DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
CMS Kansas City – Survey & Operations Group
601 E. 12th Street, Room 355
Kansas City, Missouri 64106

June 29, 2020

Carol Hudspeth
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2420 Hyde Park, Suite A
Jefferson City, MO 65109

Via Email:
carol@mahcmail.org

Dear Ms. Hudspeth,

I am responding to your letter dated March 27, 2020 requesting 1135 waivers on behalf of your home health and hospice members. On June 25, 2020, the Centers for Medicare and Medicaid Services (CMS) granted additional waivers to address the continued challenges experienced by health care facilities related to the COVID-19 pandemic. Please find a response, granting some of the waivers and modifications you requested, pursuant to section 1135 of the Act. We note that your letter mentioned personal protective equipment (PPE), which is outside the scope of 1135 Waivers. Section 1135 of the Social Security Act authorizes the Secretary to temporarily modify or waive certain Medicare, Medicaid, Children's Health Insurance Program (CHIP), and Health Insurance Portability and Accountability Act (HIPAA) requirements. However, we continue to work with the States and Health Departments to address State needs related to PPE and testing and encourage you to reach out to your State for further information.

To streamline the section 1135 waiver request and approval process, CMS has issued and may continue to issue blanket waivers for many Medicare provisions, which primarily affect requirements for individual facilities, such as hospitals, long-term care facilities, home health agencies, hospices, and others. Waiver or modification of these blanket provisions does not require individualized approval. For information on provisions waived or modified under our blanket waiver authority, please refer to guidance available at https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page. Please review the waivers often to remain updated. CMS continues to post waivers and flexibilities at the above website link. Once the national emergency terminates (including any extensions), Section 1135 waivers will no longer be available.

Provider Association Request:

Home Health:

- Temporarily suspending two-week aide supervision requirement by a registered nurse for home health agencies (42 C.F.R. § 484.36[1]);

[1] The current regulatory citation pertaining to this request can be found under 42 CFR 484.80(d), following the revised CoPs that went into effect on January 13, 2018.

- Permitting certified home health agencies to conduct a face-to-face encounter, which must occur within 90 days prior to the start of care, or within the 30 days after the start of care, by telephone or through telehealth modalities and relaxing the timeframes for compliance (42 C.F.R. § 484.55);
- Permitting a therapist to conduct the initial visit and comprehensive assessment - even for nursing referrals- when nurses are not available during the pandemic period (42 C.F.R. § 484.55(a)(1);
- Permitting home health agencies to perform certifications, initial assessments and determine patients' homebound status remotely via telephone or through telehealth modalities (42 C.F.R. § 484.55);
- Permitting "in-service" and "in-person" trainings to be conducted remotely or otherwise suspending this requirement, so that timeframes can be extended to complete trainings to avoid congregation of multiple individuals in a classroom setting (42 C.F.R. § 484.75(b)(9) and permitting any recertifications to be conducted through online competency evaluations (42 C.F.R. § 484.80);
- Suspending the requirement that home health aides be assigned to a specific patient by a registered nurse or other appropriate skilled professional (42 C.F.R. § 484.80(g)(1));
- Suspending annual in-home visits by a registered nurse or other appropriate skilled professional (42 C.F.R. § 484.80(h)(i)(iii)); and
- Extending deadlines for the submission of CMS Outcome and Assessment Information Set ("OASIS") until the end of the public health emergency (42 C.F.R. § 484.55).
- **Allow virtual/telephonic home health visits**. Current home health patients are turning away scheduled home health care visits due to fears of coronavirus. Without the ability to interact with their providers, these patients could end up needing acute care. Further, PPE is becoming increasingly unavailable, creating an urgent need for new care modalities. We request that CMS waive the requirement that home health visits occur physically in the patient's home and allow virtual and telephonic home health visits. We also request these visits to count as visits and towards LUPA thresholds. Specifically, we are requesting:
    - In the case of Medicare home health services and hospice care (as defined in section 1861(m) and 1861(dd) respectively) furnished in Missouri during the public health emergency declared for COVID-19, skilled nursing and therapy services provided by a licensed nurse or therapist using two-way audio visual technology (or by telephone if such technology is not available) shall be considered care provided in a place of residence used as a beneficiary's home, when either the patient refuses in-person care, the clinician is unable to provide in-person care due to the ongoing pandemic, or the home health agency or hospice is unable to provide in-person care due to staffing and PPE shortages. The foregoing shall be for specified services enumerated in the plan of care. Such services shall be paid by Medicare in the same manner under section 1895 and 1814(i) respectively that would apply had such care been provided in person.
- **Access to Personal Protective Equipment (PPE).** PPE supplies are running low but are critical to prevent exposure during home health visits that could harm home health workers or spread the virus to other homebound patients. HHAs will look to CMS and CDC guidance on getting the most out of PPE, but interventions through the SNS and in the supply chain should prioritize access to PPE for HHAs. Higher costs of

PPE should be considered in identifying appropriate rates for home health services during the coronavirus emergency and response.

- **Homebound Criteria**: Create "homebound" interpretation flexibility to allow more beneficiaries to obtain care at home to minimize spread of infection and prevent hospitalizations and outpatient utilization. Examples include individuals suspected of infection who don't otherwise meet home health criteria and individuals with an intermittent skilled need and multiple chronic conditions.
- **Use of Telehealth to Provide Home Health**. Despite the recent Congressional action to allow telehealth to originate from patient homes in both rural and urban areas, home health agencies cannot conduct patient visits services via telehealth. HHAs have infrastructure and expertise for remote monitoring and virtual care, but Medicare HH episodes require in person visits. Just as Medicare pays for professional services furnished remotely via telehealth, CMS should consider options to allow Home Health providers to provide telehealth services. CMS could potentially allow qualified HA personnel to provide Part B telehealth services to support access to care during high need.
- **OASIS Assessment**. Home health intake typically requires an initial visit and assessment in the patient's home that generally takes 3 hours to complete. The duration of this visit means significant exposure for home health workers. CMS could waive all or some of the OASIS assessment for COVID-positive or presumptive COVID-positive patients. CMS could also waive the requirement for this to occur based on in-person observations and instead allow portions to be completed via telephone or video conference.
- **Remote Patient Monitoring**. There are opportunities to bill under Part B, but home health is not separately paid for these services. While CMS has previously allowed investments in remote patient monitoring to be reported as home health costs, these costs are not paid for directly. In order to support use of remote patient monitoring equipment for COVID-19 patients, CMS should consider remote patient monitoring costs in determining appropriate payment for home

Hospice:

- Extending deadlines for the collection and submission of the Hospice Item Set until the conclusion of the nationwide public health emergency (42 C.F.R. § 418.312);
- Suspending all face-to-face visit requirements by hospice physicians and nurse practitioners in favor of permitted telephone and telehealth modalities (42 C.F.R. § 418.22(a)(4));
- Extending the five-day timeframe for hospice providers to submit Notices of Election and Notices of Termination/Revocation (42 C.F.R. § 418.24);
- Encouraging all included hospice services to be provided by telephone and telehealth modalities, including bereavement counseling, social work, spiritual services, dietary services, and other counseling;
- Suspending the requirement that hospices conduct background checks on employees with direct patient contact or access to records before hiring them, such that employees can be onboarded while the background check is processed (42 C.F.R. § 418.113);
- Temporarily suspending the requirement of supervision of hospice aides by a registered nurse every 14 days for hospice agencies (42 C.F.R. § 418.76);
- Suspending the requirement for certified hospices to have a contract with a

nursing home if a patient has moved (42 C.F.R. § 418.108);

- Suspending the volunteer requirements to reflect that many hospice volunteers, who tend to be elderly themselves, are not visiting patients and respecting limitations on social interaction (42 C.F.R. § 418.78(b)); and
- Limiting the provision of rehabilitative services, including physical therapy, occupational therapy, and speech therapy as these services tend to be limited in hospice care generally, workforce challenges are becoming more acute, and the suspension of these services will serve to respect calls for limited social interaction.

CMS Response:

List of approved and/or modified 1135 Waivers, based on your requests, and the associated links for your team to remain updated:

Home Health Agencies: CMS Flexibilities to Fight COVID-19, https://www.cms.gov/files/document/covid-home-health-agencies.pdf

Hospice: CMS Flexibilities to Fight COVID-19, *https://www.cms.gov/files/document/covid-hospices.pdf*

Medicare Telehealth and Telecommunications Technology
Hospice providers can provide services to a Medicare patient receiving routine home care through telecommunications technology (e.g., remote patient monitoring; telephone calls (audio only and TTY); and 2-way audio-video technology), if it is feasible and appropriate to do so. Only in-person visits are to be recorded on the hospice claim.

Face-to-face encounters for purposes of patient recertification under 418.22 for the Medicare hospice benefit can now be conducted via telehealth (i.e., 2-way audio-video telecommunications technology that allows for real-time interaction between the hospice physician/hospice nurse practitioner and the patient). *However, the encounter, whether it be through telehealth or face to face, must still occur.*

Home Health Agencies (HHAs) can provide more services to beneficiaries using telecommunications technology within the 30-day period of care, so long as it's part of the patient's plan of care and does not replace needed in-person visits as ordered on the plan of care. We acknowledge that the use of such technology may result in changes to the frequency or types of in-persons visits outlined on existing or new plans of care. Telecommunications technology can include, for example: remote patient monitoring; telephone calls (audio only and TTY); and 2-way audio-video technology that allows for real-time interaction between the clinician and patient. However, only in-person visits can be reported on the home health claim.

The required face-to-face encounter for home health can be conducted via telehealth (i.e., 2-way audio-video telecommunications technology that allows for real-time interaction between the physician/allowed practitioner and the patient). *However, the encounter, whether it be through telehealth or face to face, must still occur.*

Waived Onsite Visits for Hospice Aide Supervision. CMS is waiving the requirements at 42 CFR §418.76(h), which require a nurse to conduct an onsite supervisory visit every two weeks. This would include waiving the requirements for a nurse or other professional to conduct an onsite

visit every two weeks to evaluate if aides are providing care consistent with the care plan, as this may not be physically possible for a period of time. *Virtual supervision is encouraged during the period of the waiver.*

Training and Assessment of Aides: CMS is waiving the requirement at 42 CFR §418.76(h)(2) for Hospice and 42 CFR §484.80(h)(1)(iii) for HHAs, which require a registered nurse, or in the case of an HHA a registered nurse or other appropriate skilled professional (physical therapist/occupational therapist, speech language pathologist) to make an annual onsite supervisory visit (direct observation) for each aide that provides services on behalf of the agency. In accordance with section 1135(b)(5) of the Act, we are postponing completion of these visits. *All postponed onsite assessments must be completed by these professionals no later than 60 days after the expiration of the PHE.*

Waive Onsite Visits for HHA Aide Supervision: CMS is waiving the requirements at 42 CFR §484.80(h), which require a nurse to conduct an onsite visit every two weeks. This would include waiving the requirements for a nurse or other professional to conduct an onsite visit every two weeks to evaluate if aides are providing care consistent with the care plan, as this may not be physically possible for a period of time. This waiver is also temporarily suspending the 2-week aide supervision by a registered nurse for home health agencies requirement at §484.80(h)(1), but *virtual supervision is encouraged during the period of the waiver.*

Home Health:

Homebound Definition: A beneficiary is considered homebound when their physician advises them not to leave the home because of a confirmed or suspected COVID-19 diagnosis or if the patient has a condition that makes them more susceptible to contract COVID-19. As a result, *if a beneficiary is homebound due to COVID-19 and needs skilled services,* an HHA can provide those services under the Medicare Home Health benefit.

Initial Assessments. CMS is waiving the requirements at 42 CFR §484.55(a) to *allow HHAs to perform Medicare-covered initial assessments and determine patients' homebound status remotely or by record review*. This will allow patients to be cared for in the best environment for them 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.

12-hour Annual In-service Training Requirement for Home Health Aides. CMS is modifying the requirement at 42 CFR §484.80(d)[2] that home health agencies must assure that each home health aide receives 12 hours of in-service training in a 12-month period. In accordance with section 1135(b)(5) of the Act, *we are postponing the deadline for completing this requirement throughout the COVID-19 PHE until the end of the first full quarter after the declaration of the PHE concludes.* This will allow aides and the registered nurses (RNs) who teach in-service training to spend more time delivering direct patient care and additional time for staff to complete this requirement.

Allow Occupational Therapists (OTs), Physical Therapists (PTs), and Speech Language Pathologists (SLPs) to Perform Initial and Comprehensive Assessment for all Patients. CMS is waiving the requirements in 42 CFR § 484.55(a)(2) and § 484.55(b)(3) that rehabilitation skilled

professionals may only perform the initial and comprehensive assessment when only therapy services are ordered. This temporary blanket modification allows any rehabilitation professional (OT, PT, or SLP) to perform the initial and comprehensive assessment for all patients receiving therapy services as part of the plan of care, to the extent permitted under state law, regardless of whether or not the service establishes eligibility for the patient to be receiving home care. *The existing regulations at § 484.55(a) and (b)(2) would continue to apply; rehabilitation skilled professionals would not be permitted to perform assessments in nursing-only cases.* We would continue to expect HHAs to match the appropriate discipline that performs the assessment to the needs of the patient to the greatest extent possible. *Therapists must act within their state scope of practice laws when performing initial and comprehensive assessments, and access a registered nurse or other professional to complete sections of the assessment that are beyond their scope of practice.* Expanding the category of therapists who may perform initial and comprehensive assessments provides HHAs with additional flexibility that may decrease patient wait times for the initiation of home health services.

Reporting. CMS is providing relief to HHAs on the timeframes related to OASIS Transmission through the following actions below**:**

- Extending the 5-day completion requirement for the comprehensive assessment to 30days.
- Waiving the 30-day OASIS submission requirement. Delayed submission is permitted during the PHE.

Remote Monitoring: Home health agencies are able to furnish services using telecommunications technology during the PHE as long as such services do not substitute for in-person visits ordered on the plan of care. This can include telephone calls (audio only and TTY), two-way audio-video telecommunications that allow for real-time interaction between the patient and clinician (e.g., FaceTime, Skype), and remote patient monitoring. It would be up to the clinical judgment of the home health agency and patient's physician/practitioner as to whether such technology can meet the patient's need. The use of telecommunications technology in furnishing services under the home health benefit must be included on the plan of care and the plan of care must outline how such technology will assist in achieving the goals outlined on the plan of care. Only in-person visits are to be reported on the home health claim submitted to Medicare for payment. On an interim basis, HHAs can report the costs of telecommunications technology on the HHA cost report as allowable administrative and general (A&G) costs by identifying the costs using a subscript between line 5.01 through line 5.19.

Medicare telehealth services include many services that are normally furnished in-person. CMS maintains a list of services that may be furnished via Medicare telehealth.

This list is available here: https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes. These services are described by HCPCS codes and paid under the Physician Fee Schedule. Under the emergency declaration and waivers, these services may be provided to patients by physicians and certain non-physician practitioners regardless of the patient's location. Medicare also pays for certain other services that are commonly furnished remotely using telecommunications technology, but are not considered Medicare telehealth services. These services can always be provided to patients wherever they are located, and include physician interpretation of diagnostic tests, care management services, and virtual check-ins. You can find the payment rates for the virtual check-ins and the e-Visits here: https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf.

Hospice:

42 C.F.R. §418.22(a)(4) Certification of Terminal Illness Face-to-Face Encounter
To the extent not modified above through the allowance of **telehealth,** the face-to-face certification must still occur prior to, but no more than 30 calendar days prior to, the third benefit period recertification, and every benefit period recertification thereafter. *As stated above, the encounter may occur face to face or through telehealth, but the certification must occur in accordance with the timeframes specified.*

Comprehensive Assessments. CMS is waiving **certain** requirements at 42 CFR §418.54 related to updating comprehensive assessments of patients. This waiver applies to the timeframes for **updates** to the comprehensive assessment found at §418.54(d). *Hospices must continue to complete all required assessments and updates; however, the timeframes for updating the comprehensive assessment may be extended from 15 to 21 days.*

Hospice Aide Competency Testing Allow Use of Pseudo Patients. 42 CFR 418.76(c)(1). CMS is temporarily modifying the requirement in § 418.76(c)(1) that a hospice aide must be evaluated by observing an aide's performance of certain tasks with a patient. This modification allows hospices to utilize pseudo patients such as a person trained to participate in a role-play situation or a computer-based mannequin device, instead of actual patients, in the competency testing of hospice aides for those tasks that must be observed being performed on a patient. This increases the speed of performing competency testing and allows new aides to begin serving patients more quickly without affecting patient health and safety during the public health emergency (PHE).

Waive Requirement for Hospices to Use Volunteers. CMS is waiving the requirement at 42 CFR §418.78(e) that hospices are required to use volunteers (including at least 5% of patient care hours). It is anticipated that hospice volunteer availability and use will be reduced related to COVID-19 surge and potential quarantine.
Waive Non-Core Services. CMS is waiving the requirement for hospices to provide certain non-core hospice services during the national emergency, including the requirements at 42 CFR §418.72 for physical therapy, occupational therapy, and speech-language pathology.

1135 waivers for the following requirements *have not* been granted at the time of this response given the risk to the health and safety of home health and hospice patients. Please continue to check the website for updates and revisions.

- Permitting a therapist to conduct the initial visit and comprehensive assessment - even for nursing referrals- when nurses are not available during the pandemic period (42 C.F.R. § 484.55(a)(1)- *The existing regulations at § 484.55(a) and (b)(2) would continue to apply; rehabilitation skilled professionals would not be permitted to perform assessments in nursing-only cases.*

- Suspending the requirement that home health aides be assigned to a specific patient by a registered nurse or other appropriate skilled professional (42 C.F.R. § 484.80(g)(1));

- **42 C.F.R. §418.64 Condition of Participation: Core Services** The federal hospice regulations require that nursing services, medical social services, and counseling services, including bereavement, dietary, and spiritual counseling, must be provided by hospice employees.

- Extending the five-day timeframe for hospice providers to submit Notices of Election and Notices of Termination/Revocation (42 C.F.R. § 418.24);

- Suspending the requirement that hospices conduct background checks on employees with direct patient contact or access to records before hiring them, such that employees can be onboarded while the background check is processed (42 C.F.R. § 418.113[3]);

- Suspending the requirement for certified hospices to have a contract with a nursing home if a patient has moved (42 C.F.R. § 418.108);

Finally, in regards to the hospice item set, CMS has released guidance to providers related to relaxed reporting requirements for quality reporting programs at: https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.

These waivers apply to federal requirements only. *To the extent applicable, waivers are contingent on obtaining any necessary state approvals on licensing and any other applicable state regulatory requirements.* We appreciate the efforts of you and your staff in responding to the needs of beneficiaries in your State and health care community. If you have questions or concerns regarding this correspondence, please send inquiries to our corporate mailbox CMD@cms.hhs.gov.

Sincerely,

Elizabeth A. Henningfeld -S

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[3] This requirement falls under personnel qualification under 42 CFR 418.114. 42 CFR 418.113 pertains to emergency preparedness. Neither regulations has been waived under 1135.