California Section 1135 Waiver Request

Provider Name/Type: All California Hospitals and Health Systems

Contact person and information:

Lois Richardson, Vice President and Legal Counsel
California Hospital Association
1215 K Street, Suite 800
Sacramento, CA 95814
(916) 834-7611 (mobile)
(916) 552-7611 (office)
lrichardson@calhospital.org

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. **T**his 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.

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

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 influenzas 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 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

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.

- 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/
Lois Richardson
Vice President and Legal Counsel
California Hospital Association
1215 K Street, Suite 800
Sacramento, CA 95814
(916) 834-7611 (mobile)
(916) 552-7611 (office)
lrichardson@calhospital.org