional extension if CMS determines it is warranted.

Supporting Care for Patients in Long-Term Care Acute Hospitals (LTCHs)

- Allows a LTCH to 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.

Care for Patients in Extended Neoplastic Disease Care Hospitals

- CMS is allowing extended neoplastic disease care hospitals to exclude inpatient stays where the hospital admits or discharges patients in order to meet the demands of the emergency from the greater than 20-day average length of stay requirement, which allows these facilities to be excluded from the hospital inpatient prospective payment system and paid an adjusted payment for Medicare inpatient operating and capital-related costs under the reasonable cost-based reimbursement rules as authorized under Section 1886(d)(1)(B)(vi) of the Act and §42 CFR 412.22(i).

Long-Term Care Facilities and Skilled Nursing Facilities (SNFs) and/or Nursing Facilities (NFs)

- **3-Day Prior Hospitalization.** Using the authority under Section 1812(f) of the Act, CMS is waiving the requirement for a 3-day prior hospitalization for coverage of a SNF stay, which provides temporary emergency coverage of SNF services without a qualifying hospital stay, for those people who experience dislocations, or are otherwise affected by COVID-19. 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 will apply only for those beneficiaries who have been delayed or prevented by the emergency itself from commencing or completing the process of ending their current benefit period and renewing their SNF benefits that would have occurred under normal circumstances).
- **Reporting Minimum Data Set.** CMS is waiving 42 CFR 483.20 to provide relief to SNFs on the timeframe requirements for Minimum Data Set assessments and transmission.
- **Staffing Data Submission.** CMS is waiving 42 CFR 483.70(q) to provide relief to long-term care facilities on the requirements for submitting staffing data through the Payroll-Based Journal system.
- **Waive Pre-Admission Screening and Annual Resident Review (PASARR).** CMS is waiving 42 CFR 483.20(k) allowing states and nursing homes to suspend these assessments for new residents for 30 days. After 30 days, new patients admitted to nursing homes with a mental illness (MI) or intellectual disability (ID) should receive the assessment as soon as resources become available.

- **Physical Environment.** CMS is waiving requirements related at 42 CFR 483.90, specifically the following:
 - Provided that the state has approved the location as one that sufficiently addresses safety and comfort for patients and staff, CMS is waiving requirements under § 483.90 to allow for a non-SNF building to be temporarily certified and available for use by a SNF in the event there are needs for isolation processes for COVID-19 positive residents, which may not be feasible in the existing SNF structure to ensure care and services during treatment for COVID-19 are available while protecting other vulnerable adults. CMS believes this will also provide another measure that will free up inpatient care beds at hospitals for the most acute patients while providing beds for those still in need of care. CMS will waive certain conditions of participation and certification requirements for opening a NF if the state determines there is a need to quickly stand up a temporary COVID-19 isolation and treatment location.
 - CMS is also waiving requirements under 42 CFR 483.90 to temporarily allow for rooms in a long-term care facility not normally used as a resident's room, to be used to accommodate beds and residents for resident care in emergencies and situations needed to help with surge capacity. Rooms that may be used for this purpose include activity rooms, meeting/conference rooms, dining rooms, or other rooms, as long as residents can be kept safe, comfortable, and other applicable requirements for participation are met. This can be done so long as it is not inconsistent with a state's emergency preparedness or pandemic plan, or as directed by the local or state health department.
- **Resident Groups.** CMS is waiving the requirements at 42 CFR 483.10(f)(5), which ensure residents can participate in-person in resident groups. This waiver would only permit the facility to restrict in-person meetings during the national emergency given the recommendations of social distancing and limiting gatherings of more than ten people. Refraining from in-person gatherings will help prevent the spread of COVID-19.
- **Training and Certification of Nurse Aides.** CMS is waiving the requirements at 42 CFR 483.35(d) (with the exception of 42 CFR 483.35(d)(1)(i)), which require that a SNF and NF may not employ anyone for longer than four months unless they met the training and certification requirements under § 483.35(d). CMS is waiving these requirements to assist in potential staffing shortages seen with the COVID-19 pandemic. To ensure the health and safety of nursing home residents, CMS is not waiving 42 CFR § 483.35(d)(1)(i), which requires facilities to not use any individual working as a nurse aide for more than four months, on a full-time basis, unless that individual is competent to provide nursing and nursing related services. We further note that we are not waiving § 483.35(c), which requires facilities to ensure that nurse aides are able to demonstrate competency in skills and techniques necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.

- **Physician Visits in Skilled Nursing Facilities/Nursing Facilities.** CMS is waiving the requirement in 42 CFR 483.30 for physicians and non-physician practitioners to perform in-person visits for nursing home residents and allow visits to be conducted, as appropriate, via telehealth options.
- **Resident roommates and grouping.** CMS is waiving the requirements in 42 CFR 483.10(e) (5), (6), and (7) solely for the purposes of grouping or cohorting residents with respiratory illness symptoms and/or residents with a confirmed diagnosis of COVID-19, and separating them from residents who are asymptomatic or tested negative for COVID-19. This action waives a facility's requirements, under 42 CFR 483.10, to provide for a resident to share a room with his or her roommate of choice in certain circumstances, to provide notice and rationale for changing a resident's room, and to provide for a resident's refusal a transfer to another room in the facility. This aligns with CDC guidance to preferably place residents in locations designed to care for COVID-19 residents, to prevent the transmission of COVID-19 to other residents.
- **Resident Transfer and Discharge.** CMS is waiving requirements in 42 CFR 483.10(c)(5); 483.15(c)(3), (c)(4)(ii), (c)(5)(i) and (iv), (c)(9), and (d); and § 483.21(a)(1)(i), (a)(2)(i), and (b) (2)(i) (with some exceptions) to allow a long term care (LTC) facility to transfer or discharge residents to another LTC facility solely for the following cohorting purposes:
 1. Transferring residents with symptoms of a respiratory infection or confirmed diagnosis of COVID-19 to another facility that agrees to accept each specific resident, and is dedicated to the care of such residents;
 2. Transferring residents without symptoms of a respiratory infection or confirmed to not have COVID-19 to another facility that agrees to accept each specific resident, and is dedicated to the care of such residents to prevent them from acquiring COVID-19; or
 3. Transferring residents without symptoms of a respiratory infection to another facility that agrees to accept each specific resident to observe for any signs or symptoms of a respiratory infection over 14 days.

Exceptions:

- These requirements are **only** waived in cases where the transferring facility receives confirmation that the receiving facility agrees to accept the resident to be transferred or discharged. Confirmation may be in writing or verbal. If verbal, the transferring facility needs to document the date, time and person that the receiving facility communicated agreement.
- In § 483.10, we are only waiving the requirement, under § 483.10(c)(5), that a facility provide advance notification of options relating to the transfer or discharge to another facility. Otherwise, all requirements related to § 483.10 are not waived. Similarly, in § 483.15, we are only waiving the requirement, under § 483.15(c)(3), (c)(4)(ii), (c)(5)(i) and (iv), and (d), for the written notice of transfer or discharge to be provided before the transfer or discharge. This notice must be provided as soon as practicable.

- In § 483.21, we are only waiving the timeframes for certain care planning requirements for residents who are transferred or discharged for the purposes explained in 1–3 above. Receiving facilities should complete the required care plans as soon as practicable, and we expect receiving facilities to review and use the care plans for residents from the transferring facility, and adjust as necessary to protect the health and safety of the residents the apply to.
- These requirements are also waived when the transferring residents to another facility, such as a COVID-19 isolation and treatment location, with the provision of services “under arrangements,” as long as it is not inconsistent with a state’s emergency preparedness or pandemic plan, or as directed by the local or state health department. In these cases, the transferring LTC facility need not issue a formal discharge, as it is still considered the provider and should bill Medicare normally for each day of care. The transferring LTC facility is then responsible for reimbursing the other provider that accepted its resident(s) during the emergency period.
 - If the LTC facility does not intend to provide services under arrangement, the COVID-19 isolation and treatment facility is the responsible entity for Medicare billing purposes. The LTC facility should follow the procedures described in 40.3.4 of the Medicare Claims Processing Manual (<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c06.pdf>) to submit a discharge bill to Medicare. The COVID-19 isolation and treatment facility should then bill Medicare appropriately for the type of care it is providing for the beneficiary. If the COVID-19 isolation and treatment facility is not yet an enrolled provider, the facility should enroll through the provider enrollment hotline for the Medicare Administrative Contractor that services their geographic area to establish temporary Medicare billing privileges.

We remind LTC facilities that they are responsible for ensuring that any transfers (either within a facility, or to another facility) are conducted in a safe and orderly manner, and that each resident’s health and safety is protected.

We also remind states that under 42 CFR 488.426(a)(1), in an emergency, the State has the authority to transfer Medicaid and Medicare residents to another facility.

Home Health Agencies (HHAs)

- **Requests for Anticipated Payment (RAPs).** CMS is allowing Medicare Administrative Contractors (MACs) to extend the auto-cancellation date of Requests for Anticipated Payment (RAPs) during emergencies.
- **Reporting.** CMS is providing relief to HHAs on the timeframes related to OASIS Transmission through the following actions below:
 - Extending the 5-day completion requirement for the comprehensive assessment to 30 days.
 - Waiving the 30-day OASIS submission requirement. Delayed submission is permitted during the PHE.

- **Initial Assessments.** CMS is waiving the requirements at 42 CFR §484.55(a) to allow HHAs to perform Medicare-covered initial assessments and determine patients' homebound status remotely or by record review. This will allow patients to be cared for in the best environment for them while supporting infection control and reducing impact on acute care and long-term care facilities. This will allow for maximizing coverage by already scarce physician and advanced practice clinicians and allow those clinicians to focus on caring for patients with the greatest acuity.
- **Waive onsite visits for HHA Aide Supervision.** CMS is waiving the requirements at 42 CFR §484.80(h), which require a nurse to conduct an onsite visit every two weeks. This would include waiving the requirements for a nurse or other professional to conduct an onsite visit every two weeks to evaluate if aides are providing care consistent with the care plan, as this may not be physically possible for a period of time. This waiver is also temporarily suspending the 2-week aide supervision by a registered nurse for home health agencies requirement at §484.80(h)(1), but virtual supervision is encouraged during the period of the waiver.

Hospice

- **Waive Requirement for Hospices to Use Volunteers.** CMS is waiving the requirement at 42 CFR §418.78(e) that hospices are required to use volunteers (including at least 5% of patient care hours). It is anticipated that hospice volunteer availability and use will be reduced related to COVID-19 surge and potential quarantine.
- **Comprehensive Assessments.** CMS is waiving certain requirements at 42 CFR §418.54 related to updating comprehensive assessments of patients. This waiver applies the timeframes for updates to the comprehensive assessment found at §418.54(d). Hospices must continue to complete the required assessments and updates, however, the timeframes for updating the assessment may be extended from 15 to 21 days.
- **Waive Non-Core Services.** CMS is waiving the requirement for hospices to provide certain non-core hospice services during the national emergency, including the requirements at 42 CFR §418.72 for physical therapy, occupational therapy, and speech-language pathology.
- **Waived Onsite Visits for Hospice Aide Supervision.** CMS is waiving the requirements at 42 CFR §418.76(h), which require a nurse to conduct an onsite supervisory visit every two weeks. This would include waiving the requirements for a nurse or other professional to conduct an onsite visit every two weeks to evaluate if aides are providing care consistent with the care plan, as this may not be physically possible for a period of time.

End-Stage Renal Dialysis (ESRD) Facilities

- **Training Program and Periodic Audits.** CMS is waiving the requirement at 42 CFR §494.40(a) related to the condition on Water & Dialysate Quality, specifically that on-time periodic audits for operators of the water/dialysate equipment are waived to allow for flexibilities.
- **Defer Equipment Maintenance & Fire Safety Inspections.** CMS is waiving the requirement at 42 CFR §494.60(b) for on-time preventive maintenance of dialysis machines and ancillary dialysis equipment. Additionally, CMS is also waiving the requirements under §494.60(d) which requires ESRD facilities to conduct on-time fire inspections. These waivers are intended to ensure that dialysis facilities are able to focus on the operations related to the Public Health Emergency.
- **Emergency Preparedness.** CMS is waiving the requirements at 42 CFR §494.62(d)(1)(iv) which requires ESRD facilities to demonstrate as part of their Emergency Preparedness Training and Testing Program, that staff can demonstrate that, at a minimum, its patient care staff maintains current CPR certification. CMS is waiving the requirement for maintenance of CPR certification during the COVID-19 emergency due to the limited availability of CPR classes.
- **Ability to Delay Some Patient Assessments. CMS is not waiving subsections (a) or (c) of 42 CFR §494.80,** but is waiving the following requirements at 42 CFR §494.80(b) related to the frequency of assessments for patients admitted to the dialysis facility. CMS is waiving the “on-time” requirements for the initial and follow up comprehensive assessments within the specified timeframes as noted below. This waiver applies to assessments conducted by members of the interdisciplinary team, including: a registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian. These waivers are intended to ensure that dialysis facilities are able to focus on the operations related to the Public Health Emergency. Specifically, CMS is waiving:
 - §494.80(b)(1): An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session.
 - §494.80(b)(2): A follow up comprehensive reassessment must occur within 3 months after the completion of the initial assessment to provide information to adjust the patient’s plan of care specified in §494.90.
- **Time Period for Initiation of Care Planning and Monthly Physician Visits.** CMS is modifying two requirements related to care planning, specifically:
 - 42 CFR §494.90(b)(2): CMS is modifying the requirement that requires the dialysis facility to implement the initial plan of care within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. This modification will also apply to the requirement for monthly or annual updates of the plan of care within 15 days of the completion of the additional patient assessments.

- §494.90(b)(4): CMS is modifying the requirement that requires the ESRD dialysis facility to ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist, or physician’s assistant providing ESRD care at least monthly, and periodically while the hemodialysis patient is receiving in-facility dialysis. CMS is waiving the requirement for a monthly in-person visit if the patient is considered stable and also recommends exercising telehealth flexibilities, e.g. phone calls, to ensure patient safety.
- **Dialysis Home Visits to Assess Adaptation and Home Dialysis Machine Designation.** CMS is waiving the requirement at 42 CFR §494.100(c)(1)(i) which requires the periodic monitoring of the patient’s home adaptation, including visits to the patient’s home by facility personnel. For more information on existing flexibilities for in-center dialysis patients to receive their dialysis treatments in the home, or long-term care facility, reference QSO-20-19-ESRD.
- **Home Dialysis Machine Designation – Clarification.** The ESRD Conditions for Coverage (CFCs) do not explicitly require that each home dialysis patient have their own designated home dialysis machine. The dialysis facility is required to follow FDA labeling and manufacturer’s directions for use to ensure appropriate operation of the dialysis machine and ancillary equipment. Dialysis machines must be properly cleaned and disinfected to minimize the risk of infection based on the requirements at 42 CFR §494.30 Condition: Infection Control if used to treat multiple patients.
- **Special Purpose Renal Dialysis Facilities (SPRDF) Designation Expanded.** CMS authorizes the establishment of SPRDFs under 42 CFR §494.120 to address access to care issues due to COVID-19 and the need to mitigate transmission among this vulnerable population. This will not include the normal determination regarding lack of access to care at §494.120(b) as this standard has been met during the period of the national emergency. Approval as a Special Purpose Renal Dialysis Facility related to COVID-19 does not require Federal survey prior to providing services.
- **Dialysis Patient Care Technician (PCT) Certification.** CMS is modifying the requirement at 42 CFR §494.140(e)(4) for dialysis PCTs that requires certification under a state certification program or a national commercially available certification program within 18 months of being hired as a dialysis PCT for newly employed patient care technicians. CMS is aware of the challenges that PCTs are facing with the limited availability and closures of testing sites during the time of this crisis. CMS will allow PCTs to continue working even if they have not achieved certification within 18 months or have not met on time renewals.
- **Transferability of Physician Credentialing.** CMS is modifying the requirement at 42 CFR §494.180(c)(1) which requires that all medical staff appointments and credentialing are in accordance with state law, including attending physicians, physician assistants, nurse practitioners, and clinical nurse specialists. These waivers will allow physicians that are appropriately credentialed at a certified dialysis facility to function to the fullest extent of their licensure to provide care at designated isolation locations without separate credentialing at that facility, and may be implemented so long as they are not inconsistent with a state’s emergency preparedness or pandemic plan.

- **Expanding availability of ESRD to Nursing Home Residents.** CMS is waiving the following requirements related to Nursing Home residents:
 - **Furnishing dialysis services on the main premises:** ESRD requirements at 42 CFR §494.180(d) require dialysis facilities to provide services directly on its main premises or on other premises that are contiguous with the main premises. CMS is waiving this requirement to allow dialysis facilities to provide service to its patients in the nursing home or skilled nursing facility. CMS continues to require that services provided to these nursing home residents are under the direction of the same governing body and professional staff as the resident’s usual Medicare-certified dialysis facility. Further, in order to ensure that care is safe, effective and is provided by trained and qualified personnel, CMS requires that the dialysis facility staff: furnish all dialysis care and services, provide all equipment and supplies necessary, maintain equipment and supplies in the nursing home, and complete all equipment maintenance, cleaning and disinfection using appropriate infection control procedures and manufacturer’s instructions for use.
- **Clarification for billing procedures.** Typically, ESRD beneficiaries are transported from a SNF/NF to an ESRD facility to receive renal dialysis services. In an effort to keep patients in their SNF/NF and decrease their risk of being exposed to COVID-19, ESRD facilities may temporarily furnish renal dialysis services to ESRD beneficiaries in the SNF/NF instead of the offsite ESRD facility. The in-center dialysis center should bill Medicare using Condition Code 71 (Full care unit. Billing for a patient who received staff-assisted dialysis services in a hospital or renal dialysis facility). The in-center dialysis center should also apply condition code DR to claims if all the treatments billed on the claim meet this condition or modifier CR on the line level to identify individual treatments meeting this condition. The ESRD provider would need to have their trained personnel administer the treatment in the SNF/ NF. In addition, the provider must follow the CFCs. In particular, under the CFCs is the requirement that to use a dialysis machine, the FDA-approved labeling must be adhered to § 494.100 and it must be maintained and operated in accordance with the manufacturer’s recommendations (§ 494.60) and follow infection control requirements at § 494.30.

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

- When DMEPOS is lost, destroyed, irreparably damaged, or otherwise rendered unusable, CMS is allowing DME Medicare Administrative Contractors (MACs) to have the flexibility to waive replacements requirements such that the face-to-face requirement, a 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 are reminded to maintain documentation indicating that the DMEPOS was lost, destroyed, irreparably damaged or otherwise rendered unusable or unavailable as a result of the emergency.

Practitioner Locations

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: 1) must be enrolled as such in the Medicare program; 2) must possess a valid license to practice in the state which relates to his or her Medicare enrollment; 3) is furnishing services – whether in person or via telehealth – in a state in which the emergency is occurring in order to contribute to relief efforts in his or her professional capacity; and, 4) is not affirmatively excluded from practice in the state or any other state that is part of the 1135 emergency area.

- In addition to the statutory limitations that apply to 1135-based licensure waivers, an 1135 waiver, when granted by CMS, does not have the effect of waiving state or local licensure requirements or any requirement specified by the state or a local government as a condition for waiving its licensure requirements. Those requirements would continue to apply unless waived by the state. Therefore, in order 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.

Provider Enrollment

- **Non-Waiver CMS Action:** CMS has a 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.
- Waive the following screening requirements:
 - Application Fee - (to the extent applicable).
 - Criminal background checks associated with fingerprint-based criminal background checks (FCBC) (to the extent applicable) - 42 CFR §424.518.
 - Site visits (to the extent applicable) - 42 CFR §424.517.
- Postpone all revalidation actions.
- Allow licensed providers to render services outside of their state of enrollment.
- Expedite any pending or new applications from providers.
- Allow physicians and other practitioners to render telehealth services from their home without reporting their home address on their Medicare enrollment while continuing to bill from their currently enrolled location.
- Allow opted-out physicians and non-physician practitioners to terminate their opt-out status early and enroll in Medicare to provide care to more patients.

Medicare Appeals in Fee for Service (FFS), Medicare Advantage (MA) and Part D

CMS is allowing Medicare Administrative Contractors (MACs) and Qualified Independent Contractors (QICs) in the FFS program pursuant to 42 CFR §405.942 and 42 CFR §405.962 (including for MA and Part D plans), as well as the MA and Part D Independent Review Entities (IREs) under 42 CFR §422.562, 42 CFR §423.562, 42 CFR §422.582 and 42 CFR §423.582, to allow extensions to file an appeal. CMS is allowing MACs and QICs in the FFS program under 42 CFR §405.950 and 42 CFR §405.966 and the MA and Part D IREs to waive requests for timeliness requirements for additional information to adjudicate appeals.

- CMS is allowing MACs and QICs in the FFS program under 42 CFR §405.910 and MA and Part D plans, as well as the MA and Part D IREs, to process an appeal even with incomplete Appointment of Representation forms as outlined under 42 CFR §422.561 and 42 CFR §423.560. However, any communications will only be sent to the beneficiary.
- CMS is allowing MACs and QICs in the FFS program under 42 CFR §405.950 and 42 CFR §405.966 (also including MA and Part D plans), as well as the MA and Part D IREs, to process requests for appeals that do not meet the required elements using information that is available as outlined within 42 CFR §422.561 and 42 CFR §423.560.
- CMS is allowing MACs and QICs in the FFS program under 42 CFR §405.950 and 42 CFR §405.966 (also including MA and Part D plans), as well as the MA and Part D IREs under 42 CFR §422.562 and 42 CFR §423.562 to utilize all flexibilities available in the appeal process as if good cause requirements are satisfied.

Medicaid and CHIP (as of 3/13/2020)

States and territories can request approval that certain statutes and implementing regulations be waived by CMS, pursuant to section 1135 of the Act. To assist states in this process, CMS released an 1135 Waiver Checklist to make it easier for states to receive federal waivers and implement flexibilities in their Medicaid and CHIP programs. States' use of this 1135 checklist will expedite their ability to apply for and receive approval for 1135 waivers that are now available under the President's national emergency declaration.

States and territories may submit a Section 1135 waiver request directly to their Center for Medicaid & CHIP Services (CMCS) state lead or Jackie Glaze, Acting Director, Medicaid & CHIP Operations Group, Center for Medicaid & CHIP Services at CMS by e-mail (Jackie.Glaze@cms.hhs.gov) or letter.

The following are examples of flexibilities that states and territories may seek through a Section 1135 waiver request:

- Waive prior authorization requirements in fee-for-service programs.
- Permits providers located out of state/territory to provide care to another state's Medicaid enrollee 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.

States and territories are encouraged to assess their needs and request these available flexibilities, which are more completely outlined in the Medicaid and CHIP Disaster Response Toolkit. For more information and to access the toolkit and the [1135 waiver checklist](#), visit: <https://www.medicaid.gov/state-resource-center/disaster-response-toolkit/index.html>.

ATTACHMENT A

Blanket Waivers of Sanctions under the Physician Self-Referral Law (also known as the “Stark Law”)

CMS has issued blanket waivers of sanctions under section 1877(g) of the Act. The blanket waivers may be used now without notifying CMS. Individual waivers of sanctions under section 1877(g) of the Act may be granted upon request. For more information, visit: <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Spotlight>.

For resources and additional information on 1135 Waivers, please also visit:

- <https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page>
- <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers>

For questions please email: 1135waiver@cms.hhs.gov

Blanket Waivers: Stafford Act, Public Health Emergency (PHE) and Section 1135 Waivers

Background

On March 13, 2020, the President issued an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5207 (the “Stafford Act”) to declare a national health emergency. The Secretary of the Department of Health and Human Services (the Secretary) is authorized to waive certain Medicare, Medicaid and Children’s Health Insurance Program (CHIP) program requirements and conditions of participation under Section 1135 of the Social Security Act once the President has declared an emergency through the Stafford Act¹ and the Secretary has declared a Public Health Emergency (PHE). The Secretary issued a PHE on January 31, 2020². As a result of this authority, CMS can grant waivers that will ease certain requirements for affected providers as stated under Section 1135 of the Social Security Act³.

CMS can issue two types of waivers: blanket waivers and provider/supplier requested waivers. Specifics about the two types of waivers are outlined in detail below. Examples of these 1135 waivers or modifications include:

- Conditions of participation or other certification requirements
- Program participation and similar requirements
- Preapproval requirements
- Requirements that physicians and other health care professionals be licensed in the State in which they are providing services, so long as they have equivalent licensing in another State (this waiver is for purposes of Medicare, Medicaid, and CHIP reimbursement only – state law governs whether a non-Federal provider is authorized to provide services in the state without state licensure)
- Emergency Medical Treatment and Labor Act (EMTALA)
- Sanctions under the physician self-referral law (also known as the “Stark Law”)
- Performance deadlines and timetables may be adjusted (but not waived)
- Limitations on payment for health care items and services furnished to Medicare Advantage enrollees by non-network providers

Waivers under Section 1135 of the Social Security Act typically end no later than the termination of the emergency period, or 60 days from the date the waiver or modification is first published. The Secretary can extend the waiver by notice for additional periods of up to 60 days, up to the end of the emergency period.

¹ <https://www.whitehouse.gov/wp-content/uploads/2020/03/LetterFromThePresident.pdf>

² <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>

³ <https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx>

The 1135 waiver authority applies **only** to Federal requirements and **does not apply** to State requirements for licensure or conditions of participation.

In addition to the 1135 waiver authority, Section 1812(f) of the Social Security Act (the Act) authorizes the Secretary to provide for Skilled Nursing Facilities (SNF) coverage in the absence of a qualifying hospital stay, as long as this action does not increase overall program payments and does not alter the SNF benefit's "acute care nature" (that is, its orientation toward relatively short-term and intensive care).

Federally certified/approved providers must continue to operate under normal rules and regulations, unless they have sought and have been granted modifications under the waiver authority from specific requirements.

In addition, the Coronavirus Preparedness and Response Supplemental Appropriations Act, as signed into law by the President on March 6, 2020, includes a provision allowing the Secretary to waive certain Medicare telehealth payment requirements during the PHE the Secretary declared on January 31, 2020 to allow beneficiaries in all areas of the country to receive telehealth services, including at their home. Under the waiver, limitations on where Medicare patients are eligible for telehealth will be removed during the emergency. In particular, patients outside of rural areas, and patients in their homes will be eligible for telehealth services, effective for services starting March 6, 2020⁴.

⁴ <https://edit.cms.gov/files/document/medicare-telehealth-frequently-asked-questions-faqs-31720.pdf>

CMS Section 1135 Waiver Authority: Blanket Waivers, Provider/Supplier Individual Waivers, Medicaid and Special Waivers

Medicare Blanket Waivers

- **Approval:** CMS implements specific waivers or modifications under the 1135 authority on a “blanket” basis when a determination has been made that all similarly situated providers in the emergency area need such a waiver or modification. These waivers prevent gaps in access to care for beneficiaries impacted by the emergency. **Once approved these waivers apply automatically to all applicable providers and suppliers. Providers and suppliers do not need to apply for an individual waiver if a blanket waiver is issued by CMS.**
- **Claims Submission for Blanket Waivers:** When submitting claims covered by the blanket waivers, the “DR” (disaster-related) condition code should be used 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 should be used 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). This requirement does not apply for purposes of compliance with waivers (blanket or individual) of sanctions under the physician self-referral law.

Medicare Provider/Supplier Individual Waivers

- **Approval:** Providers and suppliers can submit requests for individual 1135 waivers. These requests must include a justification for the waiver and expected duration of the modification requested. The State Survey Agency and CMS Survey Operations Group will review the provider’s request and make appropriate decisions, usually on a case- by- case basis. Providers and suppliers should keep careful records of beneficiaries to whom they provide services, in order to ensure that proper payment may be made. Providers are expected to come into compliance with any waived requirements prior to the end of the emergency period.
- With the exception of physician self-referral law waivers, the process for requesting an 1135 waiver is managed through the Survey Operations Group, and CMS locations, previously known as the CMS Regional Offices. More information on the process is located at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers>. The website includes contact information for each CMS location. Facilities should ensure to review the process and identify the appropriate contact based on the location of the facility.

Examples of Individual Requests for 1135 Waivers

An individual hospital may request a waiver of COPs related to doubling of single occupancy patient rooms or a waiver of the requirement to discharge to a specified location or situation.

Waiver Request Process

You **do not** have to make a request for a blanket waiver that has already been issued, and you **do not** have to notify CMS if you are taking action in accordance with a waiver during the time period in which the waiver is valid. If you are requesting an 1135 waiver outside of those outlined in this document or are already available at the CMS [Current Emergencies](#) page, please send your request or questions about a request to 1135waiver@cms.hhs.gov.

Medicaid Waivers

Approval

CMS works with the states and territories to respond to public health emergencies and disasters. States and territories have multiple strategies available to support Medicaid and CHIP Operations and enrollees in times of crisis. Some of these strategies are available without needing approval from CMS while some disaster-related and Public Health Emergency legal authorities include:

- Medicaid State Plan Amendments;
- CHIP Disaster Relief State Plan Amendments;
- Verification Plans;
- 1915(c) Waivers Appendix K;
- 1135 Waivers; and
- 1115 Demonstrations.

In Medicaid and CHIP, 1135 waivers can be used to implement a range of flexibilities. Some of these include: provider enrollment and participation; Medicaid prior authorization requirements; pre-admission screening and annual resident review (PASRR) Level I and Level II Assessments for 30 days; extend minimum data set authorizations for nursing facility and SNF residents; state fair hearing and appeal process timelines; and reporting and oversight. Under 1135 waivers, states also have flexibility on public notice, tribal consultation, and the effective dates of state plan amendment (SPA) submissions. For public notice, Section 1135 authority can be used to provide flexibility related to the need and timing for public notice associated with cost sharing, Alternative Benefit Plan (ABP) benefit and payment SPAs. Section 1135 authority can be used to provide flexibility related to the timing of tribal consultation including shortening consultation or conducting tribal consultation after submission of the SPA. For SPA submission dates, Section 1135 authority can be utilized to effectively permit states to submit a Medicaid SPA after the end of this quarter and still have an effective date retroactive to the date of the declaration by the Secretary of a Public Health Emergency.

In the event of a disaster or public health emergency, state Medicaid agencies should contact CMS for questions and waiver requests. More information on this process is located at: <https://www.medicaid.gov/state-resource-center/disaster-response-toolkit/index.html>

Special Waivers

EMTALA:

Only two aspects of the EMTALA requirements can be waived under 1135 Waiver Authority: 1) Transfer of an individual who has not been stabilized, if the transfer arises out of an emergency or, 2) Redirection to another location (offsite alternate screening location) to receive a medical screening exam under a state emergency preparedness or pandemic plan. A waiver of EMTALA sanctions is effective only if actions under the waiver do not discriminate as to source of payment or ability to pay. Hospitals are generally able to manage the separation and flow of potentially infectious patients through alternate screening locations on the hospital campus.

Therefore, waivers to provide Medical Screening Examinations at an offsite alternate screening location not owned or operated by the hospital will be reviewed on a case by case basis. Please note, there is no waiver authority available for any other EMTALA requirement.

For the duration of the COVID-19 national emergency, CMS is waiving the enforcement of section 1867(a) of the Social Security Act (the Emergency Medical Treatment and Active Labor Act, or EMTALA). This will allow hospitals, psychiatric hospitals, and CAHs to screen patients at a location offsite from the hospital's campus to prevent the spread of COVID-19, in accordance with the state emergency preparedness or pandemic plan.

Individual Physician Self-Referral Law Waiver Requests:

CMS has issued blanket waivers of sanctions under the physician self-referral law. The blanket waivers may be used now without notifying CMS. For more information, visit: <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Spotlight>.

Unlike other 1135 waiver requests, any requests for individual waivers of sanctions under the physician self-referral law related to COVID-19 will be handled by CMS Baltimore. Please send your request to 1877CallCenter@cms.hhs.gov and include the words "Request for 1877(g) Waiver" in the subject line of the email. All requests should include the following minimum information:

- Name and address of requesting entity;
- Name, phone number and email address of person designated to represent the entity;
- CMS Certification Number (CCN) or Taxpayer Identification Number (TIN);
- Nature of request.

Individual waivers may be granted only upon request and on a case-by-case basis and require specific details concerning the actual or proposed financial relationship between the referring physician(s) and the referred-to entity. Unless and until a waiver of sanctions under the physician self-referral law (i.e., a waiver of section 1877(g) of the Social Security Act) is granted to the requesting party(ies), such party(ies) must comply with section 1877 of the Social Security Act and the regulations at 42 CFR §411.350 et seq.

Helpful Website Resources

- **Approved 1135 Waivers:** <https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf>
- **Approved Telehealth Waivers:** <https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet>
- **1135 Waiver Request Information:** <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers>
- **Medicare Fee-For-Service Additional Emergency and Disaster-Related Policies and Procedures That May Be Implemented Only With an §1135 Waiver:** <https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/MedicareFFS-EmergencyQsAs1135Waiver.pdf>
- **Blanket Waivers – Claims Submission:** <https://www.cms.gov/files/document/se20011.pdf>
- **Frequently Asked Questions – 1135 Waivers:** <https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/MedicareFFS-EmergencyQsAs1135Waiver.pdf>
- **Frequently Asked Questions – non-1135 Waivers:** https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Consolidated_Medicare_FFS_Emergency_QsAs.pdf
- **Medicaid Disaster Response Toolkit:** <https://www.medicare.gov/state-resource-center/disaster-response-toolkit/index.html>

CMS Oversight

CMS remains committed to ensuring continuity of oversight activities during a national public health emergency. We continue to work State Survey Agencies and accrediting organizations, charged with inspecting Medicare and Medicaid providers to ensure compliance with Federal requirements, to ensure these activities are prioritized to allow providers to focus on current health and safety threats and provide needed care to beneficiaries. We will continue to monitor program operations to support proper enrollment and accurate billing practices. CMS will coordinate our oversight activities with the OIG and GAO.



Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-20-24-ASC

DATE: April 3, 2020

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Guidance for Processing Attestation Statements from Ambulatory Surgical Centers (ASCs) Temporarily Enrolling as Hospitals during the COVID-19 Public Health Emergency

Memorandum Summary

- ***CMS is committed*** to taking critical steps to ensure America's health care facilities are prepared to respond to the COVID-19 Public Health Emergency (PHE).
- ***Waivers:*** CMS waivers adopted under the 1135 emergency waiver authority create additional flexibilities to allow enrolled ASCs to temporarily enroll as hospitals and to provide hospital services to help address the urgent need to increase hospital capacity to take care of patients.
- ***CMS Regional Office Processing of Attestations:*** This memorandum outlines the steps for processing attestations and certification kits for existing Medicare certified ASCs that choose to temporarily enroll as a hospital during the COVID-19 PHE.

Background

The Centers for Medicare & Medicaid Services (CMS) is providing needed flexibility to hospitals to ensure they have the ability to expand capacity and to treat patients during the COVID-19 PHE*. This includes waivers that permit implementation of these flexibilities. Due to the infrastructure that exists in most ASCs, these facilities have been identified as a critical resource to assist in expanding capacity for inpatient and outpatient hospital services for patients requiring a higher level of care. Consistent with the Hospitals without Walls strategy announced by the CMS Administrator, we expect ASCs to coordinate with their local healthcare systems and/or their state and local health departments operating under their state's emergency preparedness or pandemic plan during this PHE to help meet surge needs in their community.

Guidance

As part of the COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers (<https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf>),

During the COVID-19 PHE, CMS is allowing all Medicare-enrolled ASCs to enroll as hospitals and provide inpatient and outpatient hospital services to help address the urgent need to increase hospital capacity to take care of patients.

Any Medicare-certified ASC wishing to enroll as a hospital during the COVID-19 PHE should notify the Medicare Administrative Contractor (MAC) that serves their jurisdiction of its intent by calling the MAC's provider enrollment hotline and following the instructions noted in the [2019- Novel Coronavirus \(COVID-19\) Medicare Provider Enrollment Relief Frequently Asked Questions \(FAQs\)](#) document. The ASC will be asked by the MAC to submit a signed attestation statement (see attachment to this memo) to the MAC. It should be noted that the provider cannot be certified/enrolled both as an ASC and hospital at the same time. If an ASC enrolls as a hospital, it must meet the hospital Conditions of Participation, to the extent not waived, and would receive hospital payments, not ASC payments. Therefore, any ASC that is enrolled as a hospital will have its ASC billing privileges deactivated for the duration of the time it is enrolled as a hospital.

The MAC will review and forward the signed attestation statement to the CMS RO mailbox, consistent with normal processes for ASC/hospital certification for further review. Within two business days, the CMS Regional Office (RO) will review all survey activity of the facility from the previous three years (recertification and/or complaint), to determine if Immediate Jeopardy (IJ)-level deficiencies were cited. For deemed status ASCs, CMS Central Office (CO) will provide a list to the CMS Survey Operations Group of those ASCs with IJ-level deficiencies cited within the previous three years.

If no IJ-level deficiencies were found in the previous three years, or if IJ-level deficiencies were found but subsequently removed through the normal survey process, the CMS RO will:

- Review and approve the attestation statement
- Create a new facility profile and certification kit in the Automated Survey Process Environment (ASPEN) and assign a hospital CMS Certification Number (CCN)
- Send a tie-in notice as a hospital to the MAC. The effective date of enrollment is the date when the attestation was accepted by the MAC.

Note that an onsite survey is not required for approval. However, the CMS RO may authorize a survey by the State Survey Agency at a later date to ensure quality and safety. If survey activity is warranted, it will be a focused infection control survey based on [QSO-20-20-ALL](#), and the availability of PPE as needed. Any need for enforcement actions would follow what is outlined in the referenced memo or any subsequent updates to the memo.

If IJ-level deficiencies are found within the last year and enforcement activities are currently ongoing, then the CMS RO will not accept the attestation and notify the MAC of denial of temporary hospital enrollment. No further actions will be taken to enroll the ASC as a hospital under this process.

Once the Secretary of the Department of Health and Human Services (Secretary) determines there is no longer a PHE due to COVID-19, the CMS RO will terminate the hospital CCN and send a tie-out notice to the applicable MAC. The MAC will deactivate the hospital billing privileges and reinstate the ASC billing privileges effective on the date the ASC terminates its hospital status. If the temporarily enrolled hospital decides to revert back to an ASC prior to the end of the PHE period, they must notify their MAC in writing. Note that once there is no longer a need for the

ASC to be a hospital under their state's emergency preparedness or pandemic plan, the ASC should come back into compliance with all applicable ASC federal participation requirements, including the Conditions for Coverage.

If the ASC wishes to participate as a hospital after the PHE has ended, it must submit form 855A to begin the process of enrollment and initial certification as a hospital under the regular processes. An initial survey, either done by the State Agency or Accreditation Organization, will be conducted to determine compliance with all applicable hospital Conditions of Participation. CMS will provide any additional updates if this process changes as the PHE progresses or ends.

Additional Resources

*Public Health Emergency <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>

Section 3087 of the 21st Century Cures Act, signed into law in December 2016, added subsection (f) to section 319 of the Public Health Service Act. This new subsection gives the HHS Secretary the authority to waive Paperwork Reduction Act (PRA) (44 USC 3501 et seq.) requirements with respect to voluntary collection of information during a public health emergency (PHE), as declared by the Secretary, or when a disease or disorder is significantly likely to become a public health emergency (SLPHE). Under this new authority, the HHS Secretary may waive PRA requirements for the voluntary collection of information if the Secretary determines that: (1) a PHE exists according to section 319(a) of the PHS Act or determines that a disease or disorder, including a novel and emerging public health threat, is a SLPHE under section 319(f) of the PHS Act; and (2) the PHE/SLPHE, including the specific preparation for and response to it, necessitates a waiver of the PRA requirements. The Office of the Assistant Secretary for Planning and Evaluation (ASPE) has been designated as the office that will coordinate the process for the Secretary to approve or reject each request.

The information collection requirements contained in this information collection request have been submitted and approved under a PRA Waiver granted by the Secretary of Health and Human Services. The waiver can be viewed at <https://aspe.hhs.gov/public-health-emergency-declaration-pra-waivers>.

Contact

Questions about this memorandum should be addressed to QSOG_ASC@cms.hhs.gov.

Effective Date

Effective immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators immediately. This guidance will cease to be in effect when the Secretary determines there is no longer a Public Health Emergency due to COVID-19. At that time, CMS will send public notice that this guidance has ceased to be effective via its website.

/s/

David R. Wright

cc: Survey and Operations Group Management

Attachment: (1)

Ambulatory Surgical Center (ASC) Hospital Enrollment Attestation Statement
For Use During COVID-19 Public Health Emergency (PHE)*

This attestation statement applies to: _____
(Legal Business Name of Entity)

D/B/A, if any: _____

Located at: _____
(Address, including street name and number, suite number if applicable, city, state, zip code)

Existing ASC CMS Certification Number (CCN): _____

In order to enroll as a Hospital during the COVID-19 PHE, the undersigned individual authorized by the ASC entity's Governing Body attests that the entity meets and will continue to meet, during the PHE, all applicable hospital federal participation requirements and that the following safeguards are in place (Check each item for an affirmative response):

_____ The ASC named above may enroll as a hospital provided that it is not inconsistent with the state's emergency preparedness or pandemic plan.

_____ To the extent not waived, the ASC named above is compliant with the requirements of 42 CFR 482.23 Condition of Participation: Nursing Services. In particular, but not limited to:

- Ensure adequate numbers of licensed registered nurses and other personnel to provide nursing care to all patients as needed
- Provide 24 hour nursing services furnished or supervised by a registered nurse
- Ensure drugs and pharmaceuticals are prepared and administered in accordance with Federal and State laws and according to the orders of the practitioner(s) responsible for the patient's care

_____ To the extent not waived, the ASC named above is compliant with the requirements of 42 CFR 482.25 Condition of Participation: Pharmaceutical Services. In particular, but not limited to:

- Provide pharmaceutical services that meet the needs of the patients
- Have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision
- Provide a full-time, part-time or consultant pharmacist who is responsible for all activities of the pharmacy services
- Provide an adequate number of personnel to ensure high quality pharmaceutical services, including emergency services
- Ensure Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse and Prevention and Control Act of 1970 are kept locked within a secure area

_____ To the extent not waived, the ASC named above is compliant with the requirements of 42 CFR 482.42 Condition of Participation: Infection Control and Antibiotic Stewardship Programs. In particular, but not limited to:

- Appointed a qualified individual as the Infection Preventionist/Infection Control Professional
- Employ methods for preventing and controlling the transmission within the hospital and between other providers
- Create an Infection Control Surveillance plan to control Healthcare Acquired Infections
- Establish a hospital-wide antibiotic stewardship program in accord with national standards

_____ To the extent not waived, the ASC named above is compliant with the requirements of 42 CFR 482.57 Condition of Participation: Respiratory Services. In particular, but not limited to:

- Ensures that a director of respiratory care services who is a doctor of medicine or osteopathy is available on a full or part-time basis to supervise and administer respiratory services
- Ensure an adequate number of qualified respiratory therapists and technicians
- Ensure all respiratory services are delivered in accordance with medical staff directives

Attestation on behalf of the ASC named above by:

Signature _____ Title _____

Printed Name _____ Date _____

** This attestation statement will cease to be in effect and the associated hospital CCN will be terminated when the Secretary of the Department of Health and Human Services determines there is no longer a Public Health Emergency due to COVID-19. At that time, CMS will send public notice that this attestation has ceased to be effective via its website.*

Section 3087 of the 21st Century Cures Act, signed into law in December 2016, added subsection (f) to section 319 of the Public Health Service Act. This new subsection gives the HHS Secretary the authority to waive Paperwork Reduction Act (PRA) (44 USC 3501 et seq.) requirements with respect to voluntary collection of information during a public health emergency (PHE), as declared by the Secretary, or when a disease or disorder is significantly likely to become a public health emergency (SLPHE). Under this new authority, the HHS Secretary may waive PRA requirements for the voluntary collection of information if the Secretary determines that: (1) a PHE exists according to section 319(a) of the PHS Act or determines that a disease or disorder, including a novel and emerging public health threat, is a SLPHE under section 319(f) of the PHS Act; and (2) the PHE/SLPHE, including the specific preparation for and response to it, necessitates a waiver of the PRA requirements. The Office of the Assistant Secretary for Planning and Evaluation (ASPE) has been designated as the office that will coordinate the process for the Secretary to approve or reject each request.

The information collection requirements contained in this information collection request have been submitted and approved under a PRA Waiver granted by the Secretary of Health and Human Services. The waiver can be viewed at <https://aspe.hhs.gov/public-health-emergency-declaration-pra-waivers>.

Medicare Administrative Contractors (MACs)
As of June 2019

| MAC Jurisdiction | Processes Part A & Part B Claims for the following states: | MAC |
|------------------|--|---|
| DME A | Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont | Noridian Healthcare Solutions, LLC |
| DME B | Illinois, Indiana, Kentucky, Michigan, Minnesota, Ohio, Wisconsin | CGS Administrators, LLC |
| DME C | Alabama, Arkansas, Colorado, Florida, Georgia, Louisiana, Mississippi, New Mexico, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, West Virginia, Puerto Rico, U.S. Virgin Islands | CGS Administrators, LLC |
| DME D | Alaska, Arizona, California, Hawaii, Idaho, Iowa, Kansas, Missouri, Montana, Nebraska, Nevada, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming, American Samoa, Guam, Northern Mariana Islands | Noridian Healthcare Solutions, LLC |
| 5 | Iowa, Kansas, Missouri, Nebraska | Wisconsin Physicians Service Government Health Administrators |
| 6 | Illinois, Minnesota, Wisconsin **HH + H for the following states: Alaska, American Samoa, Arizona, California, Guam, Hawaii, Idaho, Michigan, Minnesota, Nevada, New Jersey, New York, Northern Mariana Islands, Oregon, Puerto Rico, US Virgin Islands, Wisconsin and Washington | National Government Services, Inc. |
| 8 | Indiana, Michigan | Wisconsin Physicians Service Government Health Administrators |
| 15 | Kentucky, Ohio **HH + H for the following states: Delaware, District of Columbia, Colorado, Iowa, Kansas, Maryland, Missouri, Montana, Nebraska, North Dakota, Pennsylvania, South Dakota, Utah, Virginia, West Virginia, and Wyoming | CGS Administrators, LLC |
| E | California, Hawaii, Nevada, American Samoa, Guam, Northern Mariana Islands | Noridian Healthcare Solutions, LLC |
| F | Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming | Noridian Healthcare Solutions, LLC |
| H | Arkansas, Colorado, New Mexico, Oklahoma, Texas, Louisiana, Mississippi | Novitas Solutions, Inc. |
| J | Alabama, Georgia, Tennessee | Palmetto GBA, LLC |
| K | Connecticut, New York, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont **HH + H for the following states: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont | National Government Services, Inc. |
| L | Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania (includes Part B for counties of Arlington and Fairfax in Virginia and the city of Alexandria in Virginia) | Novitas Solutions, Inc. |
| M | North Carolina, South Carolina, Virginia, West Virginia (excludes Part B for the counties of Arlington and Fairfax in Virginia and the city of Alexandria in Virginia) **HH + H for the following states: Alabama, Arkansas, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Mississippi, New Mexico, North Carolina, Ohio, Oklahoma, South Carolina, Tennessee, and Texas | Palmetto GBA, LLC |
| N | Florida, Puerto Rico, U.S. Virgin Islands | First Coast Service Options, Inc. |

**Also Processes Home Health and Hospice claims