

Hospitals: CMS Flexibilities to Fight COVID-19

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

The Trump Administration is issuing 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. Made possible by President Trump's recent emergency declaration and emergency rule making, 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.

Telehealth

- *Hospital Outpatient Services Accompanying Professional Services Furnished Via Telehealth:* When a physician or nonphysician practitioner who typically furnishes professional services in the hospital outpatient department furnishes telehealth services during the COVID-19 PHE, they bill with a hospital outpatient place of service since that is likely where the services would have been furnished if not for the COVID-19 PHE. The physician or practitioner is paid for the service under the PFS at the facility rate, which does not include payment for resources such as clinical staff, supplies, or office overhead since those things are usually supplied by the hospital outpatient department. During the COVID-19 PHE, if the beneficiary's home or temporary expansion site is considered to be a provider-based department of the hospital, and the beneficiary is registered as an outpatient of the hospital for purposes of receiving telehealth services billed by the physician or practitioner, the hospital may bill under the PFS for the originating site facility fee associated with the telehealth service.

CMS Hospitals Without Walls (Temporary Expansion Sites)

- *Hospitals Able to Provide Care in Temporary Expansion Sites:* As part of the CMS Hospital Without Walls initiative, hospitals can provide hospital services in other healthcare facilities and sites that would not otherwise be considered to be part of a healthcare facility; or can set up temporary expansion sites to help address the urgent need to increase capacity to care for patients. In the absence of waivers, hospitals are required to provide services to patients within their hospital departments. Hospitals have shared concerns about capacity for treating patients during the COVID-19 PHE, especially those requiring ventilator and intensive care services. CMS is providing additional flexibilities for hospitals to create surge capacity by allowing them to provide room and board, nursing, and other hospital services at remote locations or sites not normally considered parts of healthcare facilities, such as hotels or community facilities. This flexibility will allow hospitals to separate COVID-19 positive patients from other non-COVID-19 patients to help efforts around infection control and preservation of personal protective equipment (PPE). For example, for the duration of the COVID-19 PHE, CMS is allowing hospitals to screen patients at offsite locations, and furnish inpatient and outpatient services at temporary expansion sites. Hospitals would still be expected to control and oversee the services provided at an alternative location. CMS also is offering some additional flexibilities to furnish inpatient services under arrangements during the PHE.
- Under the Hospitals without Walls initiative, CMS relaxed certain conditions of participation (CoPs) and provider-based rules for hospital operations to maximize hospitals ability to focus on patient care. The same initiative also allows currently enrolled ambulatory surgical centers (ASCs), to temporarily enroll as hospitals and to provide hospital services to help address the urgent need to increase hospital capacity to take care of patients. Other interested entities, such as independent licensed emergency departments, could pursue enrolling as a hospital during the PHE. ASCs that wish to enroll to receive temporary billing privileges as a hospital should call the COVID-19 Provider Enrollment Hotline to reach the contractor that serves their jurisdiction, and then will complete and sign an attestation form specific to the COVID-19 PHE. See <https://www.cms.gov/files/document/provider-enrollment-relief-faqs-covid-19.pdf> for additional information.
- *Off Site Patient Screening:* CMS is partially waiving the enforcement of section 1867(a) of the Social Security Act (the Emergency Medical Treatment and Active Labor Act, or EMTALA). This will allow hospitals, psychiatric hospitals, and critical access hospitals (CAHs) to screen patients at a location offsite from the hospital's campus to prevent the spread of COVID-19, so long as it is not inconsistent with the state emergency preparedness or pandemic plan.
- *Paperwork Requirements:* CMS is waiving certain specific paperwork requirements under this section only for hospitals which are considered to be impacted by a widespread

outbreak of COVID-19. This allows hospitals to establish COVID-19 specific areas. Hospitals that are located in a state that has widespread confirmed cases would not be required to meet the following requirements:

- 42 CFR §482.13(d)(2) with respect to timeframes in providing a copy of a medical record.
 - 42 CFR §482.13(h) related to patient visitation, including the requirement to have written policies and procedures on visitation of patients who are in COVID-19 isolation and quarantine processes.
 - 42 CFR §482.13(e)(1)(ii) regarding seclusion.
- *Physical Environment:* CMS is waiving certain physical environment requirements under the Medicare conditions of participation at 42 CFR §482.41 and 42 CFR §485.623 to allow for increased flexibilities for surge capacity and patient quarantine at hospitals, psychiatric hospitals, and critical access hospitals (CAH) as a result of COVID-19. CMS will permit facility and non-facility space that is not normally used for patient care to be utilized for patient care or quarantine, provided the location is approved by the state (ensuring that safety and comfort for patients and staff are sufficiently addressed) and is consistent with the state's emergency preparedness or pandemic plan. This allows for increased capacity and promotes appropriate cohorting of COVID-19 patients. States are still subject to obligations under the integration mandate of the Americans with Disabilities Act, to avoid subjecting persons with disabilities to unjustified institutionalization or segregation¹.
 - *Specific Life Safety Code (LSC) for Hospitals and CAHs:* CMS is waiving and modifying particular waivers under 42 CFR §482.41(b) for hospitals and §485.623(c) for CAHs. Specifically, CMS is modifying these requirements as follows:
 - Alcohol-based Hand-Rub (ABHR) Dispensers: We are waiving the prescriptive requirements for the placement of alcohol based hand rub (ABHR) dispensers for use by staff and others due to the need for the increased use of ABHR in infection control. However, ABHRs contain ethyl alcohol, which is considered a flammable liquid, and there are restrictions on the storage and location of the containers. This includes restricting access by certain patient/resident population to prevent accidental ingestion. Due to the increased fire risk for bulk containers (over five gallons) those will still need to be stored in a protected hazardous materials area.

¹Please note that consistent with the integration mandate of Title II of the ADA and the *Olmstead vs LC* decision, States are obligated to offer/ provide discharge planning and/or case management/ transition services, as appropriate, to individuals who are removed from their Medicaid home and community based services under these authorities during the course of the public health emergency as well as to individuals with disabilities who may require these services in order to avoid unjustified institutionalization or segregation. Transition services/ case management and/or discharge planning would be provided to facilitate these individuals in their return to the community when their condition and public health circumstances permit.

Refer to: 2012 LSC, sections 18/19.3.2.6. In addition, facilities should continue to protect ABHR dispensers against inappropriate use as required by 42 CFR §482.41(b)(7) for hospitals and §485.623(c)(5) for CAHs.

- Fire Drills: Due to the inadvisability of quarterly fire drills that move and mass staff together, we will instead permit a documented orientation training program related to the current fire plan, which considers current facility conditions. The training will instruct employees, including existing, new or temporary employees, on their current duties, life safety procedures and the fire protection devices in their assigned area. Refer to: 2012 LSC, sections 18/19.7.1.6.
- Temporary Construction: CMS is waiving requirements that would otherwise not permit temporary walls and barriers between patients. Refer to: 2012 LSC, sections 18/19.3.3.2.
- *Hospital Outpatient: Use of Provider-Based Departments as Temporary Expansion Sites:* For the duration of the PHE related to COVID-19, CMS is waiving certain requirements under the Medicare conditions of participation at 42 CFR §482.41 and §485.623 (as noted above) and the provider-based department requirements at 42 CFR §413.65 to allow hospitals to expand capacity by create new or relocating existing provider-based departments. These waivers will enable hospitals to meet the needs of Medicare beneficiaries in alignment with the State or local pandemic plan.

Note regarding Payment for Certain Provider-Based Departments (PBDs) During the PHE: Hospital waivers do not impact the payment rates for covered hospital outpatient items and services, including whether the PBD is paid under the Physician Fee Schedule (PFS)-equivalent rate or under the Outpatient Prospective Payment System (OPPS) under Section 603 of the Bipartisan Budget Act of 2015.

Under section 603 rules, most new off-campus PBDs are typically paid at the Medicare PFS-equivalent rate instead of the rate determined under the OPPS. CMS has determined through rulemaking that the PFS-equivalent rate to be 40% of the OPPS rate. Most PBDs that relocate are also subject to the lower rate, unless they are eligible to seek and are approved for an extraordinary circumstances relocation exception.

CMS has made several changes to support hospitals so they can more effectively respond to the COVID-19 PHE. These changes include:

- Adopting a temporary extraordinary circumstances relocation exception policy for on-campus PBDs and excepted off-campus PBDs that are relocating off-campus during the

COVID-19 PHE. Under our existing extraordinary relocation exception policy, only relocating off-campus PBDs are eligible to request this exception.

- Streamlining the process during the COVID-19 PHE for relocating PBDs to seek the extraordinary circumstances exception so they can start seeing patients and billing for services immediately in the relocated PBD.
- Allowing PBDs to relocate into more than one PBD location, and allowing PBDs to partially relocate while still maintaining the original location. Hospitals can relocate PBDs to the patient’s home and continue to receive the full OPPS payment amount under the extraordinary circumstances relocation exception policy.

Provider Based Department (PBD) Type	Non PHE Payment Policy Before Relocation	Non PHE Payment Policy if PBD Relocates Off Campus (Absent Extraordinary Circumstance Approval)	Payment Policy During PHE Following Off Campus Relocation
On-Campus PBD	Full OPPS	PFS-equivalent (treated as new location)	Full OPPS*
Excepted* Off-Campus PBD	Full OPPS	PFS-equivalent (treated as new location)	Full OPPS*
Non-Excepted Off-Campus PBD	PFS-equivalent	PFS-equivalent	PFS-equivalent
New (since pandemic) Off-Campus PBD	PFS-equivalent	PFS-equivalent	PFS-equivalent

*PBD department relocations would need to receive extraordinary circumstances relocation approval and the relocation must not be inconsistent with state emergency preparedness or pandemic plan. Once the COVID-19 PHE ends, these relocated PBD would be expected to shut down or return to their original location; otherwise, they would be paid the PFS-equivalent rate unless, at the discretion of the CMS Regional Office, they are granted a permanent extraordinary circumstances relocation exception under our normal policy. We note that, during the COVID-19 PHE, hospitals would have flexibility to do partial relocations, and relocate their PBD to multiple new off-campus locations, including the patient’s home.

- **Hospital-Only Remote Outpatient Therapy and Education Services:** Consistent with the CMS Hospitals without Walls Initiative, we have announced that hospitals may provide behavioral health and education services furnished by hospital-employed counselors or other professionals that cannot bill Medicare directly for their professional services. This includes partial hospitalization services. These services may be furnished to a beneficiary in

their home when the beneficiary is registered as an outpatient of the hospital and the hospital considers the beneficiary's home to be a provider-based department of the hospital.

- During the PHE, a subset of therapy and educational services are eligible to be provided remotely by the hospital clinical staff so long as they are furnished to a patient in the hospital, which may include the patient's home if that home is made provider-based to the hospital during the PHE. A list of example billing codes for those services can be found on the cms.gov website.
- Counselors and other employed hospital staff may furnish these services to the beneficiary, either through telecommunications technology or in person, in a temporary expansion location, which may include the beneficiary's home so long as it has been made provider-based to the hospital.
- For Partial Hospitalization Program services, hospitals can furnish and bill for certain partial hospitalization services – that is, individual psychotherapy, patient education, and group psychotherapy -- that are delivered in temporary expansion locations, including patients' homes, so long as such locations have been made provider-based to the hospital, to ensure access to necessary services and maintain continuity of care and for purposes of infection control. When the patient is registered as an outpatient, PHP services furnished by hospital staff in that location are considered to be furnished in the hospital.
- The hospital may bill for these services as hospital outpatient services, as long as they are medically necessary and meet all requirements described by the HCPCS code, and as long as the service is furnished in a hospital outpatient department of the hospital.

Expanded Ability for Hospitals to Offer Long-term Care Services ("Swing-Beds") for Patients Who do not Require Acute Care but do Meet the Skilled Nursing Facility (SNF) Level of Care Criteria as Set Forth at 42 CFR 409.31. Under section 1135(b)(1) of the Act, CMS is waiving the requirements at 42 CFR 482.58, "Special Requirements for hospital providers of long-term care services ("swing-beds")" subsections (a)(1)-(4) "Eligibility", to allow hospitals to establish SNF swing beds payable under the SNF prospective payment system (PPS) to provide additional options for hospitals with patients who no longer require acute care but are unable to find placement in a SNF.

- In order to qualify for this waiver, hospitals must:
 - Not use SNF swing beds for acute level care.
 - Comply with all other hospital conditions of participation and those SNF provisions set

out at 42 CFR 482.58(b) to the extent not waived.

- Be consistent with the state's emergency preparedness or pandemic plan.

Hospitals must call the CMS Medicare Administrative Contractor (MAC) enrollment hotline to add swing bed services. The hospital must attest to CMS that:

- They have made a good faith effort to exhaust all other options;
- There are no skilled nursing facilities within the hospital's catchment area that under normal circumstances would have accepted SNF transfers, but are currently not willing to accept or able to take patients because of the COVID-19 public health emergency (PHE);
- The hospital meets all waiver eligibility requirements; and
- They have a plan to discharge patients as soon as practicable, when a SNF bed becomes available, or when the PHE ends, whichever is earlier.

This waiver applies to all Medicare enrolled hospitals, except psychiatric and long term care hospitals that need to provide post-hospital SNF level swing-bed services for non-acute care patients in hospitals, so long as the waiver is not inconsistent with the state's emergency preparedness or pandemic plan. The hospital shall not bill for SNF PPS payment using swing beds when patients require acute level care or continued acute care at any time while this waiver is in effect. This waiver is permissible for swing bed admissions during the COVID-19 PHE with an understanding that the hospital must have a plan to discharge swing bed patients as soon as practicable, when a SNF bed becomes available, or when the PHE ends, whichever is earlier.

- *Critical Access Hospital Bed Count and Length of Stay:* CMS is waiving the Medicare requirements that Critical Access Hospitals (CAHs) limit the number of beds to 25, and that the length of stay be limited to 96 hours under the Medicare conditions of participation regarding number of beds and length of stay at 42 CFR §485.620.
- *CAH Status and location:* CMS is waiving the requirement at 485.610(b) that the CAH be located in a rural area or an area being treated as rural, allowing the CAHs flexibility in the establishment of surge site locations. Waiving the requirement at 485.610(e) regarding off-campus and co-location requirements allows the CAH flexibility in establishing off-site locations. In an effort to facilitate the establishment of CAHs without walls, these waivers will remove restrictions on CAHs regarding their rural location and their location relative to other hospitals and CAHs. These flexibilities should be implemented so long as it is not inconsistent with State or emergency or pandemic plan.
- *Hospitals Classified as Sole Community Hospitals (SCHs):* CMS is waiving certain eligibility requirements at 42 CFR § 412.92(a) for hospitals classified as SCHs prior to the PHE.

Specifically, CMS is waiving the distance requirements at paragraphs (a), (a)(1), (a)(2), and (a)(3) of 42 CFR § 412.92, and is also waiving the “market share” and bed requirements (as applicable) at 42 CFR § 412.92(a)(1)(i) and (ii). CMS is waiving these requirements for the duration of the PHE to allow these hospitals to meet the needs of the communities they serve during the PHE, such as to provide for increased capacity and promote appropriate cohorting of COVID-19 patients. MACs will resume their standard practice for evaluation of all eligibility requirements after the conclusion of the PHE period.

- *Hospitals Classified as Medicare-Dependent, Small Rural Hospitals (MDHs):* For hospitals classified as MDHs prior to the PHE, CMS is waiving the eligibility requirement at 42 CFR § 412.108(a)(1)(ii) that the hospital has 100 or fewer beds during the cost reporting period, and the eligibility requirement at 42 CFR § 412.108(a)(1)(iv)(C) that at least 60 percent of the hospital's inpatient days or discharges were attributable to individuals entitled to Medicare Part A benefits during the specified hospital cost reporting periods. CMS is waiving these requirements for the duration of the PHE to allow these hospitals to meet the needs of the communities they serve during the PHE, such as to provide for increased capacity and promote appropriate cohorting of COVID-19 patients. MACs will resume their standard practice for evaluation of all eligibility requirements after the conclusion of the PHE period.
- *Housing Acute Care Patients in Excluded Distinct Part Units:* CMS is waiving requirements to allow acute care hospitals to house acute care inpatients in excluded distinct part units, where the distinct part unit's beds are appropriate for acute care inpatients. The Inpatient Prospective Payment System (IPPS) hospital should bill for the care and annotate the patient's medical record to indicate the patient is an acute care inpatient being housed in the excluded unit because of capacity issues related to the disaster or emergency.
- *Care for Excluded Inpatient Psychiatric Unit Patients in the Acute Care Unit of a Hospital:* CMS is waiving requirements to allow acute care hospitals with excluded distinct part inpatient psychiatric units that, as a result of a disaster or emergency, need to relocate inpatients from the excluded distinct part psychiatric unit to an acute care bed and unit. The hospital should continue to bill for inpatient psychiatric services under the Inpatient Psychiatric Facility Prospective Payment System (IPF PPS) for such patients and annotate the medical record to indicate the patient is a psychiatric inpatient being cared for in an acute care bed because of capacity or other exigent circumstances related to the COVID-19 Public Health emergency. This waiver may be utilized where the hospital's acute care beds are appropriate for psychiatric patients and the staff and environment are conducive to safe care. For psychiatric patients, this includes assessment of the acute care bed and unit location to ensure those patients at risk of harm to self and others are safely cared for.
- *Care for Excluded Inpatient Rehabilitation Unit Patients in the Acute Care Unit of a Hospital:* CMS is waiving requirements to allow acute care hospitals with excluded distinct

part inpatient Rehabilitation units that, as a result of a disaster or emergency, need to relocate inpatients from the excluded distinct part rehabilitation unit to an acute care bed and unit. The hospital should continue to bill for inpatient rehabilitation services under the Inpatient Rehabilitation Facility Prospective Payment System for such patients and annotate the medical record to indicate the patient is a rehabilitation inpatient being cared for in an acute care bed because of capacity or other exigent circumstances related to the disaster or emergency. This waiver may be utilized where the hospital's acute care beds are appropriate for providing care to rehabilitation patients and such patients continue to receive intensive rehabilitation services.

- *Flexibility for Inpatient Rehabilitation Facilities Regarding the “60 Percent Rule.”* CMS is allowing IRFs to exclude patients from the freestanding hospital's or excluded distinct part 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.
- *Telemedicine:* CMS is waiving the provisions related to telemedicine for hospitals and CAHs at 42 CFR 482.12(a)(8)-(9) and 42 CFR 485.616(c), making it easier for telemedicine services to be furnished to the hospital's patients through an agreement with an off-site hospital. This allows for increased access to necessary care for hospital and CAH patients, including access to specialty care.
- *Hospital Only Clinical Staff In-Person Services:* Hospital clinical staff must furnish certain services such as infusions and wound care in person given the nature of the services. There is no professional claim for these services.
 - The beneficiary's home would be considered a provider-based department of the hospital for purposes of receiving outpatient services and the beneficiary would be registered as a hospital outpatient.
 - These services require a health professional to furnish the service (e.g., drug administration).
 - The hospital could bill for these services as hospital outpatient services, provided the PBD is an on campus or excepted off-campus PBD that relocated to the patient's home consistent with the extraordinary circumstances relocation exception policy.

Payment for Innovative COVID-19 Therapies

- *Enhanced Medicare Payments for New COVID-19 Treatments: Hospital Inpatient Stays:* In order to mitigate potential financial disincentives for hospitals to provide new COVID-19 treatments hospital during the COVID-19 PHE, the Medicare program will provide an enhanced payment for eligible inpatient cases that involve use of certain new products authorized or approved to treat COVID-19. The enhanced payment will be equal to the lesser of: (1) 65 percent of the operating outlier threshold for the claim; or (2) 65 percent of the cost of a COVID-19 stay beyond the operating Medicare payment (including the 20 percent add-on payment under section 3710 of the CARES Act) for eligible cases.
- *Enhanced Medicare Payments for New COVID-19 Treatments: Hospital Outpatient Departments:* CMS wants to mitigate potential financial disincentives for hospitals to provide new COVID-19 treatments provided in a hospital outpatient setting during the COVID-19 PHE. Therefore, in this IFC, CMS has excluded FDA-authorized or approved drugs and biologicals (including blood products) authorized or approved to treat or prevent COVID-19 from being packaged into the Comprehensive Ambulatory Payment Classification (C-APC) payment when these treatments are billed on the same claim as a primary C-APC service. Instead, Medicare will pay for these drugs and biologicals separately throughout the course of the PHE.

COVID-19 Diagnostic Testing

- ***Price Transparency for COVID-19 Testing:* In an Interim Final Rule with Comment Period (IFC) issued October, 28, 2020, CMS implemented the CARES Act requirement that providers of a diagnostic test for COVID-19 to make public the cash price for such tests on their websites. Providers without websites will be required to provide price information in writing within two business days upon request and on a sign posted prominently at the location where the provider performs the COVID-19 diagnostic test, if such location is accessible to the public. Noncompliance may result in civil monetary penalties up to \$300 per day.
- Hospital outpatient departments can be paid for symptom assessment and specimen collection for COVID-19 using a new HCPCS code C9803 (Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), any specimen source) retroactive to March 1, 2020. The service would be conditionally packaged and not paid separately when furnished with another payable service under the OPPTS. This approach helps hospitals to operate testing sites during the PHE. Medicare will pay a national rate of roughly \$23 for HCPCS code 9803 when it is not billed with a separately payable hospital outpatient service.
- *Antibody (serology) tests:* FDA authorized COVID-19 serology testing is a Medicare covered diagnostic test for patients with known current or known prior COVID-19 infection or suspected current or suspected past COVID-19 infection. The outcome of the serology test may change the health care decisions made by a patient and their practitioner.

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.
- *Verbal Orders*: CMS is waiving the requirements of 42 CFR §482.23, §482.24 and §485.635(d)(3) to allow for additional flexibilities related to verbal orders where read-back verification is still required but authentication may occur later than 48 hours. This will allow for more efficient treatment of patients in a surge situation.
- *Reporting Requirements*: CMS is waiving reporting requirements at §482.13(g) (1)(i)-(ii) which require hospitals to report patients in an intensive care unit whose death is caused by their disease process but who required soft wrist restraints to prevent pulling tubes/IVs, may be reported later than close of business next business day, provided any death where the restraint may have contributed is continued to be reported within standard time limits. Due to current hospital surge, we are waiving this requirement to ensure that hospitals are focusing on increased care demands and patient care.
- *Limit Discharge Planning for Hospital and CAHs*: To allow hospitals and CAHs more time to focus on increasing care demands, discharge planning will focus on ensuring that patients are discharged to an appropriate setting with the necessary medical information and goals of care. CMS is waiving detailed regulatory requirements to provide information regarding discharge planning, as outlined in 42 CFR §482.43(a)(8), §482.61(e), and 485.642(a)(8). In the absence of a waiver, the hospital, psychiatric hospital, and CAH must assist patients, their families, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, home health agency (HHA), skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), and long term care hospital (LTCH) data on quality measures and data on resource use measures. These hospital types must ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and

treatment preferences. During this public health emergency, a hospital may not be able to assist patients in using quality measures and data to select a nursing home or home health agency, but must still work with families to ensure that the patient discharge is to a post-acute care provider that is able to meet the patient's care needs.

- *Modify Discharge Planning for Hospitals:* Patients must continue to be discharged to an appropriate setting with the necessary medical information and goals of care. To address the COVID-19 pandemic, CMS is waiving certain more detailed requirements related to hospital discharge planning for post-acute care services at 42 CFR §482.43(c), so as to expedite the safe discharge and movement of patients among care settings, and to be responsive to fluid situations in various areas of the country. CMS is waiving certain requirements for those patients discharged home and referred for HHA services, or for those patients transferred to a SNF for post-hospital extended care services, or transferred to an IRF or LTCH for specialized hospital services. For example, a patient may not be able to receive a comprehensive list of nursing homes in the geographic area, but must still be discharged to a nursing home that is available to provide the care that is needed by the patient.
- *Medical Records:* CMS is waiving 42 CFR §482.24(a) through (c), which cover the subjects of the organization and staffing of the medical records department, requirements for the form and content of the medical record, and record retention requirements. CMS is waiving requirements under 42 CFR §482.24(c)(4)(viii) related to medical records to allow flexibility in completion of medical records within 30 days following discharge and for CAHs that all medical records must be promptly completed. This flexibility will allow clinicians to focus on the patient care at the bedside during the pandemic.
- *Flexibility in Patient Self Determination Act Requirements (Advance Directives):* CMS is waiving the requirements at section 1902(a)(58) and 1902(w)(1)(A) for Medicaid, 1852(i) (for Medicare Advantage), and 1866(f) and 42 CFR 489.102 for Medicare, which require hospitals and CAHs to provide information about its advance directive policies to patients. We are waiving this requirement to allow for staff to more efficiently deliver care to a larger number of patients.
- *Extension for Inpatient Prospective Payment System (IPPS) Wage Index Occupational Mix Survey Submission:* CMS collects data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. CMS granted an extension for data submission for hospitals nationwide affected by COVID-19 until August 3, 2020. Due to continued COVID related concerns from hospitals about meeting this deadline, CMS is further extending this deadline to September 3, 2020. Hospitals must submit their occupational mix surveys along with complete supporting documentation to their MACs by no later than September 3, 2020. Hospitals may then

submit revisions to their occupational mix surveys to their MACs, if needed, by no later than September 10, 2020.

- *Postponement of Application Deadline to the Medicare Geographic Classification Review Board.* Per requirements at section 1886(d)(10)(C)(ii) of the Social Security Act (the Act) and 42 CFR 412.256(a)(2), September 1, 2020 is the deadline to submit an application to the Medicare Geographic Classification Review Board (MGCRB) for FY 2022 reclassifications. These provisions require applications to be filed through OH CDMS (<https://www.cms.gov/Regulations-and-Guidance/Review-Boards/MGCRB/Electronic-Filing>) not later than the first day of the 13-month period preceding the Federal fiscal year for which reclassification is requested.

Due to the COVID-19 Public Health Emergency (PHE), under the authority of section 1135(b)(5) of the Act, CMS is postponing the September 1 deadline until 15 days after the public display date of the FY 2021 IPPS/LTCH final rule by the Office of the Federal Register.

- *Utilization review:* CMS is waiving the requirements at 42 CFR §482.1(a)(3) and 42 C.F.R §482.30, that require that hospitals participating in Medicare and Medicaid to have a utilization review plan that meets specified requirements. CMS is waiving the entire Utilization Review CoP at §482.30, which requires that a hospital must have a utilization review (UR) plan with a UR committee that provides for review of services furnished to Medicare and Medicaid beneficiaries to evaluate the medical necessity of the admission, duration of stay, and services provided. These flexibilities should be implemented so long as they are not inconsistent with a State or pandemic/emergency plan. Removing these administrative requirements will allow hospitals to focus more resources on providing direct patient care.
- *Quality assessment and performance improvement program.* CMS is waiving 482.21(a)-(d) and (f), and 485.641(a), (b), and (d), which provide details on the scope of the program, the incorporation, and setting priorities for the program's performance improvement activities, and integrated QAPI programs (for hospitals that are a part of a hospital system). These flexibilities, which apply to both hospitals and CAHs, should be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan. We expect any improvements to the plan to focus on the Public Health Emergency. While this waiver decreases burden associated with the development of a hospital or CAH QAPI program, the requirement that hospitals and CAHs maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program will remain.
- *Nursing services:* CMS is waiving the provision at 42 CFR 482.23(b)(4), 42 CFR 482.23(b)(7), and 485.635(d)(4), which requires the nursing staff to develop and keep current a nursing care plan for each patient, and the provision that requires the hospital to have policies and

procedures in place establishing which outpatient departments are not required to have a registered nurse present. These waivers allow nurses increased time to meeting the clinical care needs of each patient and allows for the provision of nursing care to an increased number of patients. In addition, we expect that hospitals will need relief for the provision of inpatient services and as a result, the requirement to establish nursing-related policies and procedures for outpatient departments is likely unnecessary. These flexibilities apply to both hospitals and CAHs, and should be implemented so long as they are not inconsistent with a State or pandemic/emergency plan.

- *Food and dietetic service:* CMS is waiving the requirement at 42 CFR 482.28(b)(3) to have a current therapeutic diet manual approved by the dietitian and medical staff readily available to all medical, nursing, and food service personnel. Such manuals would not need to be maintained at surge capacity sites. These flexibilities should be implemented so long as they are not inconsistent with a State or pandemic/emergency plan. Removing these administrative requirements will allow hospitals to focus more resources on providing direct patient care.
- *Written policies and procedures for appraisal of emergencies at off campus hospital departments:* CMS is waiving 482.12(f)(3) related to Emergency services, with respect to the surge facility(ies) only, such that written policies and procedures for staff to use when evaluating emergencies are not required for surge facilities. This removes the burden on facilities to develop and establish additional policies and procedures at their surge facilities or surge sites related to the assessment, initial treatment and referral of patients. These flexibilities should be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.
- *Emergency preparedness policies and procedures:* CMS is waiving 482.15(b) and 485.625(b), which requires the hospital and CAH to develop and implement emergency preparedness policies and procedures, and 482.15(c)(1)-(5) and 485.625(c)(1)-(5) which requires that the emergency preparedness communication plans for hospitals and CAHs to contain specified elements with respect to the surge site. The requirement under the communication plan requires hospitals and CAHs to have specific contact information for staff, entities providing services under arrangement, patients' physicians, other hospitals and CAHs, and volunteers. This would not be an expectation for the temporary expansion site. This waiver removes the burden on facilities to establish these policies and procedures for their surge facilities or surge sites.
- *Signature Requirements:* CMS is not enforcing signature and proof of delivery requirements for Part B drugs and Durable Medical Equipment when a signature cannot be obtained because of the inability to collect signatures. Suppliers should document in the medical record the appropriate date of delivery and that a signature was not able to be obtained because of COVID-19.

- *Hospital Value-Based Purchasing (VBP) Program's Extraordinary Circumstances Exceptions (ECE) policy:* CMS has the ability to grant exceptions to hospitals located in entire regions or locales, which could include the entire United States, without an ECE request form where we determine that the extraordinary circumstance has affected the entire region or locale. CMS is granting an exception for certain HVBP reporting requirements in light of the COVID PHE as specified in the March 27, 2020 guidance memo: <https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf>.
- *Admission, discharge, and transfer (ADT) notification Conditions of Participation (CoPs):* The policies in the [CMS Interoperability and Patient Access final rule](#) have varied implementation dates. CMS is extending the implementation timeline for the ADT notification Conditions of Participation (CoPs) by an additional six months. In light of COVID-19, with this change, the new CoPs at 42 CFR Parts 482 and 485 will now be effective 12 months after the final rule is published in the Federal Register.
- *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).
- *Extension of Comprehensive Care for Joint Replacement (CJR) Model Year 5:* In the IFC issued October 28, 2020, CMS extended Performance Year (PY) 5 of the Comprehensive Care for Joint Replacement (CJR) model an additional 6 months, so PY 5 now ends September 30, 2021. To accommodate the extension of PY 5, CMS will perform a 12-month reconciliation period and a 9-month reconciliation period in PY 5. Further the adjustment to the extreme and uncontrollable circumstances policy for COVID-19, previously established in Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency IFC, will

now expire on March 31, 2021 or the end of the PHE, whichever occurs first. After that, the extreme and uncontrollable circumstances policy for COVID-19 will be episode-based, where, beginning after the PHE or on April 1, 2020 (whichever occurs first) and through the end of the PHE, actual episode payments are capped at the quality adjusted target price for an episode with actual episode payments that include a claim with a COVID-19 diagnosis code. Lastly, to ensure that the model continues to include the same inpatient Lower Extremity Joint Replacement (LEJR) procedures, despite the adoption of new MS-DRGs 521 and 522 to describe those procedures, CMS made a technical change, retroactive to October 1, 2020, to include these new DRGs in the model. Questions about the CJR model can be submitted via email at CJRSupport@cms.hhs.gov.

- **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.

- **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.

- **Comprehensive Care for Joint Replacement (CJR) Model:** Due to the COVID-19 public health emergency, the appeals timeline for the Comprehensive Care for Joint Replacement (CJR) model Performance Year (PY) 3 final and PY 4 initial reconciliation reports is modified for participant hospitals. Specifically, CMS is modifying participant hospital deadlines set forth at 42 CFR §510.310(a)(1)-(2), for (a) all participant hospitals that owe repayment to CMS for PY 3 final reconciliation and PY 4 initial reconciliation; and (b) upon request, any participant hospital that is eligible for a reconciliation payment for PY 3 final reconciliation and PY 4 initial reconciliation. The regulations provide that unless the participant hospital provides written notice of a calculation error, CMS deems the CJR reconciliation report to be final 45 calendar days after it is issued and that CMS responds to the notice of calculation error if it is received within 45 calendar days of the issuance of the reconciliation report.

We are modifying the participant hospital deadlines to permit the participant hospital 120 calendar days after the reconciliation report is issued to appeal a determination that such hospital owes repayment to CMS, or upon request, to appeal a determination that such

hospital is eligible for a reconciliation payment. If a notice of calculation error is received by CMS within the 120-day period, then consistent with the existing regulation, CMS responds in writing within 30 calendar days to either confirm that there was an error in the calculation or verify that the calculation is correct, although CMS reserves the right to an extension upon written notice to the participant hospital.

Hospitals receiving a reconciliation payment that do not request a 120-day appeal period have 45 days to provide a notice of calculation error. Unless the participant hospital provides written notice of the calculation error, CMS deems the CJR reconciliation report to be final 45 calendar days after it is issued, and proceeds with the payment.

- *Requirement for Hospitals and CAHs to report COVID-19 Data.* Hospitals and CAHs are to report information in accordance with a frequency and in a standardized format as specified by the Secretary during the PHE for COVID-19. More information is available at <https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf>.

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.

Workforce

- *Sterile Compounding:* CMS is waiving hospital sterile compounding requirements (also outlined in USP797) at 42 CFR §482.25(b)(1) and §485.635(a)(3) to allow used face masks to be removed and retained in the compounding area to be re-donned and reused during the same work shift in the compounding area only. This will conserve scarce face mask supplies. CMS will not be reviewing the use and storage of facemasks under these requirements.
- *Medical Staff Requirements:* CMS is waiving the Medical Staff requirements at 42 CFR §482.22(a)(1)-(4) to allow for physicians whose privileges will expire to continue practicing at the hospital and for new physicians to be able to practice in the hospital before full medical staff/governing body review and approval to address workforce concerns related to COVID-19. CMS is waiving §482.22(a) (1)-(4) regarding details of the credentialing and privileging process.
- *Physician services:* CMS is waiving 482.12(c)(1)–(2) and §482.12(c)(4), which requires that Medicare patients be under the care of a physician. This allows hospitals to use other practitioners, such as physician's assistant and nurse practitioners to the fullest extent possible. This waiver should be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.
- *Anesthesia services.* CMS is waiving the requirements at 42 CFR 482.52(a)(5), 42 CFR 485.639(c)(2), and 42 CFR 416.42 (b)(2) that a certified registered nurse anesthetist (CRNA) is under the supervision of a physician. CRNA supervision will be at the discretion of the hospital or Ambulatory Surgical Center (ASC), and state law. This waiver applies to hospitals, CAHs, and ASCs. These waivers will allow CRNAs to function to the fullest extent of their licensure, and should be implemented so long as they are not inconsistent with a State or pandemic/emergency plan.
- *Respiratory care services:* We are waiving the requirement at 42 CFR 482.57(b)(1) that hospitals designate in writing the personnel qualified to perform specific respiratory care procedures and the amount of supervision required for personnel to carry out specific procedures. These flexibilities should be implemented so long as they are not inconsistent with a State or pandemic/emergency plan. Not being required to designate these

professionals in writing will allow qualified professionals to operate to the fullest extent of their licensure and training in providing patient care for respiratory illnesses.

- *CAH Personnel qualifications:* CMS is waiving the minimum personnel qualifications for clinical nurse specialist, nurse practitioners, and physician assistants described at 42 CFR 485.604(a)(2), 42 CFR 485.604(b)(1)-(3), and 42 C.F.R 485.604(c)(1)-(3). Clinical Nurse Specialists, Nurse Practitioners, and Physician Assistants will still have to meet state requirements for licensure and scope of practice, but not additional Federal requirements that may exceed State requirements. This will give States and facilities more flexibility in using clinicians in these roles to meet increased demand. These flexibilities should be implemented so long as they are not inconsistent with a State or pandemic/emergency plan.
- *CAH staff licensure:* CMS is deferring to staff licensure, certification, or registration to State law by waiving the requirement at 42 CFR 485.608(d) that staff of the CAH be licensed, certified, or registered in accordance with applicable Federal, State, and local laws and regulations. The CAH and its staff must still be in compliance with applicable Federal, State and Local laws and regulations, and all patient care must be furnished in compliance with State and local laws and regulations. This waiver would defer all licensure, certification, and registration requirements for CAH staff to the state, which would add flexibility where Federal requirements are more stringent. These flexibilities should be implemented so long as they are not inconsistent with a State or pandemic/emergency plan.
- *Responsibilities of physicians in CAHs.* 42 C.F.R. § 485.631(b)(2). CMS is waiving the requirement for CAHs that a doctor of medicine or osteopathy be physically present to provide medical direction, consultation, and supervision for the services provided in the CAH at § 485.631(b)(2). CMS is retaining the regulatory language in the second part of the requirement at § 485.631(b)(2) that a physician be available “through direct radio or telephone communication, or electronic communication for consultation, assistance with medical emergencies, or patient referral.” Retaining this longstanding CMS policy and related longstanding subregulatory guidance that further described communication between CAHs and physicians will assure an appropriate level of physician direction and supervision for the services provided by the CAH. This will allow the physician to perform responsibilities remotely, as appropriate. This also allows CAHs to use nurse practitioners and physician assistants to the fullest extent possible, while ensuring necessary consultation and support as needed.
- *GME Affiliation Agreements Extended Deadline.* Due to the COVID-19 Public Health Emergency (PHE), under the authority of section 1135(b)(5) of the Social Security Act (the Act), CMS is waiving the July 1 submission deadline under 42 CFR 413.79(f)(1) for new Medicare GME affiliation agreements and the June 30 deadline under the May 12, 1998 Health Care Financing Administration Final Rule (63 FR 26318, 26339, 26341) for amendments of existing Medicare GME affiliation agreements. That is, during the COVID-

19 PHE, instead of requiring that new Medicare GME affiliation agreements be submitted to CMS and the MACs by July 1, 2020 (for the academic year starting July 1, 2020), and that amendments to Medicare GME affiliation agreements be submitted to CMS and the MACs by June 30, 2020 (for the academic year ending June 30, 2020), CMS is allowing hospitals to submit new and/or amended Medicare GME affiliation agreements as applicable to CMS and the MACs by October 1, 2020. As under existing procedures, hospitals should email new and/or amended agreements to CMS at Medicare_GME_Affiliation_Agreement@cms.hhs.gov, and indicate in the subject line whether the affiliation agreement is a new one or an amended one.

Community Mental Health Centers (CMHC)

- *Quality assessment and performance improvement (QAPI):* CMS is modifying the requirements for CMHC's quality assessment and performance improvement (QAPI). Specifically, we are retaining the overall requirement that CMHC's maintain an effective, ongoing, CMHC-wide, data-driven QAPI program, while providing flexibility for CMHCs to use their QAPI resources to focus on challenges and opportunities for improvement related to the PHE by waiving the specific detailed requirements for the QAPI program's organization and content at § 485.917(a)-(d). Waiving the requirements related to the details of the QAPI program's organization and content will make it easier for CMHCs to reconfigure their QAPI programs, as needed, to adapt to specific needs and circumstances that arise during the PHE. These flexibilities may be implemented so long as they are consistent with a state's emergency preparedness or pandemic plan.
- *Provision of Services:* CMS is waiving the specific requirement at § 485.918(b)(1)(iii) that prohibits CMHCs from providing partial hospitalization services and other CMHC services in an individual's home so that clients can safely shelter in place during the PHE while continuing to receive needed care and services from the CMHC. This waiver is a companion to regulatory changes that clarify how CMHCs should bill for services provided in CMHC temporary expansion locations, including an individual's home, and how such services should be documented in the medical record. While this waiver will now allow CMHCs to furnish services in temporary expansion locations, including an individual's home, using telecommunication technology, CMHCs continue to be, among other things, required to comply with the non-waived provisions of 42 CFR Part 485, Subpart J, requiring that CMHCs: 1) assess client needs, including physician certification of the need for partial hospitalization services, if needed; 2) implement and update each client's individualized active treatment plan that sets forth the type, amount, duration, and frequency of the services; and 3) promote client rights, including a client's right to file a complaint.
- For Partial Hospitalization Program services, CMHCs can furnish and bill for certain partial hospitalization services – that is, individual psychotherapy, patient education, and group psychotherapy – that are delivered in temporary expansion locations, including patients'

homes, to ensure access to necessary services and maintain continuity of care and for purposes of infection control. When the patient is registered as an outpatient, PHP services furnished by CMHC staff in that location are considered to be furnished in the CMHC. Counselors and other employed CMHC staff may furnish these services to the beneficiary, either through telecommunications technology or in-person, in a temporary expansion location, which may include the beneficiary's home, so long as it has been made an expanded CMHC. The CMHC may bill for these services as CMHC outpatient services, as long as they are medically necessary and meet all requirements described by the HCPCS code, and as long as the service is furnished in an expanded CMHC.

- *40 percent rule:* CMS is waiving the requirement at § 485.918(b)(1)(v) that a CMHC provides at least 40 percent of its items and services to individuals who are not eligible for Medicare benefits. Waiving the 40 percent requirement will facilitate appropriate timely discharge from inpatient psychiatric units and prevent admissions to these facilities because CMHCs will be able to provide PHP services to Medicare beneficiaries without restrictions on the proportion of Medicare beneficiaries that they are permitted to treat at a time. This will allow communities greater access to health services, including mental health services.

Additional Guidance

- The Interim Final Rules 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 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>
- CMS has released guidance to describe standards of practice and flexibilities within the current regulations for hospitals (including critical access hospitals and psychiatric hospitals) at <https://www.cms.gov/files/document/qso-20-13-hospitalspdf.pdf-2>.
- CMS guidance also addresses hospital flexibilities under the Emergency Medical Treatment and Labor Act (EMTALA) to establish alternate testing and triage sites to address the pandemic at <https://www.cms.gov/files/document/qso-20-15-hospitalcahemtala.pdf>.