April 6, 2020

Submitted via email to ROSFOSO@cms.hhs.gov

Western Consortium
Centers for Medicare and Medicaid Services ("CMS")

Re: OAHHS Second Request for Waivers Under Section 1135 of the Social Security Act

Dear CMS:

Oregon Association of Hospitals and Health Systems ("OAHHS") respectfully requests, on behalf of all Oregon hospitals, that the Centers for Medicare and Medicaid Services ("CMS") grant the waivers described below, which would greatly assist Oregon hospitals as they address the substantial challenges posed by the COVID-19 pandemic. OAHHS requests that the requested waivers be granted effective March 1, 2020.

As background, on Friday, March 20, 2020, the Oregon Health Authority ("OHA") submitted its 1135 waiver request to CMS. On Wednesday, March 25, 2020, OHA received a response from CMS granting some of the requested waivers and modifications. By letter dated March 26, 2020, CMS granted more requested waivers and modifications. We greatly appreciate the waivers and modifications that have already been granted specifically to Oregon, and through the national blanket waivers. Those waivers and modifications better position Oregon hospitals to respond to the challenges posed by the COVID-19 pandemic.

Oregon is in an unprecedented health care crisis related to the impacts of COVID-19. Oregon has over 1,000 confirmed cases of COVID-19 and community transmission of COVID-19 is occurring. The Governor of Oregon has directed that schools be closed statewide and ordered that Oregonians "Stay Home, Save Lives". On March 19, 2020, the Governor of Oregon ordered the postponement of non-urgent health care procedures in order to conserve personal protective equipment and hospital beds for the State’s response to the COVID-19 pandemic.

Oregon hospitals have been working closely with OHA to implement the 1135 waivers received, respond to this emergency, and care for Oregonians. Many providers in the state have opened or are planning to open new sites to screen patients for COVID-19 and provide care to patients diagnosed with COVID-19 and those who are otherwise in need of health care services during this emergency period.

Waiving or modifying the requirements listed below will allow Oregon hospitals to focus on COVID-19 response and the treatment of patients.
I. New Requests

1. Medical Screening Exams. Waive 42 C.F.R. § 489.24 and any other requirements applicable to this waiver to allow medical screening exams to be performed by qualified medical staff authorized by the hospital, such as registered nurses, who are acting within their scope of practice and licensure, yet are not designated in the bylaws to perform medical screening exams.

2. Medical Staff. Waive 42 C.F.R. § 482.22 and any other requirements applicable to this waiver to allow hospitals to recognize, without further action, the full range of credentials and privileges of medical staff members and allied health professionals granted, and in good standing, by any other hospital within the hospital’s integrated delivery system.

3. Expand Telehealth Practitioners. Waive the limitation established by Section 1834(m) of the Social Security Act and 42 C.F.R. § 410.78(b)(2) that permits only certain categories of “practitioners” to furnish Medicare covered telehealth services and expressly expand the list of professionals who can furnish telehealth services to include physical therapists (PTs), physical therapist assistants (PTAs), occupational therapists (OTs), occupational therapist assistants (OTAs), speech-language pathologists (SLPs), and speech-language pathologist assistants (SLPAs). We further request Medicare coverage of telehealth services delivered by these categories of practitioners when furnished to hospital outpatients, and clarification that the hospitals providing those services to patients in their home or another alternative care site are permitted to bill the technical component of all visit codes provided via telehealth using the hospital’s staff, equipment, and telecommunications systems. Consistent with the Secretary’s expanded authority under the CARES Act, allow PTs, PTAs, OTs, OTAs, SLPs, and SLPAs to be eligible distant site practitioners who can bill and be paid for HCPCS 97161-68, 97110-16, 97535, 97750, 97760-61, 92521-92524, and 92507. Allow licensed clinical social workers, clinical psychologists, PTs, PTAs, OTs, OTAs, SLPs, and SLPAs to bill for HCPCS 99421-23 in addition to G2061-63 for both new and established patients.

4. Telehealth - Cardiac Rehabilitation and Pulmonary Rehabilitation. Waive the limitation in 42 C.F.R. § 410.78 permitting Medicare coverage only for services that were added to the list of the services covered as telehealth services through the annual physician fee schedule rulemaking process and expressly expand the list of services to include cardiac rehabilitation and pulmonary rehabilitation services.

5. Average Daily Census and Average Length of Stay. To the extent a children’s hospital is required by federal, state or local government order to modify admissions practices or a children’s hospital otherwise elects to modify admissions practices in response to the COVID-19 emergency, the Centers for Medicare and Medicaid Services and/or survey agencies acting on their behalf will adjust consideration of the hospital’s average daily census and average length of stay for purposes of next determining the hospital’s compliance thresholds under 42 C.F.R. § 412.23(d)(2), whenever that occurs.
6. **Grievances.** Waive the provisions of 42 C.F.R. § 482.13(a)(2) requiring hospitals to review and resolve grievances through the governing board or a grievance committee, and within a specified timeframe.

7. **Certification on Inpatient Admissions.** In the interest of paperwork reduction, waive the requirements of 42 C.F.R. § 424.13 requiring physician certification and recertification for inpatient admissions with greater than a 20-day length of stay, greater than $200,000 in expenses, or outlier cases to be certified as medically necessary.

8. **Annual Recertification and Training.** Delay any annual recertification and training requirements for physicians, nurses, and other health care providers (e.g. respiratory therapists, medical laboratory technicians, physical therapists, occupational therapists) for the duration of the public health emergency.

9. **Pause Audits.** Direct Medicare Administrative Contractors, Recovery Audit Contractors, Unified Program Integrity Contractors, Quality Improvement Organizations and all other contractors performing Medicare program integrity activities under 42 U.S.C. § 1395ddd to suspend efforts to collect information and documentation from providers and extend timeframes to allow providers to respond to outstanding requests at a later date without penalty, following the expiration of the COVID-19 emergency.

10. **MAC.** Direct Medicare Administrative Contractors not to issue notices of program reimbursement or engage in cost report settlement activities until after the emergency is over, so as to allow providers to focus all resources on clinical care.

11. **Medical Transportation.** Waive 42 C.F.R. § 489.24(e)(2)(iv) to the extent it could be interpreted as prohibiting a healthcare provider, including hospital providers, from recommending to the patient and/or the patient’s representative that transfer to another medical facility can safely occur without medical transportation equipment and personnel.

12. **Homebound Requirements.** Waive the homebound requirement set forth in Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Social Security Act and Sections 409.42(a) and 424.22(a)(1)(ii) of Title 42 of the Code of Federal Regulations to permit Medicare coverage of home health services for patients who are not confined to the home.

13. **Home Oxygen.** Waive limitations on coverage of home oxygen and other respiratory systems set forth in National Coverage Determinations, Local Coverage Determinations, and any other Medicare coverage guidelines to the extent any limitations could be interpreted as restricting coverage of home oxygen or other respiratory systems for patients with diagnosed COVID-19 or patients who are under investigation for COVID-19.

14. **CAH: Periodic Evaluation and Quality Assurance Review.** Waive 42 C.F.R. § 485.641 and any other requirements applicable to this waiver in order to delay the requirement that Critical Access Hospitals perform a Periodic Evaluation and Quality Assurance Review.
15. **Suspend Provider Enrollment Timing Requirements.** Suspend the timeframes set forth in 42 C.F.R. § 424.516 for providers and suppliers to report changes of information and grant billing privileges retroactive to March 1, 2020 for new practice locations and reassignments.

16. **Delivery of Services in Alternate Clinic Locations.** 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.

17. **Delay Posting Requirement.** Waive enforcement of the Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First in order to delay the requirement that by January 1, 2021, hospitals must publicly post standard charge information, including charges and information based on negotiated rates and for common or shoppable items and services, in an easy-to-understand, consumer-friendly, and machine-readable format using consensus-based data standards that will meaningfully inform patients’ decision making and allow patients to compare prices across hospitals.

II. **Joining with Washington State Hospital Association’s Second and Third Waiver Requests**

On March 22, 2020, the Washington State Hospital Association (“WSHA”) submitted its Second Washington State Section 1135 Waiver Request, attached hereto. On March 28, 2020, WSHA submitted its third waiver request, attached hereto. WSHA’s third waiver request focused on home health and hospice services, which have an important impact on Oregon hospitals’ ability to respond to the COVID-19 pandemic. OAHHS respectfully requests that the requests in WSHA’s second and third waiver requests that have not yet been granted through a national blanket waiver be granted to all Oregon hospitals, effective March 1, 2020.

III. **Pending Requests**

We understand that CMS is continuing to review the additional waiver or modification requests submitted by OHA on Friday, March 20, 2020, that have not yet been approved by letter to OHA or OAHHS, or addressed in a national blanket waiver. To the extent any waivers requested by OHA or OAHHS have not yet been granted, we renew the request to waive or modify the portions not yet granted. We have not restated all requests, such as those involving Oregon’s Medicaid program, as we understand OHA is working with CMS to continue to address those requests. To be helpful, we have listed a few of our pending requests below.

1. **Infection Control.** Waive requirements of 42 C.F.R. §482.42(a)(2)-(3) to permit the use of personal protective equipment outside of and beyond the specific manufacturer’s instructions for use. This is including but not limited to surgical masks, N95 masks, face shields and gowns.
2. **Timing Filing Requirements.** Waive timely filing requirements in 42 C.F.R. § 424.44 to allow providers to build correct coding and other structural pieces into their systems and even payer ability to adjudicate.

3. **Staff Training.** Waive requirement of 42 C.F.R. § 482.13(f)(4) to allow a hospital to not document in the staff personnel records that the applicable training and demonstration of competency were successfully completed.

We are also seeking clarification that the waiver below, which was granted to OHA on March 25, 2020, includes hospitals and critical access hospitals as "facilities."

CMS approves a waiver under section 1135(b)(1) of the Act to allow facilities, including NFs, intermediate care facilities for individuals with intellectual and developmental disabilities (ICF/IDDs), psychiatric residential treatment facilities (PRTFs), and hospital NFs, to be fully reimbursed for services rendered to an unlicensed facility (during an emergency evacuation or due to other need to relocate residents where the placing facility continues to render services) provided that the State makes a reasonable assessment that the facility meets minimum standards, consistent with reasonable expectations in the context of the current public health emergency, to ensure the health, safety and comfort of beneficiaries and staff. The placing facility would be responsible for determining how to reimburse the unlicensed facility. This arrangement would only be effective for the duration of the section 1135 waiver.

If you have questions or would like further information, please do not hesitate to contact me.

Sincerely,

Rebecca Hultberg
President and CEO, OAHHS
March 22, 2020

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

Re: Second Washington State Section 1135 Waiver Request for All Washington State Hospitals and Health Systems

Dear Mr. Bunch:

This letter serves as a second request for additional blanket waivers under Section 1135 for all affected similarly situated hospitals in Washington State based on the COVID-19 pandemic. As you know our first request was submitted to your office on March 15, 2020. Individual hospitals may submit additional requests based on their unique circumstances.

Brief summary of why the waiver is needed. Please see the background section of our prior letter. Since that letter was submitted, needs in our state have grown and intensified, necessitating this second waiver request. COVID-19 cases continue to grow in our state. As of March 21, Washington State has 1,793 cumulative cases. On March 21 there were 269 new cases over the prior day, which represents 18 percent increase in a single day. There have been 93 deaths total. 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 the state is poised to trigger Crisis Standards of Care. The Governor has issued proclamations on a number of measures designed to curb the spread, including additional measures on social distancing and cancelling elective surgeries: https://www.governor.wa.gov/office-governor/official-actions/proclamations. We are being asked to undertake unprecedented changes in the way we deliver health care with no corresponding waivers or federal and state protections for our systems.

Request for additional waivers. If CMS is unable to approve a broad waiver, we reiterate our request made on March 15 (attached for your convenience), 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 letter with detailed requests to Secretary Azar on March 16, 2020. WSHA endorses those requests. We request the waivers described below extend 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.

**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 certification for involuntary mental health holds held in non-psychiatric units, 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, life safety code and CoPs do not apply. Allow ASCs, CAHs, and other licensed independent facilities to serve as “overflow” for patients transferred from acute care hospitals, with waivers of CoP or certification requirements for those entities to allow them to accept such patients, and provide adequate federal health care program reimbursement for those facilities. We acknowledge that the blanket waiver of March 13 waives “certain” CoPs but does not specify which ones. Suspend the requirement to submit enrolment (855 form) updates for temporary locations that are stood up for pandemic response. Reimburse providers for a service provided in an unlicensed location.

**Deadlines.** Suspend billing timeframes and require Medicare Advantage and Part D plans to do the same. Suspend cost report settlement timeframes, including repayment due dates. Suspend HIPAA breach notification timeframes. 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 signature requirements for MOON. Waive patient cost-sharing for observation services. Waive any limitations under Medicare or Medicaid for the number of reimbursable hours of observation. Permit for billing of observation services rendered via remote monitoring methods.

**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 DP NF 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. Create a billing code for this.

**Freestanding rehabilitation and psychiatric hospital services.** The blanket waiver issued by CMS on March 13, 2020, allows distinct part units (SNF, rehab and psych) to provide acute inpatient care if the patient meets level-of-care criteria. We request the same for freestanding SNFs, RFS, rehab and psych hospitals, and ambulatory care centers. We also request clarify on which facility bills and any codes/modifiers required.

**72-hour Window Rule for IPPS Hospitals/1-Day Rule for CAHs.** Waive this rule related to billing outpatient services pre-dating an inpatient admission on the inpatient claim so that beneficiaries may be seen in a hospital, or affiliated clinic, or via telehealth and reimbursement will be made to that provider separately for the outpatient services by CMS, and reimburse hospitals for the full DRG for a subsequent hospitalization.
Transfer Reductions. Remove federal healthcare program transfer-related reductions to payment for transfers that are driven by the pandemic and need to free up acute care beds for the highest acuity patients.

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 the region’s acute care capacity, whether those beds are used for inpatient or SNF-level care, to maximize the acute care capacity available statewide and the availability of those beds in hospitals with specialized capabilities for the most acutely ill patients.

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. Require these plans to consider presenting symptoms as a basis for coverage, not final diagnosis.

Inpatient Rehabilitation Facilities. Waive the IRF 3-hour rule (3 hours daily of one-on-one therapy).

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, without requiring privileging.

3-day qualifying stay for SNFs. 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. 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 timeframes 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.

**Waxe IMD Medicaid exclusion.** National hospital capacity is expected to be pushed to its limits during the COVID-19 pandemic. 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 would free up beds in local communities’ hospitals, allowing them to better manage the 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 lockdown orders are 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) and without patient consent.

**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 translation services.** Clarify that providers may rely on family members or friends if a professional interpreter or translator (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 regardless of network status of the receiving provider and regardless of patient choice. 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.

**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 portions of CCRCs 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 is 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. This 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 (MAC).
• 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.

**Rural Health Clinics, FQHCs, CHCs.** If Congress does not act, allow rural health clinics, FQHCs, and CHCs in all areas to provide and bill for telehealth services Including, but not limited to, as distant sites. Allow rural health clinics that temporarily relocate in order to reduce risk of spread to maintain their RHC status, billing and encounter rate so long as they maintain the same providers and services, and serve the same geographic area.

**Conclusion.** Washington’s hospitals and health care systems are being directed to discontinue all but emergent or urgent services, limit testing to only patients meeting CDC criteria, ration PPE, and take unprecedented steps with regard to isolating or secluding patients with potential COVID-19 infection – all without the protection of federal or state waivers that address these necessary steps. We are on the front line of the war to curb the pandemic, but we are not being given the necessary protections to focus our resources on the patients most in need or the means to protect our caregivers. We need to have confidence that we will receive sufficient resources, including reimbursements, to maintain ongoing operations in this time of emergency, and the liability protections necessary to defend the extraordinary steps we are being asked (if not ordered, at threat of criminal penalty) to carry out. We will do everything we can to partner closely with the federal, state and local regulators and public health authorities to carry out these mandates, but we need urgent assistance to do so in a way that will not permanently disrupt our health care system or sideline our ability to effectively respond to this national emergency.

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,

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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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