

California Section 1135 Waiver Request

Provider Name/Type: All California Hospitals and Health Systems

Contact person and information:

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Email to CMS Regional Office: ROSFOSO@cms.hhs.gov

Thank you for confirming that the CMS blanket waivers under Section 1135 dated March 13, 2020, apply automatically to all hospitals. This letter serves as a request for additional blanket waivers under Section 1135 for all affected similarly situated hospitals in California based on the COVID-19 pandemic.

Expected duration of the waiver. The expected duration of the waiver is from March 1, 2020 (the effective date of the President's declaration under the National Emergencies Act) until the COVID-19 national public health emergency terminates.

Brief summary of why the waiver is needed.

1. **Background.** On January 31, 2020, as a result of confirmed cases of 2019 Novel Coronavirus, Secretary of Health and Human Services, Alex M. Azar II determined a nationwide public health emergency exists. On March 4, 2020, California Governor Gavin Newsom declared a statewide State of Emergency due to the outbreak in California of COVID-19, the illness caused by the SARS-CoV2 virus. Governor Newsom directed state agencies and departments to do everything reasonably possible to assist affected political subdivisions in an effort to respond to and recover from the outbreak. On March 13, 2020, the President declared a national emergency under the National Emergencies Act, which allows, among other things, the opportunity for CMS to waive requirements under Medicare, Medicaid, and CHIP, and CMS announced the availability of multiple blanket waivers, as well as the process for requesting additional flexibilities.
2. California early on experienced a serious COVID-19 outbreak. As of March 14, 2020, the Department of Public Health reports that there have been 335 confirmed cases of COVID-19 in California, and 5 deaths. Over 700 persons under investigation are awaiting test results. In addition, local health jurisdictions throughout California are monitoring over 11,400 individuals who are isolated. Community transmission of COVID-19 is occurring. Santa Clara County has been identified by the Centers for Disease Control and Prevention as one of the three hardest-hit areas of the country. Epidemiologists believe that the number of COVID-19 cases in California will continue to significantly increase for an undetermined period of time. Today, Governor Newsom ordered home isolation for all Californians over the age of 65 and with significant health conditions.
3. At this time many hospitals in the state have opened or are working to open alternative care sites, and the Department of Public Health is urging hospitals to prepare for a sustained surge in patients. As of March 14, the Department of Public Health has issued over 135 waivers or program flexibilities to health care facilities to assist in this effort.

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4. Governor Newsom and local health jurisdictions have ordered a significant number of public health measures, including cancellations of events, cancellation of schools, closure of public facilities and implementation of additional social distancing measures.
5. Taking immediate steps to stem the spread of the pandemic in California is so urgent that all California hospitals have worked collectively with the California Hospital Association on this consolidated waiver request as a means to expedite approval. Although we understand that the Secretary takes into account the number and volume of provider requests for waivers that a CMS Regional Office receives when determining the need for and geographic scope of an 1135 waiver, the intent of this collective approach is to avoid inundating Region IX with multiple requests to which they would need to respond separately. This request is supported by the California Department of Public Health, the California Hospital Association, and its members.
6. **Situation – Health Care Delivery System.** The health care delivery system is currently experiencing severe stress as a result of the COVID-19 outbreak in California, including in the areas of staffing, supplies, space and equipment:
 - a. **Staffing:** Health care providers report that:
 - i. **Increased Volume:** The COVID-19 outbreak, and the predictable fears of residents that they may have COVID-19, have caused a major increase in the volume of emergency department (ED) and clinic visits, significantly longer ED wait times, the creation of new clinics and screening sites to handle potential COVID-19 patients, an increase in intensive care and inpatient hospitalizations, and difficulty in discharging hospital inpatients to lower-acuity sites of care, all resulting in a demand for additional clinical care providers and support staff; current staff are already working overtime and additional shifts to the maximum extent possible consistent with safe patient care;
 - ii. **Staff Quarantine:** Due to the sudden onset of COVID-19 cases, and based on the recommendations of the U.S. Centers for Disease Control and Prevention, a significant number of clinical care providers and support staff are currently quarantined until it can be determined whether they will develop the disease. In addition, health care workers over age 65 or with significant health conditions are increasing feeling unable to work. These developments are resulting in additional staff shortages to deal with the increased volume of patients;
 - iii. **Available On-Call Staff:** Health care providers have attempted to obtain additional clinical care staff from their on-call pool of employees and from staffing agencies providing temporary workers; these sources have been insufficient to meet the demand based on patient volumes;
 - iv. **Staff Lack of Availability:** Many clinical care providers have school-age children or older family members who require supportive care; school closures due to COVID-19, the closure of senior centers and the relocation of adults from nursing homes and other residential facilities to reduce their risk of developing the disease, have caused these clinical care providers to stay home to care for their families, resulting in additional staff shortages to deal with the increased volume of patients.
 - b. **Supplies:** Health care providers report that:
 - i. Health care providers are currently experiencing a critical shortage of supplies, including personal protective equipment (PPE) such as masks, eye protection, N-95 respirators, powered air purifying respirators (PAPRs), gloves, and gowns. Regional and national stockpiles of some supplies may be insufficient to meet the expected demand. Many items of PPE are primarily manufactured in China, and

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production there is not expected to meet demand given the worldwide spread of COVID-19 and the drastically reduced production from Chinese factories;

ii. In addition, due in part to PPE shortages and impacts on the ability to compound drugs, certain medications are already or may become in short supply; these include medications used to treat COVID-19 patients, as well as medications used by individuals with co-morbid conditions that put them at increased risk for developing COVID-19, as a result of which it is anticipated that additional cases of COVID-19 will occur due to these medication shortages;

iii. Testing kits, swabs and testing medium remain in short supply even as testing capacity at state and private labs has increased.

c. **Facilities:** California hospitals, including critical access hospitals, routinely experience challenges with limited bed capacity even during a typical influenza season. The high volume of patients and the need to separate potentially infectious COVID-19 patients from other patients in ED and clinic waiting and treatment areas has exceeded the physical space limitations of some health care providers. Currently, many California hospitals are at or near full capacity due to COVID-19 response, increasing the need to transfer patients to other facilities. Some California hospitals – including all in Santa Clara County – have cancelled elective surgeries. Some nursing homes are requiring a negative COVID-19 test prior to accepting patients for transfer or due to COVID-19 outbreaks are unable to accept patients, increasing overall state demand for inpatient hospital beds.

d. **Equipment:** The increased volume of COVID-19 patients has caused a shortage of equipment needed to treat them, which is expected to worsen as the number of COVID-19 patients increases. In particular, ventilators are in limited supply.

Additional Blanket Waiver Flexibility Requested. In addition to the blanket waivers announced by CMS dated March 13, 2020, California's hospitals are requesting the following blanket waivers:

- Medicare Conditions of Participation (CoPs). The hospitals are requesting blanket waivers to the following CoPs:
 - Discharge Planning. 42 C.F.R. §482.43(a)(8), 485.642(a)(8) – Allow hospitals to discharge patients who no longer need acute care based solely upon which post-acute providers can accept them, without sharing the detailed quality measures and data on resource use measures as required by the regulations. This will allow for discharges in an efficient manner to free beds for acutely ill patients.
 - Physical Environment. 42 C.F.R. §482.41; A-0700 et seq. -
 - Allow non-hospital buildings/space to be used for patient care, provided sufficient safety and comfort is provided for patients and staff, and allow hospitals to treat medical/surgical patients in non-PPS hospitals. This is another measure that will free up inpatient care beds for the most acute patients while providing beds for those still in need of care. It will also promote appropriate cohorting of COVID-19 patients.
 - Approve the use of technology and physical barriers that limit exposure and potential spread of the virus, such as video and audio resources for limiting direct contact between physicians and other providers in the same clinical facility.
 - Permit services to be provided to patients in their vehicles, assuming patient safety and comfort. Many facilities are setting up drive-through specimen

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- collection sites, We are requesting the ability to provide basic evaluation and testing in patient vehicles to prevent potential spread of the virus in the facility.
- Sterile Compounding. 42 C.F.R. §482.25(b)(1) and USP 797 - Permit face masks to be removed and retained in the compounding area, to be re-donned and reused during the same work shift only. This will conserve scarce face mask supplies which will help with the impending shortage of medications.
 - Verbal Orders §482.24, A-0407, A-0454, A-0457 - Allow verbal orders to be used more than "infrequently" and allow authentication to occur later than 48 hours. This will allow physicians to prioritize how they allocate their time to best treat ill patients during this surge situation.
 - Reporting Requirements. 42 C.F.R. §482.13(g) (1)(i)-(ii), A-0214 - Postpone reporting of ICU patients whose death is caused by their disease process but who required soft wrist restraints to prevent pulling tubes/IVs. Allow this reported later than close of business next business day, provided any death where restraint may have contributed is continued to be reported within standard time limits. This is necessary because hospital reporting may be delayed due to increased care demands. Eliminating penalties keeps the focus on urgent patient care.
 - Medical Staff. 42 C.F.R. §482.22(a); A-034 - Allow physicians whose privileges will expire during the emergency period, and new physicians, to practice before full medical staff/governing body review and approval. This will keep clinicians on the front line and allow hospitals and health systems to prioritize patient care needs during the emergency.
 - Medical Records Timing. 42 C.F.R. §482.24; A-0469 - Suspend the requirement that medical records be fully completed within 30 days following discharge during the emergency period. This flexibility will allow clinicians to focus on the care needs at hand and deal with paperwork later.
- Telehealth. 42 C.F.R. §410.78(b) -
 - Consistent with the authority granted the Secretary under the *Coronavirus Preparedness and Response Supplemental Appropriations Act*, eliminate Medicare restrictions on licensing for telehealth and geographic restrictions on originating sites. Allow billing using CPT codes 99444 and 98969 for both new and established patients. Ask the HHS OIG to confirm that telemedicine screenings without co-pays and deductibles do not violate the CMP law or anti-kickback statute.
 - Permit distant site (provider) services to be rendered in a rural health clinic (RHC). Currently, Medicare prohibits distant site telehealth to be rendered by a provider in a RHC. This limitation is not by regulation, but rather, sub regulatory guidance (Medicare Policy Manual, chapter 13, section 200. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c13.pdf>).
 - Eliminate the requirement that in order to bill for a telehealth service a provider must have billed that Medicare enrollee for a service within the previous three years.
 - These steps will allow providers to screen and treat significantly more patients, reduce risk to front line health care providers, and assist in resolving the shortage of providers.
 - Allow for reimbursement for telephone visits at the same rate as telehealth video visits. In many cases, the video aspect does not add value to the patient interaction – it's the information relayed to the patient that matters. See CPT codes 99441, 99442, 99443; HCPCS G2012, G0071.

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- Home Health. 42 C.F.R. § 484.55(a) – Allow home health agencies to perform certifications, initial assessments and determine patients' homebound status remotely or by record review. This will allow patients to be cared for in the best environment 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.
- HIPAA Security Requirements. 45 C.F.R. 164.312(e)(1); transmission security - Waive the security requirements for video communication in a telehealth visit. While CMS has lifted many of the patient site requirements to allow telehealth in the home as well as non-rural areas, many facilities are not prepared with secure platforms that they own and control which are also accessible to the patient. This request is to allow providers to use readily available platforms like Facetime, WhatsApp, Skype, etc. to facilitate the telehealth visit with the patient at home.
- Delivery of Services in Alternate Clinic Locations. We request a waiver to allow Federally Qualified Health Centers (FQHC) and Rural Health Clinics (RHC) providers to bill for their Prospective Payment System (PPS) rate, or other permissible reimbursement, when providing services at alternative physical settings, such as a mobile clinic or temporary location. This will allow flexibility in site of clinics to promote appropriate infection control.
- Flexibility for Teaching Hospitals. Medicare generally requires that a teaching physician be physically present in the room/area with the patient and medical resident in order to bill as the teaching physician. Because hospitals are running low on PPE and also want to limit exposure of both patients and staff to other people as much as possible, we request flexibility in this requirement. Flexible approaches might include real-time audio/video or supervision through a window for the teaching physician. These flexible approaches should be covered and reimbursed.

Conclusion. The trajectory of the COVID-19 outbreak in California is very similar to that in Northern Italy, where the healthcare system quickly became overwhelmed. California hospitals are struggling with ongoing shortages of staffing, supplies, and facilities, as more and more COVID-19 cases in the state are confirmed. A blanket waiver of the foregoing federal requirements is necessary to allow California's hospitals to properly focus their efforts on curtailing the spread of the pandemic.

Sincerely,

/s/

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Re: California Section 1135 Waiver Request

Dear Mr. Bunch:

As you know, on March 15, 2020, the California Hospital Association (CHA), on behalf of all California hospitals, submitted a request to CMS for waivers under Section 1135 of the Social Security Act. Since that date, the COVID-19 pandemic and its impact on the health care community has drastically worsened. In response, the California Department of Public Health (CDPH) has taken the unprecedented step of waiving **all** state hospital licensing requirements, with the following exceptions:

1. Hospitals must report to CDPH any adverse events, unusual occurrences, or staffing/supply shortages that jeopardize patient care.
2. Hospitals must provide necessary patient care and act in the best interests of patients.
3. Hospitals must follow their disaster response plan.
4. Hospitals must follow infection control guidelines from CMS and CDC as well as local public health directives.

CDPH took this unprecedented step in response to unprecedeted circumstances. CHA urgently requests that CMS take a similar posture and immediately suspend all hospital and critical access hospital Conditions of Participation, regulatory deadlines, and audit activity.

If CMS is unable to approve a broad waiver, we reiterate our request made on March 15 (repeated below so all requests are in one document), and make the additional requests below. We are aware that the American Hospital Association has requested waivers related to the Emergency Medical Treatment and Labor Act (EMTALA) and Stark/anti-kickback statute, as well as a broad request to Secretary Azar dated March 16, 2020. CHA endorses those requests and includes them herein by reference. We request all waivers from March 1, 2020 (the effective date of the President's declaration under the National Emergencies Act) until the COVID-19 national public health emergency terminates, except as otherwise specified.

Brief summary of why the waiver is needed: See letter from CHA to CMS dated March 15, 2020.

Waivers Previously Requested: In addition to the blanket waivers announced by CMS and dated March 13, 2020, California's hospitals requested the waivers listed below on March 15, 2020. (Please note that we have deleted the telehealth requests that have already been approved.)

Medicare Conditions of Participation (CoPs)

- Discharge Planning. 42 C.F.R. §482.43(a)(8), 485.642(a)(8) – Allow hospitals to discharge patients who no longer need acute care based solely upon which post-acute providers can accept them, without sharing the detailed quality measures and data on resource use measures as required by the regulations. This will allow for discharges in an efficient manner to free beds for acutely ill patients.
- Physical Environment. 42 C.F.R. §482.41; A-0700 et seq.
 - Allow non-hospital buildings/space to be used for patient care, provided sufficient safety and comfort are provided for patients and staff, and allow hospitals to treat medical/surgical patients in non-PPS hospitals. This is another measure that will free up inpatient care beds for the most acute patients while providing beds for those still in need of care. It will also promote appropriate cohorting of COVID-19 patients.
 - Approve the use of technology and physical barriers that limit exposure and potential spread of the virus, such as video and audio resources for limiting direct contact between physicians and other providers in the same clinical facility.
 - Permit services to be provided to patients in their vehicles, assuming patient safety and comfort. Many facilities are setting up drive-through specimen collection sites. We are requesting the ability to provide basic evaluation and testing in patient vehicles to prevent potential spread of the virus in the facility.
- Sterile Compounding. 42 C.F.R. §482.25(b)(1) and USP 797 – Permit face masks to be removed and retained in the compounding area, to be re-donned and reused during the same work shift only. This will conserve scarce face mask supplies, which will help with the impending shortage of medications.
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- Reporting Requirements. 42 C.F.R. §482.13(g) (1)(i)-(ii), A-0214 – Postpone reporting of ICU patients whose death is caused by their disease process but who required soft wrist restraints to prevent pulling tubes/IVs. Allow this to be reported later than close of business next business day, provided any death where restraint may have contributed is continued to be reported within standard time limits. This is necessary because hospital reporting may be delayed due to increased care demands. Eliminating penalties keeps the focus on urgent patient care.
- Medical Staff. 42 C.F.R. §482.22(a); A-034 – Allow physicians whose privileges will expire during the emergency period, and new physicians, to practice before full medical staff/governing body review and approval. This will keep clinicians on the front line and allow hospitals and health systems to prioritize patient care needs during the emergency.
- Medical Records Timing. 42 C.F.R. §482.24; A-0469 – Suspend the requirement that medical records be fully completed within 30 days following discharge during the emergency period. This flexibility will allow clinicians to focus on the care needs at hand and deal with paperwork later.

Home Health. 42 C.F.R. § 484.55(a) – Allow home health agencies to perform certifications and initial assessments, and to determine patients’ homebound status, remotely or by record review. This will allow patients to be cared for in the best environment while supporting infection control and reducing

impact on acute care and long-term care facilities. It will also 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.

Delivery of Services in Alternate Clinic Locations. Allow Federally Qualified Health Centers (FQHC) and Rural Health Clinics (RHC) to bill for their prospective payment system (PPS) rate, or other permissible reimbursement, when providing services at alternative physical settings, such as a mobile clinic or temporary location. This will allow flexibility in site of clinics to promote appropriate infection control.

Flexibility for Teaching Hospitals. Medicare generally requires that a teaching physician be physically present in the room/area with the patient and medical resident in order to bill as the teaching physician. Because hospitals are running low on PPE and also want to limit exposure of both patients and staff to other people as much as possible, we request flexibility in this requirement. Flexible approaches might include real-time audio/video or supervision through a window for the teaching physician. These flexible approaches should be covered and reimbursed.

Additional Waivers Requested

Alternate Care Sites. Allow non-licensed facilities to take patients who do not need acute care but are in the hospital for other reasons: single bed cert, awaiting a guardian, awaiting Medicaid approval so they can be discharged, etc. Allow alternative care sites (like tents or “hospital from home”) and clarify that the provider-based rules and CoPs do not apply. We acknowledge that the blanket waiver of March 13 waives “certain” CoPs, but it does not specify which ones. Suspend the requirement to submit 855 updates for temporary locations that are stood up for pandemic response. Reimburse providers for a service provided in an unlicensed location.

Deadlines. Suspend billing time frames and require Medicare Advantage and Part D plans to do the same. Suspend cost report settlement time frames, including repayment due dates. Suspend HIPAA breach notification time frames. We request that all requirements be waived permanently or suspended until at least 180 days after termination of the COVID-19 emergency.

Audits and Reporting. Pause all audit activity and require Medicare Advantage and Part D plans to do the same. Waive various reporting deadlines (including quality reporting) permanently or until 180 days after termination of the COVID-19 emergency.

Medicare Observation Requirements. Suspend the requirement to provide the MOON and the 23-hour rule. Waive patient cost-sharing for observation services.

Hospital Reimbursement. Clarify that hospitals may bill special care unit codes (ICU, CCU, NICU, ED) if the patient meets level-of-care criteria, even if the patient is cared for in what is usually considered a PACU, OR suite, or med/surg bed or space. Similarly, clarify that a hospital may bill at acute or special unit levels for what are usually considered distinct-part nursing facility beds if the patient meets acute level criteria. Clarify that hospitals may bill for ED/provider-based reimbursement for newly established services, such as drive-through, tent, and off-site screening and testing locations. Reimburse hospitals for “administrative days” in addition to the DRG payment, once a Medicare beneficiary is ready for discharge but there’s no place for them to go due to COVID-19 status or lack of post-acute care capacity.

Freestanding Rehabilitation and Psychiatric Hospital Services. The blanket waiver issued by CMS on March 13, 2020, allows distinct part units (skilled-nursing facility, rehabilitation, and psychiatric) to provide acute inpatient care if the patient meets level-of-care criteria. We request the same for freestanding skilled-nursing facilities (SNFs), IRFs, rehabilitation and psychiatric hospitals, and

ambulatory care centers. We also request clarify on which facility bills and any codes/modifiers required.

Three-Day Window Rule. Waive this rule so that beneficiaries may be seen in a clinic or via telehealth with reimbursement made to that provider by CMS, while reimbursing hospitals for the full DRG for a subsequent hospitalization.

Swing Beds. Allow critical access hospitals that do not usually provide swing beds to accept and be paid for swing bed patients from other facilities to maximize their acute care capacity.

Medicare Advantage and Part D Plans. Allow out-of-network providers to be reimbursed for medically necessary acute care and post-acute care without prior authorization. Require these plans to suspend utilization management activities and to consider presenting symptoms as a basis for coverage, not final diagnosis.

Inpatient Rehabilitation Facilities. Waive the inpatient rehabilitation facility three-hour standard for intensive therapy (three hours daily of one-on-one therapy). Additionally, waive the 60% rule that requires that at least 60 percent of the total population requires IRF treatment for one or more of 13 conditions listed in 42 C.F.R. section 412.29(b)(2).

Employee Certifications. Many hospital employees are required to have current certificates evidencing training in basic life support, advanced life support, cardiopulmonary resuscitation, pediatric advanced life support, electronic fetal monitoring, neonatal resuscitation, and similar skills. The American Heart Association and the American Academy of Pediatrics have recommended that regulatory bodies consider extending recognition of these certifications beyond their renewal dates for at least 60 days and perhaps longer depending on the pandemic. The Joint Commission has agreed. We request that CMS consider valid any training certificates required for hospital employees for at least 180 days following termination of the COVID-19 emergency, regardless of their usual expiration date. In addition, we request the ability to allow non-certified personnel to take vital signs upon basic training.

Staffing. Allow hospitals to disregard provisions in their medical staff by laws relating to expiration of and granting of privileges – 42 C.F.R. section 482.22. Authorize military health care personnel to work in civilian settings.

Three-day qualifying stay. We understand that this requirement has been waived. However, some SNFs are interpreting the waiver to apply only to COVID-19 patients. Please clarify that the waiver applies to all Medicare beneficiaries.

EMTALA. We are aware that the American Hospital Association has requested waivers related to the Emergency Medical Treatment and Labor Act (EMTALA). We support those requests and herein incorporate them by reference. We request the ability to redirect individuals who come to the emergency department without an obvious emergency medical condition to non-hospital-controlled locations even in the absence of a state plan – California is a very large state with more local response plans. We request the ability to designate qualified medical providers to perform EMTALA screenings without the usual administrative/board action or incorporation into the medical staff bylaws or rules and regulations. We request that CMS expand the definition of appropriate transfer to allow for the transfer of patients to a facility offering a lower level of care, so long as the accepting facility has the capacity and capability to treat the patient. Similarly, we request that hospitals be allowed to deny a transfer unless the accepting facility offers a level of care needed by the patient that cannot be provided by the transferring facility. Waive sanctions for transfer of an unstabilized patient as needed by the public health emergency.

HIPAA. In addition to suspending the HIPAA breach notification time frames until at least 180 days after termination of the COVID-19 emergency as requested above, we request that CMS clarify that the current HPAAs waiver lasts for the duration of the COVID-19 emergency, and not just for the first 72 hours after the hospital activates its emergency response plan.

Waive IMD Medicaid Exclusion. National hospital capacity is expected to be pushed to its limits during the COVID-19 pandemic. California projects that 25.5 million people in the state will be infected over an eight-week period, which will require roughly 20,000 more beds than we currently have. Homeless individuals are particularly vulnerable to COVID-19 as they experience high rates of respiratory diseases. Waiving the exclusion to Medicaid funding for inpatient behavioral health treatment in a facility with more than 16 beds would allow hospitals to better manage surge capacity in both inpatient and emergency departments to care for COVID-19 patients.

Behavioral Health. Allow patients to remain eligible for partial hospitalization and intensive outpatient programs despite potential disruptions to their care due to social distancing or suspension of services in states where stay-at-home guidance is in place. Allow therapy hours to be provided via telehealth or a blend of in-person and telehealth care for both reimbursement purposes and compliance with program requirements. Waive the time, distance, and attendance standards for reimbursement purposes.

Texting. Allow texting of patient orders. See S&C 18-10-ALL.

Seclusion. Allow mandatory seclusion of all infected and potentially infected COVID-19 patients without a physician order (see 42 C.F.R. section 482.13(e)(ii)).

Stark. We are aware that the blanket waiver issued on March 13 waives sanctions under section 1877(g) “under such conditions and in such circumstances as the Centers for Medicare & Medicaid Services determines appropriate.” We request that CMS clarify that sanctions will be waived for all hospitals and physicians acting in good faith while responding to the COVID-19 pandemic.

Interpreter and Services. Clarify that providers may rely on family members or friends if a professional interpreter (even remote) is not reasonably available.

Administrative Requirements. Allow hospital staff to focus on the most urgent patient care needs by suspending the requirement for hospitals to provide each patient an individual notice of rights, including requirements under the Patient Self-Determination Act, and to respond to patient grievances.

Efficient Patient Discharge. Clarify that a patient who no longer needs acute care may be discharged to any appropriate post-acute care provider that will accept the patient. Suspend the requirement to provide patients the Important Message from Medicare, which allows them to appeal discharge and effectively delay it for a day or two.

Home Health. 42 C.F.R. § 484.55(a) – Waive the “Face to Face Requirement” which requires that the certifying physician document a face-to-face encounter with a patient prior to certifying eligibility for the home health benefit, allowing them to be performed remotely or by record review. This will allow patients to be cared for in the best environment while supporting infection control and reducing the impact on acute care and long-term care facilities. This will also maximize coverage by already scarce physicians and advanced practice clinicians and allow those clinicians to focus on caring for patients with the greatest acuity.

Additionally, waive the requirement that a beneficiary be “homebound” in order to receive home health services to allow beneficiaries to obtain care while minimizing the risk to themselves or others.

Long term acute care hospitals (LTCHs). Waive the requirement that LTCHs have no more than 50% of Medicare cases paid at the site-neutral rate to help ensure LTCHs are able to add capacity to care for appropriate patients, without penalty.

Skilled-Nursing Facilities (SNFs). Waive the SNF conditions of participation to allow SNFs to establish alternative sites of care. We are aware of empty apartments, hotels, and congregate living centers that could be used for patients (including COVID-19 positive patients), but they cannot be used in the absence of CoP waivers, including:

- Physical Environment. – Allow non-SNF/NF buildings/space to be certified for use as a temporary SNF/NF, provided sufficient safety and comfort are provided for residents and staff. This will allow states to open temporary COVID-19 nursing facilities to assist COVID 19 positive SNF/NF residents to receive SNF/NF care and services during treatment for the virus while protecting other vulnerable adults. It will also free up inpatient care beds at hospitals for the most acute patients while providing beds for those still in need of care and promote appropriate cohorting of COVID-19 residents.
- Expedite certification process and expedite approval process from the Medicare Administrative Contractor.
- Expedite Life Safety Code Process.
- Suspend compliance with 42 C.F.R. section 483.10 relating to residents’ rights, such as patient notices regarding change of roommates and that residents can refuse transfer to rooms between distinct-part and non-distinct parts of SNFs/NFs.

The trajectory of the COVID-19 outbreak in California is very similar to that in Northern Italy, where the health care system quickly became overwhelmed. California hospitals are struggling with ongoing shortages of staffing, supplies, and facilities, as more and more COVID-19 cases in the state are confirmed. A waiver of the foregoing federal requirements is necessary to allow California’s hospitals to properly focus their efforts on curtailing the spread of the pandemic.

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March 28, 2020

Julius P. Bunch, Jr. VIA Email with copy to: Regional Manager ROSFOSO@cms.hhs.gov
San Francisco & Seattle
Acute & Continuing Care Branch
Centers for Medicare & Medicaid Services
701 5th Ave. Suite 1600
Seattle, WA 98104

Re: Third Washington State and California Section 1135 Waiver Request for All Washington State and California Hospitals and Health Systems – Home Health and Hospice Agencies

Dear Mr. Bunch:

WSHA and CHA submit this third request for additional blanket waivers under Section 1135, on behalf of all our member hospitals and health facilities. This request concentrates on waiver requests related to home health and hospice services in Washington State and California—many of which are operated by our member hospitals as part of their services to their communities and which nevertheless have important impacts on hospitals' ability to maintain enough bed capacity to respond to the COVID-19 pandemic.

At the outset we acknowledge and thank CMS for the initial waiver approvals granted in its letters dated March 26, 2020 related to home health and hospice . This letter requests more comprehensive waivers for these care settings —a request which is consistent with the recent passage of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, which expands the list of health care professionals authorized to order home health services, among other provisions relating to home-based services. We will soon submit another general waiver request to address further blanket waiver needs.

Since our second request for blanket waivers was submitted, needs in both our states have continued to grow and intensify, including for home health and hospice agencies affiliated with hospital systems. The number of cumulative cases has grown significantly in the last week, since our second request. As of March 27, 2020, there are 3,768 confirmed cases of COVID-19 in Washington, with exponential growth day over day. In the last seven days, there have been an additional 1,975 confirmed cases, with 82 additional deaths. There have now been 175 deaths total. The situation in California is equally dire. California has 4,643 confirmed cases of COVID-19, an increase of 842 since yesterday. In addition, we've had 107 deaths, an increase of 30 since yesterday.

Resources continue to be scarce, especially personal protective equipment including gowns, masks and glove, testing kits and reagents. ICU beds and staff are beginning to stretch thin and our states have been forced to prepare Crisis Standards of Care. On March 23, 2020, the Governor of Washington issued a “Shelter in Place” order to maximize efforts to slow the spread. California’s Governor did the same on March 19, 2020. We are being asked to undertake unprecedented changes in the way we deliver health care and the waivers granted so far at the federal level are not sufficient to address the needs of our systems on the grounds.

Section 1135 waivers are intended to ensure health care items and services, including hospice and home health, remain available during emergencies and that the providers who furnish the items and services in good faith are reimbursed even if the provider cannot comply with all statutory and regulatory requirements.

Section I below discusses the current situation for hospice and home health in our states and the types of requirements for which relief is requested, including face to face contact requirements and deadlines and timetables. Section II addresses specific requests relating to hospice services and Section III addresses specific requests for home health agencies. Again, we thank you for the initial waivers and ask that you provide more comprehensive waivers aimed at better addressing the needs of these specific facility types.

I. Background – Situation for Hospice and Home Health Agencies; Categories of Requirements Needing Waiver.

The health care delivery system in Washington and California is under severe stress, including the hospice and home health agencies affiliated with hospital systems. Providers are delivering care in environments where patients, staff and other facilities such as skilled nursing are reluctant to have, or outright refuse, in-person encounters due to concerns regarding COVID 19 exposure. We are experiencing shortages of staffing, supplies, space and equipment – including severe shortages of personal protective equipment (**PPE**), an essential precaution during F2F contact. All indications are that the shortages will continue and increase during the coming weeks.

On-site Visits – Face-to-Face (F2F) Contact. We are requesting waiver from COP and similar requirements so that all encounters that can safely and effectively be performed telephonically (i.e., via telephone) or through a virtual visit (i.e. via a remote video telehealth platform) may be conducted using such means. Every in-person contact has the potential to spread the virus. Every in-person patient encounter requires using precious PPE supplies. Eliminating in-person encounters when it is safe to do so minimizes unnecessary risks to patients and providers and saves PPE supplies for patient care that must be provided in person (such as wound care). It is consistent with Section 1135 to reimburse providers for patient care provided during an emergency, regardless of whether the care is delivered in-person, telephonically or virtually. The requests below take into account the waivers granted in the approvals letter dated March 26, 2020.

Deadlines and Timetables. We are requesting modification of, and flexibility with respect to, COP and similar requirements imposing deadlines on home health and hospice. Section 1135 recognizes regulatory timeframes may need to be modified during an emergency. Again, the requests below take into account the waivers granted in the approvals letter dated March 26, 2020.

Blanket Waivers Requested by Other Associations. WSHA and CHA support the March 10, 2020 letter from the National Association for Home Care & Hospice to CMS and the March 12, 2020 letter from the National Hospice and Palliative Care Organization to CMS, which we have attached for reference.

II. Hospice Conditions of Participation and timing requirements:

Skilled nursing and assisted living facilities are refusing or limiting entry to hospice providers, precluding or delaying timely delivery of required services, including initial, comprehensive, and updated assessments. Shortages of personal protective equipment (PPE) limit implementation of plans of care and all core services from multiple licensed professionals. Staff shortages are also occurring due to child care issues from school closures and quarantine of exposed and infected providers. Exposed and infected hospice parties may also be subject to quarantine.

WSHA and CHA request Blanket Waivers under Section 1135 for hospice for the following:

1. **Minimize face-to-face and on-site encounters (F2F);** by waiving F2F requirements except when necessary for safe and effective patient care; including:
 - a. the requirement under **42 CFR 418.76(h)(1)** for an onsite visit by RN at least every 14 days to supervise hospice aids
 - b. the requirement under **42 CFR 418.22** for a F2F visit before the third and each subsequent re-certification
 - c. all applicable F2F requirements related to initial assessments and the hospice plan of care including under **42 CFR 418.54** and **42 CFR 418.56**
 - d. permit patients to change attending physicians by making verbal elections that are documented in the patient's records by hospice staff; waiving the requirements under **42 CFR 418.24(g)** to file a signed election
 - e. postpone in-service training deadlines under **42 CFR 418.76(d)**
 - f. permit core services (nursing, physical therapy, occupational therapy, language speech pathology and social work) to be provided telephonically or virtually unless a F2F encounter is clinically necessary; also permit core services through use of contracted providers as necessary, waiving the requirements of **42 CFR 418.64** that limit the foregoing.
2. **Modify deadlines and timetables for performance of certain activities;** including:
 - a. Extend the submission deadline for certifications of terminal illness under **42 CFR 418.22**.
 - b. Exercise the authority under **42 CFR 418.24(4)(iv)** to waive the consequences of failure to submit a timely notice of election as required by **42 CFR 418.24(3)**.
 - c. Extend the submission deadlines for notices of termination under **42 CFR 418.26** and notices of revocation under **42 CFR 418.38**.

- d. Extend timeframes in **42 CFR 418.54(a)** and**(b)** for completion of the initial and the comprehensive assessments and updates of the comprehensive assessment, respectively.
 - e. Modify deadlines and provide flexibility as to the above filings.
 - f. Waive or provide flexibility as to the deadline under **42 CFR §418.56(d)** which requires that the plan of care be reviewed and updated with any change in patient condition, at least every 15 days.
 - g. Postpone from October 1, 2020 to April 1, 2021 the effective date of the changes to 42 CFR 418.24(b)(3)-(7) regarding the contents of election statements and 42 CFR 418(24)(c) regarding elective statement addendums
3. **Anticipate increases in patient populations and further resource shortages:**
- a. Waive accreditation requirements for DME suppliers under **42 CFR 418.106 (f)(3)** when a non-accredited supplier is the only reasonably available source for needed DME (**Reason for request:** hospices have been advised by their contracted DME suppliers of the potential for shortages in available DME).
 - b. Waive strict adherence to the privacy, space, visitor and atmosphere requirements in **42 CFR 418.110(f)** to permit hospice care centers to impose reasonable social distancing limits and when necessary to accommodate space and occupancy waivers under **42 CFR 418.110(g)(4)** (**Reason for request:** to permit social distancing within facilities; to accommodate anticipated increased patient volumes).
 - c. Exercise CMS' authority in **42 CFR 418.110(g)(4)** to waive the space and occupancy requirements for patient rooms under **42 CFR 418.110(g)(2)(iv) and (g)(2)(v)** so long as patient health and safety are not adversely affected (**Reason for request:** to accommodate anticipated increased patient volumes).
4. **Special coverage requirements.** We request waiver of **42 CFR §418.204** which specifies requirements for hospice nursing care in times of crisis, including use of inpatient care for respite. During the COVID-19 outbreak, the requirements for continuous home care and the description of periods of crisis require modification, to keep the patient at home when possible, rather than sending them to an inpatient facility.

III. Home Health Conditions of Participation and similar requirements:

Home health patients are refusing entry to home health providers, precluding timely delivery of required services including assessments, visits in accordance with physician orders and transfer/discharge planning. Shortages of personal protective equipment (PPE) limit implementation of plans of care involving services by multiple providers. Staff shortages are also occurring due to school closures and child care issues and quarantine of infected providers. Home health patients will also be subject to quarantine if infected.

WSHA and CHA request Blanket Waivers for home health under Section 1135 Waiver Authority to the following:

1. **Anticipate Staffing Shortages by permitting non-physician practitioners to care for home health patients**, including:
 - a. **Providers.** Permit non-physician practitioners (nurse practitioners, clinical nurse specialists and physician assistants) to certify eligibility for home health benefits under **42 CFR 424.22(a)(1)**; establish and review plans of care under **42 CFR 484.55**; and sign plans of care as required by **42 CFR 484.60**.
 - b. **Comprehensive Assessments.** Permit comprehensive assessments required by **42 CFR 484.55** to be performed by physicians, nurse practitioners, clinical nurse specialists, physician assistants, registered professional nurses, licensed practical nurses, licensed or certified social workers and/or physical, speech and occupational therapists.
2. **Minimize face-to-face and on-site encounters (F2F)**: by waiving, modifying or providing flexibility with respect to F2F and home health benefit requirements except when necessary for safe and effective patient care; including:
 - a. Permit assessments required by **42 CFR 440.70(f)** (home health services); **42 CFR 484.55(b), (d)** (comprehensive and updated assessments), and **42 CFR 440.70(g)** (home health DME) to be performed telephonically (i.e., via telephone) and virtually (i.e. via a remote video telehealth platform) as contemplated in **42 CFR 440.70(f)(6)**. We acknowledge and thank CMS for waiver of the F2F requirements of **42 CFR 484.55 (a)** in its letter to WSHA dated March 26, 2020.
 - b. Allow telephonic and virtual visits to satisfy the “personal contact” requirements of **42 CFR 409.48(c)**.
 - c. Waive and provide flexibility as to F2F requirements under **42 USC 1395f (a)(2)(C) and 42 USC 1395n (a)(2)(A)**, so that virtual and telephone visits may be performed and reimbursed as if F2F.
 - d. Waive F2F requirements for home health visits as may be contemplated in a plan of care under **42 CFR 484.60** to allow telephonic and virtual visits.
 - e. Confirm that telephonic and virtual visits will be considered “visits” for purposes of Low Utilization Payment Adjustment (LUPA) thresholds for billing under **42 CFR 484.230**.
3. **Modify deadlines and timetables for performance of certain activities**; including:
 - a. **Submission of Discharge and Transfer Summaries 42 CFR 484.110(a)(6)**: Provide flexibility as to deadlines under **42 CFR 484.110(a)(6)** to permit providers to submit discharge and transfer summaries through termination of the public health emergency.

- b. **Face to Face Encounter Deadlines.** Provide flexibility as to the timing requirements for face to face encounters for home health services (currently within 90 days before or 30 days after the start of services).
 - c. **Assessment Submission Deadlines.** Provide flexibility as to the deadlines for the initial assessment required under **42 CFR 484.55(a)**, and deadlines for comprehensive and updated assessments under **42 CFR 484.55(b) and (d)**, through termination of the public health emergency.
 - d. **Review and Revision of the Plan of Care.** Provide flexibility and modify the timing requirements under **42 CFR §484.60(c)(1)** for documenting reviews and revisions to the patient's plan of care.
 - e. **Retrieval of Clinical Records.** Provide flexibility as to deadlines under **42 CFR §484.110(e)** which requires that a patient's clinical record must be made available to a patient upon request at the next home visit, or within 4 business days (whichever comes first).
4. **Transfers and Discharges, Including under State or Federally Mandated Crisis Standards of Care 42 CFR 484.50(d)(1).** We seek clarification that the "safe and appropriate transfer" requirements of 42 CFR 484.50(d)(1) will be met by the transfer or discharge of a home health patient that is consistent with the facilities then-currently available, and application of any state or federally mandated "crisis standards of care." (**Reason for request:** we anticipate severe shortages that may require more flexibility in where and when a patient will be discharged and/or transferred, particularly if crisis standards of care are mandated.)
5. **Homebound Status.** We request CMS relax the definition of "homebound" for purposes of **42 USC 1395f (a)(2)(C), 42 USC 1395n (a)(2)(A), and 42 CFR 484.55** to permit home health agencies to provide services to patients in need. (**Reason for request:** patients may be unable to access any other services due to capacity issues at hospitals and clinics as the COVID 19 crisis escalates).
6. **Plan of Care (42 CFR 484.60(a)).** Consistent with the requested modifications to the timelines for documenting changes to the plan of care (Section III(2)(d) above), we seek clarification and assurance from CMS that providers who alter a patient's plan of care when required by the patient's condition and needs will not be in violation of **42 CFR 484.60(a)** because changes to the plan of care were not documented. Further, for purposes of an existing plan of care under **42 CFR 484.60(a)**, we seek flexibility from CMS to allow for deviation from written plan requirements regarding the frequency and duration of visits and supplies and equipment. (**Reason for request:** we anticipate shortages of staff, PPE, DME and other supplies and equipment making plan modifications and plan implementation very difficult to achieve).
7. **Anticipate increases in patient populations and further resource shortages.** Waive accreditation requirements for DME suppliers under 42 CFR 418.106 (f)(3) when a non-accredited supplier is the only reasonably available source for needed DME (Reason for request: hospices have been advised by their contracted DME suppliers of the potential for shortages in available DME).

Thank you for considering our requests and thank you for all you and others in the federal government are doing to support our response. Your assistance is desperately needed for us to collectively succeed in protecting the public health.

Sincerely,

/s/

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Washington State Hospital Association



CALIFORNIA HOSPITAL ASSOCIATION

April 10, 2020

Julius P. Bunch, Jr. Via Email with copy to: Regional Manager ROSFOSO@cms.hhs.gov
San Francisco & Seattle
Acute & Continuing Care Branch
Centers for Medicare & Medicaid Services
701 5th Ave. Suite 1600
Seattle, WA 98104

Re: **Fourth Washington State and California Section 1135 Waiver Request for All Washington State and California Hospitals and Health Systems**

Dear Mr. Bunch:

The Washington State Hospital Association (WSHA) and the California Hospital Association (CHA) submit this fourth request for additional blanket waivers under Section 1135, on behalf of all our member hospitals and health facilities. At the outset we acknowledge and thank CMS for the waiver approvals granted to date. We also hereby renew our requests for waivers that have not yet been acted upon by CMS. Please let me know if you would like a list of those outstanding waiver requests.

Since our third request for blanket waivers was submitted, needs in both our states have continued to expand and intensify. The number of cumulative cases has grown significantly. As of April 9, 2020, there are 3,768 confirmed cases of COVID-19 in Washington, with exponential growth day over day. In the last seven days, there have been an additional 1,975 confirmed cases, with 82 additional deaths. There have now been 175 deaths total. The situation in California is equally dire. California has had 18,309 confirmed cases of COVID-19 — a number universally acknowledged as a vast undercount due to lack of adequate testing capability — and 492 deaths. On April 8, California had 5,628 hospitalized patients with suspected or confirmed COVID-19; of these, 1,662 were in ICU beds. The state of California will release guidance in the next few days for Crisis Standards of Care. Our hospitals are being asked to undertake unprecedented changes in the way we deliver health care and the waivers granted so far at the federal level, while appreciated, are not sufficient to address the needs of our systems on the ground.

Section 1135 waivers are intended to ensure health care items and services remain available during emergencies and that the providers who furnish the items and services in good faith are reimbursed even if the provider cannot comply with all statutory and regulatory requirements during the

disaster/emergency. In this spirit, we again thank you for the initial waivers and ask that you: (1) grant our outstanding waiver requests, and (2) provide additional waivers as described below.

Discharge. Suspend requirements relating to the notice of discharge appeal rights under 42 CFR §422.620, and the right to immediate QIO review of a decision to discharge an inpatient under 42 CFR §422.622. These waivers are desperately needed so that hospitals can discharge patients who no longer need acute care to more appropriate settings in a timely manner, making room for patients who need acute hospital care.

Staffing. Allow hospitals, SNFs, ICF/IIDs, home health agencies, hospices and primary care clinics to use health care professionals licensed in foreign countries but not yet licensed in the U.S. to fully act within their discipline. This will allow facilities to expand their capacity to treat patients.

Space. Waive the room size requirement for all sub-acute beds to allow the use of rooms that meet all other regulations except square footage requirements to expand bed capacity in facilities.

Space flexibility. Allow SNFs to relocate residents to other rooms, locations or SNFs to create isolation areas or to cohort patients by infectious disease status by waiving resident rights in 42 CFR § 483.10(e) regarding right to roommate of choice, right to refuse transfer to another room, and right to receive written notice of the change in room or roommate and the reason for the change.

SNF notice to ombudsman. Suspend the requirement to send a notice to the ombudsman program for skilled nursing facility-initiated discharges of residents, allowing staff to focus on providing patient care services rather than administrative tasks. 42 CFR § 483.15(c)(3).

Hospital and SNF visitor policy. Waive 42 CFR § 482.13(h) and 42 CFR § 483.10(f) to the extent necessary to allow hospitals to implement policies that restrict, deny or place conditions upon visitors into the facility to maintain patient safety. Suspend the requirement to inform each patient of his or her right to “receive the visitors whom he or she designates,” as long as no visitor is excluded on the basis race, color, national origin, religion, sex, gender identity, sexual orientation, or disability (except infectious disease status).

Border areas. Maintain federal eligibility and allow hospitals and SNF funding for treatment of patients that receive care in or from neighboring states, in the event the local area neighboring state borders are impacted and the transfer of patients across state lines allows timely access to care.

Telehealth. Expand the definition of distant providers to include pharmacists who conduct medication management consults and registered nurses who provide specialty education (such as for diabetes), thereby allowing pharmacists and nurses to bill as professional providers. This action will facilitate social distancing and protect health care providers as well as patients. It would also encourage patients who are hesitant to come to health care facilities to get the care they need, conserve personal protective equipment, and minimize exposure to COVID-19 for all parties.

Outdated products. Waive 42 CFR § 482.25(b)(3) to allow the pharmacist-in-chief to authorize the use of outdated products to the extent no acceptable alternative can be procured. Also allow personal protective equipment to be used beyond its shelf date to the extent that no acceptable alternative can be procured.

Alternative office space. Allow practitioners to use their vehicle as their office for billing purposes. Practitioners are driving to patients' homes or other locations to provide services, eliminating the need for an infectious patient to come to a facility and potentially expose other providers and patients to COVID-19, or to prevent an immunocompromised or otherwise high-risk patient from being exposed to infectious patients in the facility.

Observation services. Waive the requirement to provide a notice of observation services (MOON) under 42 CFR §489.20(y).

Emergency Medical Treatment & Labor Act (EMTALA). Waive the enforcement of section 1867(c) of the Act to allow hospitals, psychiatric hospitals, and critical access hospitals (CAHs) to transfer an unstabilized individual, so long as it is not inconsistent with a state's emergency preparedness or pandemic plan. This will allow communities to cohort patients in different facilities depending on the patient's infectious disease status.

HIPAA. Clarify that the current HIPAA waiver is in force for the duration of the emergency, not only for the first 72 hours following the hospital's activation of its emergency preparedness plan. The Washington and California hospital associations urge you to confirm the interpretation of the HIPAA waiver authority in accordance with the March 25, 2020 letter submitted to Secretary Azar by the American Hospital Association. In addition, announce general enforcement discretion with respect to unauthorized disclosures that may occur in spaces and locations that were not designed primarily for the purpose of patient care.

Thank you for considering our requests and thank you for all you and others in the federal government are doing to support our response to the COVID-19 pandemic. Your assistance is desperately needed for us to collectively succeed in protecting the public health.

Sincerely,

/s/

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