March 28, 2020

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San Francisco & Seattle
Acute & Continuing Care Branch
Centers for Medicare & Medicaid Services
701 5th Ave. Suite 1600
Seattle, WA 98104

VIA Email with copy to: Regional Manager ROSFOSO@cms.hhs.gov

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 reflief 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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