

Home Health Agencies: CMS Flexibilities to Fight COVID-19

** Indicates items added or revised in the most recent update

Since the beginning of the COVID-19 Public Health Emergency, the Trump Administration has issued an unprecedented array of temporary regulatory waivers and new rules to equip the American healthcare system with maximum flexibility to respond to the 2019 Novel Coronavirus (COVID-19) pandemic. These temporary changes will apply immediately across the entire U.S. healthcare system for the duration of the emergency declaration. The goals of these actions are to 1) expand the healthcare system workforce by removing barriers for physicians, nurses, and other clinicians to be readily hired from the community or from other states; 2) ensure that local hospitals and health systems have the capacity to handle a potential surge of COVID-19 patients through temporary expansion sites (also known as CMS Hospital Without Walls); 3) increase access to telehealth in Medicare to ensure patients have access to physicians and other clinicians while keeping patients safe at home; 4) expand in-place testing to allow for more testing at home or in community based settings; and 5) put Patients Over Paperwork to give temporary relief from many paperwork, reporting and audit requirements so providers, health care facilities, Medicare Advantage and Part D plans, and States can focus on providing needed care to Medicare and Medicaid beneficiaries affected by COVID-19.

****Ensuring all Americans Have Access to a COVID-19 Vaccine When One Becomes Available**

On October 28, 2020, CMS released an Interim Final Rule with Comment Period (IFC) that establishes that any vaccine that receives Food and Drug Administration (FDA) authorization, through an Emergency Use Authorization (EUA) or licensed under a Biologics License Application (BLA), will be covered under Medicare as a preventive vaccine at no cost to beneficiaries. The IFC also implements provisions of the CARES Act that ensure swift coverage of a COVID-19 vaccine by most private health insurance plans without cost sharing from both in and out-of-network providers during the course of the public health emergency (PHE).

After the FDA either approves or authorizes a vaccine for COVID-19, CMS will identify the specific vaccine codes, by dose if necessary, and specific vaccine administration codes for each dose for Medicare payment. CMS and the American Medical Association (AMA) are working collaboratively on finalizing a new approach to report use of COVID-19 vaccines.

The Medicare payment rates for COVID-19 vaccine administration will be \$28.39 to administer single-dose vaccines. For a COVID-19 vaccine requiring a series of 2 or more doses, the initial dose(s) administration payment rate will be \$16.94, and \$28.39 for the administration of the final dose in the series. These rates will be geographically adjusted and recognize the costs involved in administering the vaccine, including the additional resources involved with required public health reporting, conducting important outreach and patient education, and spending additional time

with patients answering any questions they may have about the vaccine. Medicare beneficiaries, those in Original Medicare or enrolled in Medicare Advantage, will be able to get the vaccine at no cost.

For calendar years 2020 and 2021, Medicare will pay directly for the COVID-19 vaccine and its administration for beneficiaries enrolled in Medicare Advantage (MA) plans. Providers should submit COVID-19 claims to Original Medicare for all patients enrolled in MA in 2020 and 2021. MA plans will not be responsible for reimbursing providers to administer the vaccine during this time. MA beneficiaries also pay nothing for COVID-19 vaccines and their copayment/coinsurance and deductible are waived.

CMS is working to increase the number of providers that will administer a COVID-19 vaccine to Medicare beneficiaries when it becomes available, to make it as convenient as possible for America's seniors. New providers are now able to enroll as a "Medicare mass immunizers" through an expedited 24-hour process. The ability to easily enroll as a mass immunizer is important for some pharmacies, schools, and other entities that may be non-traditional providers or otherwise not eligible for Medicare enrollment. To further increase the number of providers who can administer the COVID -19 vaccine, CMS will continue to share approved Medicare provider information with states to assist with Medicaid provider enrollment efforts. CMS is also making it easier for newly enrolled Medicare providers also to enroll in state Medicaid programs to support state administration of vaccines for Medicaid recipients.

For more information, view our COVID-19 vaccine toolkits for providers, private health plans and state Medicaid programs at www.cms.gov/covidvax.

Medicare Telehealth and Telecommunications Technology

- 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).

Patients Over Paperwork

- **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.

- **Detailed Information Sharing for Discharge Planning for Home Health Agencies.** CMS is waiving the requirements of 42 CFR §484.58(a) to provide detailed information regarding discharge planning, to patients and their caregivers, or the patient’s representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, (another) home health agency (HHA), skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), and long-term care hospital (LTCH) quality measures and resource use measures. This temporary waiver provides facilities the ability to expedite discharge and movement of residents among care settings. CMS is maintaining all other discharge planning requirements.
- **Plans of Care and Certifying/Recertifying Patient Eligibility:** In addition to a physician, section 3708 of the CARES Act allows a Medicare-eligible home health patient to be under the care of a nurse practitioner, clinical nurse specialist, or a physician assistant who is working in accordance with State law. These physicians/practitioners can: (1) order home health services; (2) establish and periodically review a plan of care for home health services (e.g., sign the plan of care), (3) certify and re-certify that the patient is eligible for Medicare home health services. These changes, effective March 1, 2020, provide the flexibility needed for more timely initiation of services for home health patients, while allowing providers and patients to practice social distancing. Specifically, for Medicare, these changes are effective for Medicare claims with a “claim through date” on or after March 1, 2020.
- **Clinical Records:** In accordance with section 1135(b)(5) of the Act, CMS is extending the deadline for completion of the requirement at 42 CFR §484.110(e), which requires HHAs to provide a patient a copy of their medical record at no cost during the next visit or within four business days (when requested by the patient). Specifically, CMS will allow HHAs ten business days to provide a patient’s clinical record, instead of four.
- **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.
- **12-hour annual in-service training requirement for home health aides:** CMS is modifying the requirement at 42 C.F.R. §484.80(d) 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.

- **Quality Assurance and Performance Improvement (QAPI):** CMS is modifying the requirement at 42 CFR §418.58 for Hospice and §484.65 for HHAs, which requires these providers to develop, implement, evaluate, and maintain an effective, ongoing, hospice/HHA-wide, data-driven QAPI program. Specifically, CMS is modifying the requirements at §418.58(a)–(d) and §484.65(a)–(d) to narrow the scope of the QAPI program to concentrate on infection control issues, while retaining the requirement that remaining activities should continue to focus on adverse events. This modification decreases burden associated with the development and maintenance of a broad-based QAPI program, allowing the providers to focus efforts on aspects of care delivery most closely associated with COVID-19 and tracking adverse events during the PHE. The requirement that HHAs and hospices maintain an effective, ongoing, agency-wide, data-driven quality assessment and performance improvement program will remain.
- **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.
- **Reporting:** CMS is providing relief to HHAs on the timeframes related to OASIS transmission through the following 1) extending the 5-day completion requirement for the comprehensive assessment to 30 days; and 2) waiving the 30-day OASIS submission requirement. Delayed submission is permitted during the PHE. We are now allowing 30 days for the completion of the comprehensive assessment. HHAs must submit OASIS data prior to submitting their final claim in order to receive Medicare payment.
- **Home Health Quality Reporting Program:** HHAs are exempted from the Home Health Quality Reporting Program reporting requirements. The time period covered by this exemption is October 1, 2019 through June 30, 2020. HHAs that do not submit data for those quarters will not have their annual market basket percentage increase reduced by two percentage points. CMS is also delaying the compliance dates for collecting and reporting the Transfer of Health Information quality measures and certain standardized patient assessment data elements (SPADEs) adopted for the HH Quality Reporting Program. HHAs will be required to begin collecting the Transfer of Health Information

quality measures and certain SPADEs on January 1st of the year that is at least one calendar year after the end of the public health emergency.

- **Home Health Value Based Purchasing (HHVBP) Model:** CMS is implementing a policy to align HHVBP data submission requirements with any exceptions or extensions granted for purposes of the Home Health Quality Reporting Program during the PHE for the COVID-19 pandemic, as well as a policy for granting exceptions to the New Measures data reporting requirements under the HHVBP Model during the PHE for the COVID-19 pandemic.
- **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.
- **Requests for Anticipated Payments (RAPs):** MACs can extend the auto-cancellation date of RAPs during emergencies. RAPs are a pre-payment for home health services.
- **Review Choice Demonstration for Home Health Services:** CMS is offering flexibilities for home health agencies in the Review Choice Demonstration for Home Health Services. CMS is phasing in participation in the Review Choice Demonstration for Home Health Agencies (HHAs) in North Carolina and Florida, for a limited period of time, to help ease the transition during the current public health emergency. If Florida and North Carolina HHAs wish to participate, they may submit pre-claim review requests for billing periods beginning August 31, 2020. Florida and North Carolina providers who have already made a choice selection do not need to take any further action if they choose not to participate. CMS plans to reassess this phased-in approach in 60 days. In Illinois, Ohio, and Texas, claims submitted under Choice 1 without going through the pre-claim review process will not be subject to a 25% payment reduction until further notice, but will be subject to prepayment review. Cycle 2 in Illinois and Cycle 1 in Texas will end on September 30, 2020. Cycle 2 in Ohio will begin on August 31, 2020, as previously stated.

Medicare appeals in Fee for Service, Medicare Advantage (MA) and Part D

- CMS is allowing Medicare Administrative Contractors (MACs) and Qualified Independent Contractor (QICs) in the FFS program 42 CFR 405.942 and 42 CFR 405.962 and MA and Part D plans, as well as the Part C and Part D Independent Review Entity (IREs), 42 CFR 562, 42 CFR 423.562, 42 CFR 422.582 and 42 CFR 423.582 to allow extensions to file an appeal;
- CMS is allowing MACs and QICs in the FFS program 42 CFR 405.950 and 42 CFR 405.966 and the Part C and Part D IREs to waive requirements for timeliness for requests for additional information to adjudicate appeals; MA plans may extend the timeframe to adjudicate organization determinations and reconsiderations for medical items and services (but not Part B drugs) by up to 14 calendar days if: the enrollee requests the extension; the extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or, the extension is justified due to extraordinary, exigent, or other non-routine circumstances and is in the enrollee's interest 42 CFR § 422.568(b)(1)(i), § 422.572(b)(1) and § 422.590(f)(1);
- CMS is allowing MACs and QICs in the FFS program 42 C.F.R 405.910 and MA and Part D plans, as well as the Part C and Part D IREs to process an appeal even with incomplete Appointment of Representation forms 42 CFR § 422.561, 42 CFR § 423.560. However, any communications will only be sent to the beneficiary;
- CMS is allowing MACs and QICs in the FFS program 42 CFR 405.950 and 42 CFR 405.966 and MA and Part D plans, as well as the Part C and Part D IREs to process requests for appeal that don't meet the required elements using information that is available 42 CFR § 422.562, 42 CFR § 423.562.
- CMS is allowing MACs and QICs in the FFS program 42 CFR 405.950 and 42 CFR 405.966 and MA and Part D plans, as well as the Part C and Part D IREs, 42 CFR 422.562, 42 CFR 423.562 to utilize all flexibilities available in the appeal process as if good cause requirements are satisfied.
- **Accelerated/Advance Payments:** In order to provide additional cash flow to healthcare providers and suppliers impacted by COVID-19, CMS expanded and streamlined the Accelerated and Advance Payments Program, which provided conditional partial payments to providers and suppliers to address disruptions in claims submission and/or claims processing subject to applicable safeguards for fraud, waste and abuse. Under this program, CMS made successful payment of over \$100 billion to healthcare providers and suppliers. As of April 26, 2020, CMS is reevaluating all pending and new applications for the Accelerated Payment Program and has suspended the Advance Payment Program, in light of direct payments made available through the Department of Health & Human Services' (HHS) Provider Relief Fund. Distributions made through the Provider Relief Fund do not need to be repaid. For providers and suppliers who have received accelerated or advance payments related to the COVID-19 Public Health Emergency, CMS will not pursue recovery

of these payments until 120 days after the date of payment issuance. Providers and suppliers with questions regarding the repayment of their accelerated or advance payment(s) should contact their appropriate Medicare Administrative Contractor (MAC).

- **Provider Enrollment:** CMS has established toll-free hotlines for all providers as well as the following flexibilities for provider enrollment:
 - Waive certain screening requirements.
 - Postpone all revalidation actions.
 - Expedite any pending or new applications from providers.

Cost Reporting

- CMS is delaying the filing deadline of certain cost report due dates due to the COVID-19 outbreak. We are currently authorizing delay for the following fiscal year end (FYE) dates. CMS will delay the filing deadline of FYE 10/31/2019 cost reports due by March 31, 2020 and FYE 11/30/2019 cost reports due by April 30, 2020. The extended cost report due dates for these October and November FYEs will be June 30, 2020. CMS will also delay the filing deadline of the FYE 12/31/2019 cost reports due by May 31, 2020. The revised extended cost report due date for FYE 12/31/2019 will be August 31, 2020. For the FYE 01/31/2020 cost report, the extended due date is August 31, 2020. For the FYE 02/29/2020 cost report, the extended due date is September 30, 2020.

COVID-19 Diagnostic Testing

- If a patient is already receiving Medicare home health services, the home health nurse, during an otherwise covered visit, could obtain the sample to send to the laboratory for COVID-19 diagnostic testing.

Workforce

- **Ordering Medicaid Home Health Services and Equipment:** Medicaid home health regulations now allow non-physician practitioners to order medical equipment, supplies and appliances, home health nursing and aide services, and physical therapy, occupational therapy or speech pathology and audiology services, in accordance with state scope of practice laws.
- **Waived onsite visits for both 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 2-week aide supervision requirement at 42 CFR §484.80(h)(1) by a registered nurse for home health agencies, but virtual supervision is encouraged during the period of the waiver.

- **Allow Occupational Therapists (OTs) to Perform Initial and Comprehensive Assessment for all Patients:** 42 CFR 484.55(a)(2) and 484.55(b)(3). CMS is waiving the requirement that OTs may only perform the initial and comprehensive assessment if occupational therapy is the service that establishes eligibility for the patient to be receiving home health care. This temporary blanket modification allows OTs 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 occupational therapy is the service that establishes eligibility. The existing regulations at § 484.55(a) and (b)(2) would continue to apply that OTs and other therapists 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 to include OTs provides HHAs with additional flexibility that may decrease patient wait times for the initiation of home health services.
- **Certification for Payment of Medicare Home Health Services:** As required under section 3708 of the CARES Act, CMS is allowing nurse practitioners, clinical nurse specialists and physician assistants to certify the need for home health services as defined under 42 CFR § 424.507(b)(1) payment requirements for covered Part A or Part B home health services.

Patients Over Paperwork

- **“Stark Law” Waivers:** The physician self-referral law (also known as the “Stark Law”) prohibits a physician from making referrals for certain healthcare services payable by Medicare if the physician (or an immediate family member) has a financial relationship with the entity performing the service. There are statutory and regulatory exceptions, but in short, a physician cannot refer a patient to any entity with which he or she has a financial relationship. On March 30, 2020, CMS issued blanket waivers of certain provisions of the Stark Law regulations. These blanket waivers apply to financial relationships and referrals that are related to the COVID-19 emergency. The remuneration and referrals described in the blanket waivers must be solely related to COVID-19 Purposes, as defined in the blanket waiver document. Under the waivers, CMS will permit certain referrals and the submission of related claims that would otherwise violate the Stark Law. These flexibilities include:
 - Hospitals and other health care providers can pay above or below fair market value for the personal services of a physician (or an immediate family member of a physician), and parties may pay below fair market value to rent equipment or purchase items or services. For example, a physician practice may be willing to rent or sell needed equipment to a hospital at a price that is below what the practice could charge another party. Or, a hospital may provide space on hospital grounds

at no charge to a physician who is willing to treat patients who seek care at the hospital but are not appropriate for emergency department or inpatient care.

- Health care providers can support each other financially to ensure continuity of health care operations. For example, a physician owner of a hospital may make a personal loan to the hospital without charging interest at a fair market rate so that the hospital can make payroll or pay its vendors.
- Hospitals can provide benefits to their medical staffs, such as multiple daily meals, laundry service to launder soiled personal clothing, or child care services while the physicians are at the hospital and engaging in activities that benefit the hospital and its patients.
- Health care providers may offer certain items and services that are solely related to COVID-19 Purposes (as defined in the waivers), even when the provision of the items or services would exceed the annual non-monetary compensation cap. For example, a home health agency may provide continuing medical education to physicians in the community on the latest care protocols for homebound patients with COVID-19, or a hospital may provide isolation shelter or meals to the family of a physician who was exposed to the novel coronavirus while working in the hospital's emergency department.
- Physician-owned hospitals can temporarily increase the number of their licensed beds, operating rooms, and procedure rooms, even though such expansion would otherwise be prohibited under the Stark Law. For example, a physician-owned hospital may temporarily convert observation beds to inpatient beds to accommodate patient surge during the COVID-19 pandemic in the United States. Some of the restrictions regarding when a group practice can furnish medically necessary designated health services (DHS) in a patient's home are loosened. For example, any physician in the group may order medically necessary DHS that is furnished to a patient by one of the group's technicians or nurses in the patient's home contemporaneously with a physician service that is furnished via telehealth by the physician who ordered the DHS. Group practices can furnish medically necessary MRIs, CT scans or clinical laboratory services from locations like mobile vans in parking lots that the group practice rents on a part-time basis.

Additional Guidance

- The Interim Final Rule and waivers can be found at: <https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers>.

- CMS has released guidance to describe standards of practice for infection control and prevention of COVID-19 in home health agencies at <https://www.cms.gov/files/document/qso-20-18-hha.pdf>.
- 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>.