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

Since the beginning of the COVID-19 Public Health Emergency, the Centers for Medicare & Medicaid Services 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) ensure all Americans have access to a COVID-19 vaccine;
2) 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;
3) ensure that local hospitals and health systems have the capacity to handle a potential surge of COVID-19 patients through temporary expansion sites;
4) increase access to telehealth in Medicare to ensure patients have access to physicians and other clinicians while keeping patients safe at home;
5) expand in-place testing to allow for more testing at home or in community based settings; and
6) 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

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**

- Telehealth may be used to fulfill the requirement for physicians to conduct the required face-to-face visits at least 3 days a week for the duration of a Medicare Part A fee-for-service patient’s stay in an inpatient rehabilitation facility.

**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.

- **Intensity of Therapy Requirement (“3-Hour Rule”):** The Coronavirus Aid, Relief, and Economic Security (CARES) Act requires the Secretary to waive § 412.622(a)(3)(ii) (commonly referred to as the “3-hour rule”), the criterion that patients treated in inpatient rehabilitation facilities generally receive at least 15 hours of therapy per week. The waiver of this requirement for all beneficiaries treated in a hospital-based or freestanding IRF provides flexibility for IRFs to provide care for patients during the PHE for the COVID-19 pandemic. IRFs should strive to provide typical IRF levels of care for beneficiaries admitted during the COVID-19 crisis who require and can benefit from the IRF levels of care.

- **Standards to Rehabilitate Patients:** Medicare payment regulations require IRFs to meet certain standards to rehabilitate patients, including ensuring that admitted patients are stable enough for rehabilitation therapy, need at least two types of therapy, and develop plans of care. During the PHE, these standards do not have to apply to patients who are admitted to freestanding IRFs solely for surge capacity reasons in a state that is currently in Phase 1 or has not yet entered Phase 1 of the White House’s Guidelines for Opening Up America Again, but would continue to apply to patients who are admitted for the IRFs’ standard rehabilitative services. We anticipate that freestanding IRFs will take advantage of these flexibilities for some of their beneficiaries (those who are surge patients from inpatient hospitals), while continuing to provide standard IRF-level care for those
beneficiaries who would benefit from IRF-level care and would otherwise receive such care in the absence of the PHE.

- **IRF Teaching Status Adjustment Payments:** To ensure that teaching IRFs can alleviate bed capacity issues by taking patients from the inpatient acute care hospitals without being penalized by lower teaching status adjustments, we are freezing the IRFs’ teaching status adjustment payments at their values prior to the PHE. For the duration of the COVID-19 PHE, an IRF’s teaching status adjustment payments will be the same as they were on the day before the COVID-19 PHE was declared.

- **IRF Quality Reporting Program:** We are delaying the compliance dates for collecting and reporting of the Transfer of Health Information quality measures and certain standardized patient assessment data elements (SPADEs) adopted for the IRF Quality Reporting Program. IRFs will be required to begin collecting the Transfer of Health Information quality measures and certain SPADEs on October 1st of the year that is at least one fiscal year after the end of the public health emergency.

- **Post Admission Evaluations:** Physicians are no longer required to conduct and document post-admission evaluations for Medicare patients admitted to an IRF during the PHE. The post-admission evaluation covers much of the same information as continues to be included in the pre-admission screening of the patient and the patient’s plan of care. This reduction in burden gives more time for physicians to take care of patients.

- **Flexibility for Inpatient Rehabilitation Facilities Regarding the “60 Percent Rule”:** CMS is waiving requirements to allow IRFs to exclude patients from the IRF freestanding hospital’s or unit’s inpatient population for purposes of calculating the applicable thresholds associated with the requirements to receive payment as an IRF (commonly referred to as the “60 percent rule”) if an IRF admits a patient solely to respond to the emergency and the patient’s medical record properly identifies the patient as such. In addition, during the applicable waiver time period, we would also apply the exception to facilities not yet classified as IRFs, but that are attempting to obtain classification as an IRF.

- Freestanding IRFs are able to work with acute care hospitals under arrangements to provide surge capacity for the community.

- **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.

### 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.

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.

- 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).

Additional Information
