

Hospitals: CMS Flexibilities to Fight COVID-19

The Trump Administration is issuing an unprecedented array of temporary regulatory waivers and new rules to equip the American healthcare system with maximum flexibility to respond to the 2019 Novel Coronavirus (COVID-19) pandemic. Made possible by President Trump's recent emergency declaration and emergency rule making, these temporary changes will apply immediately across the entire U.S. healthcare system for the duration of the emergency declaration. The goals of these actions are to 1) to ensure that local hospitals and health systems have the capacity to handle a potential surge of COVID-19 patients through temporary expansion sites (also known as CMS Hospital Without Walls); 2) remove barriers for physicians, nurses, and other clinicians to be readily hired from the community or from other states so the healthcare system can rapidly expand its workforce; 3) increase access to telehealth in Medicare to ensure patients have access to physicians and other clinicians while keeping patients safe at home; 4) expand in-place testing to allow for more testing at home or in community based settings; and 5) put Patients Over Paperwork to give temporary relief from many paperwork, reporting and audit requirements so providers, health care facilities, Medicare Advantage and Part D plans, and States can focus on providing needed care to Medicare and Medicaid beneficiaries affected by COVID-19.

CMS Hospital without Walls (Temporary Expansion Sites)

- **Hospitals Able to Provide Inpatient Care in Temporary Expansion Sites:** As part of the CMS Hospital Without Walls initiative, hospitals can provide hospital services in other healthcare facilities and sites not currently considered to be part of a healthcare facility or set up temporary expansion sites to help address the urgent need to increase capacity to care for patients. Previously, hospitals were required to provide services to patients within their hospital departments, and have shared concerns about capacity for treating patients during the COVID-19 Public Health Emergency, especially those requiring ventilator and intensive care services. CMS is providing additional flexibilities for hospitals to create surge capacity by allowing them to provide room and board, nursing, and other hospital services at remote locations or sites not considered part of a healthcare facility such as hotels or community facilities. This flexibility will allow hospitals to separate COVID-19 positive patients from other non-COVID-19 patients to help efforts around infection control and preservation of personal protective equipment (PPE). For example, for the duration of the Public Health Emergency, CMS is allowing hospitals to screen patients at offsite locations, furnish inpatient and outpatient services at temporary expansion sites. Hospitals would still be expected to control and oversee the services provided at an alternative location.

- Under an additional initiative, CMS is relaxing certain conditions of participation (CoPs) for hospital operations to maximize hospitals ability to focus on patient care. The same initiative will also allow currently enrolled ambulatory surgical centers (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. Other interested entities, such as freestanding emergency departments, could pursue enrolling as an ASC and then pursue converting their enrollment to hospital during the PHE. ASCs that wish to enroll to receive temporary billing privileges as a hospital should call the COVID-19 Provider Enrollment Hotline to reach the contractor that serves their jurisdiction, and then will complete and sign an attestation form specific to the COVID-19 PHE. See <https://www.cms.gov/files/document/provider-enrollment-relief-faqs-covid-19.pdf> for additional information.
- **Off Site Patient Screening:** 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 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 the state emergency preparedness or pandemic plan.
- **Paperwork Requirements:** CMS is waiving certain specific paperwork requirements under this section only for hospitals which are considered to be impacted by a widespread outbreak of COVID-19. This allows hospitals to establish COVID-10 specific areas. Hospitals that are located in a state that has widespread confirmed cases would not be required to meet the following requirements:
 - 42 CFR §482.13(d)(2) with respect to timeframes in providing a copy of a medical record.
 - 42 CFR §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.
 - 42 CFR §482.13(e)(1)(ii) regarding seclusion.
- **Physical Environment:** CMS is waiving certain requirements under the conditions 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 safety and comfort for patients and staff are sufficiently addressed). This allows for increased capacity and promotes appropriate cohorting of COVID-19 patients.
- **Temporary Expansion Sites:** 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 above) and the provider-based department requirements at 42 CFR §413.65 to allow hospitals to establish and operate as part of the hospital any location meeting the conditions of participation for hospitals in operation 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 waiver will enable hospitals to meet the needs of Medicare beneficiaries. CMS also is offering some additional flexibilities to furnish inpatient services under arrangements.

- **Critical Access Hospital Length of Stay:** CMS is waiving the Medicare requirements that Critical Access Hospitals (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 regarding number of beds and length of stay at 42 CFR §485.620.
- **CAH Status and location:** CMS is waiving the requirement at 485.610(b) that the CAH be located in a rural area or an area being treated as rural, allowing the CAHs flexibility in the establishment of surge site locations. Waiving the requirement at 485.610(e) regarding off-campus and co-location requirements allows the CAH flexibility in establishing off-site locations. In an effort to facilitate the establishment of CAHs without walls, these waivers will remove restrictions on CAHs regarding their rural location and their location relative to other hospitals and CAHs. These flexibilities should be implemented so long as it is not inconsistent with State or emergency or pandemic plan.
- **Housing Acute Care Patients in Excluded Distinct Part Units:** CMS is waiving requirements to allow acute care hospitals to house acute care inpatients in excluded distinct part units, where the distinct part unit's beds are appropriate for 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 waiving requirements to allow acute care hospitals with excluded distinct part inpatient psychiatric units that, as a result of a disaster or emergency, need to relocate inpatients from the excluded distinct part psychiatric unit to an acute care bed and unit. The hospital should continue to bill for inpatient psychiatric services under the Inpatient Psychiatric Facility Prospective Payment System (IPF PPS) for such 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 Public Health 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 waiving requirements to allow 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. The hospital should continue to bill for inpatient rehabilitation services under the Inpatient Rehabilitation Facility Prospective Payment System for such patients and annotate the medical record to indicate the patient is a rehabilitation inpatient being cared for in an acute care bed because of capacity or other exigent circumstances related to the 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.

- **Telemedicine:** CMS is waiving the provisions related to telemedicine for hospitals and CAHs at 42 CFR 482.12(a)(8-9) and 42 CFR 485.616(c), 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.

Patients Over Paperwork

- **Verbal Orders:** CMS is waiving the requirements of 42 CFR §482.23, §482.24 and §485.635(d)(3) to allow for additional flexibilities related to verbal orders where read-back verification is still required but authentication may occur later than 48 hours. This will allow for more efficient treatment of patients in a surge situation.
- **Reporting Requirements:** CMS is waiving reporting requirements at §482.13(g) (1)(i)-(ii) which require hospitals to report patients in an intensive care unit whose death is caused by their disease process but who required soft wrist restraints to prevent pulling tubes/IVs, may be reported later than close of business next business day, provided any death where the restraint may have contributed is continued to be reported within standard time limits. Due to current hospital surge, we are waiving this requirement to ensure that hospitals are focusing on increased care demands and patient care.
- **Limit Discharge Planning for Hospital and CAHs:** To allow hospitals and CAHs more time to focus on increasing care demands, discharge planning will focus on ensuring that patients are discharged to an appropriate setting with the necessary medical information and goals of care. CMS is waiving detailed regulatory requirements to provide information regarding discharge planning, as outlined in 42 CFR §482.43(a)(8), §482.61(e), and 485.642(a)(8). 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) data on quality measures and data on resource use measures. The hospital must ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences. During this public health emergency, a hospital may not be able to assist patients in using quality measures and data to select a nursing home or home health agency, but must still work with families to ensure that the patient discharge is to a post-acute care provide that is able to meet the patient's care needs.

- **Modify Discharge Planning for Hospitals:** Patients must continue to be discharged to an appropriate setting with the necessary medical information and goals of care. To address the COVID-19 pandemic, CMS is waiving certain requirements related to hospital discharge planning for post-acute care services at 42 CFR §482.43(c), 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 waiving certain requirements for those patients discharged home and referred for HHA services, or for those patients transferred to a SNF for post-hospital extended care services, or transferred to an IRF or LTCH for specialized hospital services. For example, a patient may not be able to receive a comprehensive list of nursing homes in the geographic area, but must still be discharged to a nursing home that is available to provide the care that is need by the patient.
- **Medical Records:** CMS is waiving 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. CMS is waiving requirements under 42 CFR §482.24(c)(4)(viii) and §485.638(a)(4)(iii) related to medical records to allow flexibility in completion of medical records within 30 days following discharge and for CAHs that all medical records must be promptly completed. 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 section 1902(a)(58) and 1902(w)(1)(A) for Medicaid, 1852(i) (for Medicare Advantage), and 1866(f) and 42 CFR 489.102 for Medicare, which require hospitals and CAHs to provide information about its advance directive policies to patients. We are waiving this requirement to allow for staff to more efficiently deliver care to a larger number of patients.
- **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. CMS is currently granting an extension for data submission 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.
- **Utilization review:** CMS is waiving these requirements at 42 CFR §482.1(a)(3) and 42 C.F.R §482.30, that requires that hospitals participating in Medicare and Medicaid to have a utilization review plan that meets specified requirements. CMS is waiving the entire Utilization Review CoP at §482.30, which requires that a hospital must have a utilization review (UR) plan with a UR committee that provides for 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 should be implemented so long as they are not inconsistent with a State or pandemic/emergency plan. Removing these administrative requirements will allow hospitals to focus more resources on providing direct patient care.

- **Quality assessment and performance improvement program.** CMS is waiving 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 QAPI programs (for hospitals that are a part of a hospital system). These flexibilities, which apply to both hospitals and CAHs, should 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. 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.
- **Nursing services:** CMS is waiving the provision at 42 CFR 482.23(b)(4), 42 CFR 482.23(b)(7), and 485.635(d)(4), which requires the nursing staff to develop and keep current a nursing care plan for each patient, and the provision that requires the hospital to have policies and procedures in place establishing which outpatient departments are not required under to have a registered nurse present. These waivers allow nurses increased time to meeting 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 unnecessary. These flexibilities apply to both hospitals and CAHs, and should be implemented so long as they are not inconsistent with a State or pandemic/emergency plan.
- **Food and dietetic service:** CMS is waiving the requirement at 42 CFR 482.28(b)(3) 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 should be implemented so long as they are not inconsistent with a State or pandemic/emergency 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 482.12(f)(3) related to Emergency services, with respect to the surge facility(ies) 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 should 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 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 temporary expansion site. This waiver removes the burden on facilities to establish these policies and procedures for their surge facilities or surge sites.
- **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.
- **Accelerated/Advance Payments:** In order to increase cash flow to providers impacted by COVID-19, CMS has expanded our current Accelerated and Advance Payment Program. An accelerated/advance payment is a payment intended to provide necessary funds when there is a disruption in claims submission and/or claims processing. CMS is authorized to provide accelerated or advance payments during the period of the public health emergency to any Medicare provider/supplier who submits a request to the appropriate Medicare Administrative Contractor (MAC) and meets the required qualifications. Each MAC will work to review requests and issue payments within seven calendar days of receiving the request. Traditionally repayment of these advance/accelerated payments begins at 90 days, however for the purposes of the COVID-19 pandemic, CMS has extended the repayment of these accelerated/advance payments to begin 120 days after the date of issuance of the payment. Providers can get more information on this process here: www.cms.gov/files/document/Accelerated-and-Advanced-Payments-Fact-Sheet.pdf.
- **Cost Reporting:** CMS is delaying the filing deadline of certain cost report due dates due to the COVID-19 outbreak. We are currently authorizing delay for the following fiscal year end (FYE) dates. CMS will delay the filing deadline of FYE 10/31/2019 cost reports due by March 31, 2020 and FYE 11/30/2019 cost reports due by April 30, 2020. The extended cost report due dates for these October and November FYEs will be June 30, 2020. CMS will also delay the filing deadline of the FYE 12/31/2019 cost reports due by May 31, 2020. The extended cost report due date for FYE 12/31/2019 will be July 31, 2020.
- **Provider Enrollment:** CMS has established toll-free hotlines for all providers as well as the following flexibilities for provider enrollment:
 - Waive certain screening requirements.
 - Postpone all revalidation actions.
 - Expedite any pending or new applications from providers.

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

- CMS is allowing Medicare Administrative Contractors (MACs) and Qualified Independent Contractor (QICs) in the FFS program 42 CFR 405.942 and 42 CFR 405.962 and MA and Part D plans, as well as the Part C and Part D Independent Review Entity (IREs), 42 CFR 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 42 CFR 405.950 and 42 CFR 405.966 and the Part C and Part D IREs to waive requirements for timeliness for requests for additional information to adjudicate appeals; MA plans may extend the timeframe to adjudicate organization determinations and reconsiderations for medical items and services (but not Part B drugs) by up to 14 calendar days if: the enrollee requests the extension; the extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or, the extension is justified due to extraordinary, exigent, or other non-routine circumstances and is in the enrollee's interest 42 CFR § 422.568(b)(1)(i), § 422.572(b)(1) and § 422.590(f)(1);
- CMS is allowing MACs and QICs in the FFS program 42 C.F.R 405.910 and MA and Part D plans, as well as the Part C and Part D IREs to process an appeal even with incomplete Appointment of Representation forms 42 CFR § 422.561, 42 CFR § 423.560. However, any communications will only be sent to the beneficiary;
- CMS is allowing MACs and QICs in the FFS program 42 CFR 405.950 and 42 CFR 405.966 and MA and Part D plans, as well as the Part C and Part D IREs to process requests for appeal that don't meet the required elements using information that is available 42 CFR § 422.562, 42 CFR § 423.562.
- CMS is allowing MACs and QICs in the FFS program 42 CFR 405.950 and 42 CFR 405.966 and MA and Part D plans, as well as the Part C and Part D IREs, 42 CFR 422.562, 42 CFR 423.562 to utilize all flexibilities available in the appeal process as if good cause requirements are satisfied.

Workforce

- **Sterile Compounding:** CMS is waiving hospital sterile compounding requirements 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 be reviewing the use and storage of facemasks under these requirements.
- **Medical Staff Requirements:** CMS is waiving the Medical Staff requirements at 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 in the hospital before full medical staff/governing body review and approval to address workforce concerns related to COVID-19.

- **Physician services:** CMS is waiving 482.12(c), which requires that Medicare patients be under the care of a physician. This allows hospitals to use other practitioners, such as physician’s assistant and nurse practitioners to the fullest extent possible. This waiver should be implemented so long as they are not inconsistent with a state’s emergency preparedness or pandemic plan.
- **Anesthesia services.** CMS is waiving the requirements at 42 CFR 482.52(a)(5), 42 CFR 485.639(c)(2), and 42 CFR 416.42 (b)(2) that a certified registered nurse anesthetist (CRNA) is under the supervision of a physician. CRNA supervision will be at the discretion of the hospital or Ambulatory Surgical Center (ASC), and state law. This waiver applies to hospitals, CAHs, and ASCs. These waivers will allow CRNAs to function to the fullest extent of their licensure, and should be implemented so long as they are not inconsistent with a State or pandemic/emergency plan.
- **Respiratory care services:** We are waiving the requirement at 42 CFR 482.57(b)(1) that hospitals 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 should be implemented so long as they are not inconsistent with a State or pandemic/emergency 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 for respiratory illnesses.
- **CAH Personnel qualifications:** CMS is waiving the minimum personnel qualifications for clinical nurse specialist, nurse practitioners, and physician assistants described at 42 CFR 485.604 (a)(2), 42 CFR 485.604 (b)(1-3), and 42 C.F.R 485.604 (c)(1-3). Clinical Nurse Specialists, Nurse Practitioners, and Physician Assistants will still have to meet state requirements for licensure and scope of practice, but not additional Federal requirements that may exceed State requirements. This will give States and facilities more flexibility in using clinicians in these roles to meet increased demand. These flexibilities should be implemented so long as they are not inconsistent with a State or pandemic/emergency plan.
- **CAH staff licensure:** CMS is deferring to staff licensure, certification, or registration to State law by waiving the requirement at 42 CFR 485.608(d) that staff of the CAH be licensed, certified, or registered in accordance with applicable Federal, State, and local laws and regulations. The CAH and its staff must still be in compliance with applicable Federal, State and Local laws and regulations, and all patient care must be furnished in compliance with State and local laws and regulations. This waiver would defer all licensure, certification, and registration requirements for CAH staff to the state, which would add flexibility where Federal requirements are more stringent. These flexibilities should be implemented so long as they are not inconsistent with a State or pandemic/emergency plan.

Additional Guidance

- The Interim Final Rule and waivers can be found at: <https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers>.
- CMS has released guidance to providers related to relaxed reporting requirements for quality reporting programs at <https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting>.
- CMS has released guidance to describe standards of practice and flexibilities within the current regulations for hospitals (including critical access hospitals and psychiatric hospitals) at <https://www.cms.gov/files/document/qso-20-13-hospitalspdf.pdf-2>.
- CMS guidance also addresses hospital flexibilities under the Emergency Medical Treatment and Labor Act (EMTALA) to establish alternate testing and triage sites to address the pandemic at <https://www.cms.gov/files/document/qso-20-15-hospitalcahemtala.pdf>.