Guidance – COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers

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Federal Section 1135 Waivers affecting hospitals and CAHs

The following guidance pertains only to federal waivers and flexibilities. For information regarding state waivers and obligations, please consult legal counsel.

On March 13, 2020, the President formally proclaimed the coronavirus disease/COVID-19 a National Emergency under the National Emergencies Act and/or the Stafford Disaster Relief and Emergency Assistance Act[1]. Prior to that, on January 31, 2020, the HHS Secretary had declared a public health emergency under the Public Health Service Act. These actions allowed the Secretary of HHS to invoke the emergency provisions of Section 1135 of the Social Security Act and waive certain requirements of the Act[2]. These Section 1135 waivers take effect beginning March 1, 2020 (the effective date of the president's declaration of a national emergency) and apply to all providers in the United States. The March 1, 2020 effective date also applies to any authorized waiver approved by CMS.

On March 13, 2020, the HHS Secretary then issued several waivers under 1135(b) of the Social Security Act, 42 U.S.C. 1320b-5 (Authority to waive requirements during national emergencies).[3] Further, HHS authorized CMS to issue 1135 waivers under the Act. However, any waivers issued by CMS apply only to federal requirements, and do not apply to state requirements for licensure and conditions of participation.[4]

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[1]https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/ (Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak).

[2] Specifically, 42 CFR 489.24(a)(2)(i) provides, "[w]hen a waiver has been issued in accordance with section 1135 of [the Social Security Act], that includes a waiver of section 1135(b)(3) of the Act, sanctions under this section for an inappropriate transfer or for the direction or relocation of an individual to received medical screening at an alternate location do not apply to a hospital with a dedicated emergency department if the following conditions are met:
(A) The transfer is necessitated by the circumstances of the declared emergency in the emergency area during the emergency period.
(B) The direction or relocation of an individual to receive medical screening at an alternate location is pursuant to an appropriate State emergency preparedness plan or, in the case of a public health emergency that involves a pandemic infectious disease, pursuant to a State pandemic preparedness plan.

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

[4] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Downloads/1135-Waivers-At-A-Glance.pdf (*See* CMS 1135 "Waiver at a Glance" bottom of page 1.)

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With respect to 1135 waivers, providers must apply one of the following claim-level identifiers for disaster or emergency-related claims[5]:

- The CR Modifier or
- DR Condition Code

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.[6]

A. General Waivers – CMS has identified a number of waivers specifically designed to reduce administrative burdens and focus attention on patient care.

1. Verbal Orders.[7]

    a. Authentication may occur later than 48 hours.
    b. If verbal orders are used for the use of drugs and biologicals (except immunizations), it is not required that they are only to be used infrequently.[8]
    c. Not required that 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.[9]
    d. Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders.[10]
    e. 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.[11]

2. Reporting Requirements.[12]

[5] https://www.cms.gov/media/137186 (Medicare Claims Processing Manual); https://www.cms.gov/files/document/se20011.pdf (CMS MLN Matters Number SE 20011, March 20, 2020).

[6] https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf (CMS COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers).

[7] CMS COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers, cited *supra*.

[8] 42 CFR 482.23(c)(3)(i).

[9] 42 CFR 482.24(c)(2).

[10] 42 CFR 482.24(c)(3) (This would include all subparts at section 482.24(c)(3)).

[11] 42 CFR 485.635(d)(3).

[12] CMS COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers, cited *supra*.

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a. Not required for hospitals to 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.
b. Any death where the restraint may have contributed must still be reported within standard time limits (*i.e.,* close of business on the next business day following knowledge of the patient's death).

3. Patient Rights.

CMS is waiving certain requirements[13] only for hospitals that are considered to be impacted by a widespread outbreak of COVID-19. Hospitals that are located in a state that 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, are eligible for these waivers:

a. Not required to provide the patient the right to access their medical records, upon oral or written request, in the form and format requested by the individual within a reasonable time frame – reasonable time frame requirement relaxed (CMS does not indicate how much).[14]
b. Not required to have written policies and procedures on visitation of patients who are in COVID-19 isolation and quarantine processes.[15]
c. Patient does not have a right to be free from seclusion.[16]

4. Sterile Compounding.[17]

a. used face masks may be removed and retained in the compounding area to be re-donned and reused during the same work shift in the compounding area only.
b. CMS will not review the use and storage of facemasks under these requirements.[18]

5. Detailed Information Sharing for Discharge Planning for Hospitals and CAHs.[19]

[13] *Id*.

[14] 42 CFR 482.13(d)(2).

[15] *See* 42 CFR 482.13(h).

[16] *See* 42 CFR 482.13(e)(1)(ii).

[17] CMS COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers, cited *supra*.

[18] *See* 42 CFR 482.25(b)(1) and 485.635(a)(3).

[19] *See* 42 CFR 482.43(a)(8), 482.61(e), and 485.642(a)(8).

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a. Not required that the hospital, psychiatric hospital, and CAH to assist patients, their families, or the patient's representative in selecting a post-acute care provider by using sharing data; and the hospital does not need to 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.
b. Still required to ensure a patient is discharged to an appropriate setting with the necessary medical information and goals of care required by law.[20]

6. Limiting Detailed Discharge Planning for Hospitals.[21]

a. Not required to include in the discharge plan a list of HHAs, SNFs, IRFs, or LTCHs that are available to the patient in the geographic area.
b. Not required to inform the patient or the patient's representative of their freedom to choose among participating Medicare providers and suppliers of post-discharge services.
c. Not required to 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.
d. Still required to ensure a patient is discharged to an appropriate setting with the necessary medical information and goals of care as currently required by law.[22]

7. Medical Staff - CMS is waiving requirements regarding details for the credentialing and privileging process.

a. Physicians whose privileges will expire may continue practicing at the hospital and new physicians may practice before full medical staff/governing body review and approval so that hospitals may address workforce concerns related to COVID-19.[23]

(i) The medical staff is not required to periodically conduct appraisals of its members
(ii) The medical staff is not required to examine the credentials of all eligible candidates for medical staff membership
(iii) Waiver of credentialing and privileging pertains to telemedicine

8. Medical Records.

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[20] *See* 42 CFR 482.43(a)(1)-(7) (outlining requirement for discharge planning).

[21] CMS COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers, cited *supra*.

[22] 42 CFR 482.43(c).

[23] Under 42 CFR 482.22(a)(1)-(4).

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CMS is waiving certain requirements[24] that 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.

a. Not required for the organization of the medical record service to be appropriate to the scope and complexity of the services performed; not required for the hospital to employ adequate personnel to ensure prompt completion, filing, and retrieval of records.
b. Not required for the hospital to maintain a medical record for each inpatient and outpatient and for such medical records to be accurately written, promptly completed, properly filed and retained, and accessible, or for the hospital to use a system of author identification and record maintenance that ensures the integrity of all authentification and protects the security of all record entries.
c. These flexibilities may be implemented *so long as they are not inconsistent with the state's emergency preparedness or pandemic plan.*
d. Medical records not required to be completed within 30 days following discharge from a hospital.[25]
e. Remember that the integrity of your medical records will still be the best defense to subsequent claims against hospitals and providers.

9. Flexibility in Patient Self Determination Act Requirements (Advance Directives)[26].

Hospitals and CAHs are not required to provide information about their advance directive policies to patients.[27]

10. Physical Environment - CMS is waiving certain requirements[28] to allow for flexibilities during hospital, psychiatric hospital, and CAH surges.

a. Non-hospital buildings/space may 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).

[24] 42 CFR 482.24(a) –(c); a general outline is provided here, but the regulations contain more detail on the requirements outlined in the rule.

[25] 42 CFR 482.24(c)(4)(viii).

[26] CMS COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers, cited *supra*.

[27] Requirements of 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.

[28] 42 CFR 482.41 and 485.623.

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b. These changes will be permissible *so long as they are not inconsistent with a state's emergency preparedness or pandemic plan*.
c. This allows for increased capacity and promotes appropriate cohorting of COVID-19 patients.

11. Telemedicine

CMS is waiving some of the provisions related to telemedicine[29] for hospitals and CAHs, making it easier for telemedicine services to be furnished to the hospital's patients through and agreement with an off-site hospital. *See* Telemedicine Guidance sheet for further details regarding telemedicine.

12. Physician Services.

Modified to allow hospitals to use other practitioners to the fullest extent possible.

a. Not required for Medicare patients to be under the care of a physician.[30] This allows hospitals to use other practitioners to the fullest extent possible.
b. *This waiver may be implemented so long as it is not inconsistent with a state's emergency preparedness or pandemic plan.*
c. A doctor of medicine or osteopathy still must be on duty or on call at all times.[31]

13. Anesthesia Services.

a. Under the Medicare waivers, Certified Registered Nurse Anesthetists (CRNA) are not required to be under the supervision of a physician. 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.
b. There is no similar state waiver at this time.

14. Utilization Review.

a. Under the Medicare waivers, hospitals will not be required to have a Utilization Review plan with a UR committee that provides for a review of services furnished

[29] 42 CFR 482.12(a)(8)-(9) for hospitals and 485.616(c) for CAHs.

[30] 42 CFR 482.12(c)(1)(2) and 482.12(c)(4).

[31] 42 CFR 482.12(c)(3).

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to Medicare and Medicaid beneficiaries to evaluate the medical necessity of the admission, duration of stay and services provided.[32]

b. *These flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.*

c. There is no similar state waiver at this time with respect to utilization except with respect to certain pharmacy ancillary personnel.[33]

15. Written Policies and Procedures for Appraisal of Emergencies at Off Campus Hospital Departments.

    a. Off campus surge facilities are not required 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,[34]with respect to surge facilities only.
    b. *These flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.*

16. Emergency Preparedness Policies and Procedures – Medicare waivers.

    a. Hospitals and CAHs are not required to develop and implement emergency preparedness policies and procedures.[35]
    b. Hospitals and CAHs emergency preparedness communication plans not required to contain specified elements with respect to the surge facilities or surge sites[36]:
       (i) specific contact information for staff
       (ii) entities providing services under arrangement
       (iii) patients' physicians
       (iv) other hospitals and CAHs
       (v) volunteers

17. Quality Assessment and Performance Improvement Program.

CMS is waiving requirements to 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

[32] 42 CFR 482.1(a)(3) and 42 CFR 482.30.

[33] *See* governor's proclamation 20-36 and WACs 246-901-035, 246-901- 100.

[34] 42 CFR 482.12(f)(3).

[35] 42 CFR 482.15(b) and 485.625(b).

[36] 42 CFR482.15(c)(1)-(5) and 485.625(c)(1)-(5).

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hospitals that are part of a hospital system).[37]

a. CMS expects any improvements to focus on the Public Health Emergency (PHE).
b. 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.
c. *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.*
d. All state CQIP requirements are still in place

18. Nursing Services.

    a. Hospital not required to ensure that the nursing staff develops and keeps current a nursing care plan for each patient.[38]
    b. Hospital not required to have policies and procedures in place establishing which outpatient departments are not required to have a registered nurse present.[39]
    c. *These flexibilities apply to both hospitals and CAHs and may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan*.

19. Food and Dietetic Services.[40]

    a. Providers are not required to have a current therapeutic diet manual approved by the dietitian and medical staff readily available to all medical, nursing, and food service personnel.
    b. Such manuals would not need to be maintained <u>at surge capacity sites.</u>
    c. *These flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.*

20. Respiratory Care Services.[41]

    a. Hospitals not required 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.

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[37] 42 CFR 482.21(a).

[38] 42 CFR 482.23(b)(4).

[39] 42 CFR 482.23(b)(7).

[40] 42 CFR 482.28(b)(3).

[41] 42 CFR 482.57(b)(1).

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b. *These flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.*

21. Temporary Expansion Locations: For the duration of the PHE related to COVID-19, CMS is waiving certain Medicare conditions of participation requirements.[42]

    a. Hospitals may establish and operate as part of the hospital any location meeting those conditions of participation for hospitals that continue to apply during the PHE.
    b. This waiver 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*.
    c. This extends to any entity operating as a hospital (whether a current hospital establishing a new location or an 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.

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

22. Specific Physical Environment Waiver Information.[43]

    a. Facilities may adjust scheduled inspection, testing and maintenance (ITM) frequencies and activities for facility and medical equipment, while still ensuring an acceptable level of safety and quality.[44]
    b. The Life Safety Code (LSC) and Healthcare Facilities Code (HCFC) are temporarily modified to the extent necessary to permit these facilities to adjust scheduled ITM frequencies and activities required by the LSC and HCFC. The following LSC and HCFC ITM are considered critical are not included in this waiver[45]:
        (i) Sprinkler system monthly electric motor-driven and weekly diesel engine-driven fire pump testing
        (ii) Portable fire extinguisher monthly inspection
        (iii) Elevators with firefighters' emergency operations monthly testing
        (iv) Emergency generator 30 continuous minute monthly testing and associated transfer switch monthly testing

[42] 42 CFR 482.41, 485.623, 413.65.

[43] CMS COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers, cited *supra*.

[44] 42 CFR 482.41(d) for hospitals, 485.623(b) for CAH.

[45] 42 CFR 482.41(b)(1)(i) and (c) for hospitals, 485.623(c)(1)(i) and (d) for CAHs.

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(v) Means of egress daily inspection in areas that have undergone construction, repair, alterations or additions to ensure its ability to be used instantly in case of emergency.

c. Facilities not required to have an outside window or outside door in every sleeping room, so that these providers may utilize facility and non-facility space that is not normally used for patient care to be utilized for temporary patient care or quarantine.[46]

B. Acute Care Hospitals – Exemptions[47]

1. Housing Acute Care Patients In Excluded Distinct Part Units.

    a. Acute care hospitals may house acute care inpatients in excluded distinct part units, where the distinct part unit's beds are appropriate for acute care inpatients.
    b. Inpatient Prospective Payment System (IPPS) hospitals 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.

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

    a. 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, may do so.
    b. The hospital should continue to bill for inpatient psychiatric services under the Inpatient Psychiatric Facility Prospective Payment System 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 COVID-19.
    c. This 1135 waiver may be utilized only 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.

3. Care for Excluded Inpatient Rehabilitation Unit Patients in the Acute Care Unit of a Hospital.

[46] 42 CFR 482.41(b)(9) for hospitals, 485.623(c)(7) for CAHs.

[47] CMS COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers, cited *supra*.

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a. Acute care hospitals with excluded distinct part inpatient Rehabilitation units that, *as a result of a disaster or emergency*, may relocate inpatients from the excluded distinct part rehabilitation unit to an acute care bed and unit.
b. The hospital should continue to bill for inpatient rehabilitation services under the inpatient rehabilitation facility prospective payment system for such patients.
c. The hospital should 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.
d. This waiver may be utilized only where the hospital's acute care beds are appropriate for providing care to rehabilitation patients and such patients continue to receive intensive rehabilitation services.

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

   a. CMS is currently granting an extension for hospitals nationwide affected by COVID-19 until August 3, 2020 for completed 2019 Occupational Mix Surveys, Hospital Reporting Form CMS-10079, for the Wage Index Beginning FY 2022, 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
   b. 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

C. Critical Access Hospitals (CAHs)

1. Responsibilities of Physicians in Critical Access Hospitals.[48]

   a. A doctor of medicine or osteopath is not required to be physically present to provide medical direction, consultation, and supervision for the services provided in the CAH.[49]
   b. A physician still must be available "through direct radio or telephone communication, or electronic communication for consultation, assistance with medical emergencies, or patient referral."[50]

[48] CMS COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers, cited *supra*.

[49] 42 CFR 485.631(b)(2).
[50] *Id.*

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c. This will allow physicians to perform responsibilities remotely, as appropriate and also allow CAHs to use nurse practitioners and physician assistants to the fullest extent possible, while ensuring necessary consultation and support as needed.[51]

2. CAH personnel qualifications.

CMS is waiving minimum personnel qualifications for the following professions to allow CAHs to employ individuals in these roles <u>who meet state licensure requirements</u> and provide maximum staffing flexibility:

a. Clinical nurse specialists[52] – Not required to hold a master's or doctoral level degree in a defined clinical area of nursing from an accredited educational institution.
b. Nurse practitioners[53] -
   (i) Not required to be certified as a primary care nurse practitioner by the ANA or by the PNCB
   (ii) Not required to have successfully completed a 1 year certificate or degree academic program meeting federal statutory requirements or have been performing an expanded role in the delivery of primary care as required by federal law.
   (iii) These flexibilities do not affect state law requirements for licensure.

c. Physician Assistants[54]
   (i) Not required to be certified by the NCCPA to assist primary care physicians
   (ii) Not required to have satisfactorily completed a program for preparing physician assistants meeting federal statutory requirements or have been preforming an expanded role in the delivery of primary care prior to June 25, 1993.
   (iii) These flexibilities do not affect state law requirements for licensure.

d. *These flexibilities should be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.*

3. CAH Staff Licensure.

a. CMS is deferring to staff licensure, certification, or registration to state law by waiving the requirement that staff of the CAH be licensed, certified, or registered in accordance with applicable federal, state, and local laws and regulations.

[51] CMS COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers, cited *supra*.

[52] 42 CFR 485.604(a)(2).

[53] 42 CFR 485.604(b)(1)-(3).

[54] 42 CFR 485.604(c)(1)-(3).

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b. *These flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.*

4. CAH Status and Location.

a. Not required for the CAH to 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.[55]
b. Not required to adhere to off-campus and co-location requirements[56] allowing the CAH flexibility in establishing temporary off-site locations.
c. 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.
d. *These flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.*

5. CAH Length of Stay.

CMS will not count:[57]

a. any bed use that exceeds the 25 inpatient bed; or
b. 96-hour average length of stay (LOS) limits.

6. Certain Staffing Requirements for RHCs and FQHCs.[58]

a. A nurse practitioner, physician assistant, or certified nurse-midwife is not required to be available to furnish patient care services at leave 50 percent of the time the RHC operates.
b. It is still required that a physician, nurse practitioner, physician assistant, certified nurse-midwife, clinical social worker, or clinical psychologist be available to furnish patient care services at all times the clinic or center operates.

[55] 42 CFR 610(b).

[56] 42 CFR 485.610(e).

[57] 42 CFR 485.620.

[58] CMS COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers, cited *supra.*

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