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VIA email with copy to:
ROSFOSO@cms.hhs.gov

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 unprecedented 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.)

<u>Medicare Conditions of Participation (CoPs)</u>

- 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 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.

- 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 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 HPAA 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-to-face encounter with a patients 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.

Sincerely,

/s/

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