Hospitals and CAHs (including Swing Beds, DPUs), ASCs and CMHCs: CMS Flexibilities to Fight COVID-19

At the beginning of the COVID-19 Public Health Emergency (PHE), CMS used emergency waiver authorities and various regulatory authorities to enable flexibilities so providers could rapidly respond to people impacted by COVID-19. CMS developed a cross-cutting initiative to use a comprehensive, streamlined approach to reestablish certain health and safety standards and other financial and program requirements at the eventual end of the COVID-19 public health emergency.

This CMS cross-cutting initiative focused on evaluating CMS-issued PHE waivers and flexibilities to prepare the health care system for operation after the PHE. This review happened in three concurrent phases:

1. CMS assessed the need for continuing certain waivers based on the current phase of the PHE. Since the beginning of the PHE, CMS has both added and terminated flexibilities and waivers as needed. In doing so, CMS considered the impacts on communities — including underserved communities — and the potential barriers and opportunities that the flexibilities may address.

2. CMS assessed which flexibilities would be most useful in a future PHE, such as natural and man-made disasters and other emergencies, to ensure a rapid response to future emergencies, both locally and nationally, or to address the unique needs of communities that may experience barriers to accessing health care.

3. CMS is continuing to collaborate with federal partners and the health care industry to ensure that the health care system is holistically prepared for addressing future emergencies.

As CMS identified barriers and opportunities for improvement, the needs of each person and community served were considered and assessed with a health equity lens to ensure our analysis, stakeholder engagement, and policy decisions account for health equity impacts on members of underserved communities and health care professionals disproportionately serving these communities.

Please note: This fact sheet focuses on Medicare and Medicaid flexibilities only.

COVID-19 Vaccines

On October 28, 2020, CMS released an Interim Final Rule with comment period (IFC) announcing that Medicare Part B would establish coding and payment rates for COVID-19 vaccines and their administration as preventive vaccines, without cost-sharing, as soon as the Food and Drug Administration (FDA) authorized or approved the product through an Emergency Use Authorization (EUA) or Biologics License Application (BLA). The IFC also implemented provisions of the CARES Act to ensure swift coverage of COVID-19 vaccines by private health insurance plans participating in the Health Insurance Marketplace, without cost sharing, from both in- and out-of-network providers, during the course of the public health emergency (PHE).

Payment After the End of the PHE

CMS will continue to pay approximately $40 per dose for administering COVID-19 vaccines in most outpatient settings for Medicare beneficiaries through the end of the calendar year in which the Secretary ends the EUA declaration for drugs and biologicals with respect to COVID-19. The EUA declaration is distinct from, and not dependent on, the PHE for COVID-19.

Effective January 1 of the year following the year in which the EUA declaration ends, CMS will set the payment rate for administering COVID-19 vaccines to align with the payment rate for administering other Part B preventive vaccines, that is, approximately $30 per dose.

Additional Payment for Administering the Vaccine in the Patient's Home

In calendar year 2023, CMS will pay approximately $36 in addition to the standard administration amount (approximately $40) per dose to administer COVID-19 vaccines in the home for certain Medicare patients. For vaccines requiring multiple doses, this payment applies for each dose in the series, including any additional or booster doses. We also geographically adjust the additional amount and administration rate based on where you administer the vaccine. Starting January 1, 2023, we'll also annually update the additional in-home payment rate for administering the COVID-19 vaccine to reflect changes in costs related to administering preventive vaccines.

Additional Payment for Administering the Vaccine in the Patient's Home After the End of the

We'll continue to pay a total payment of approximately $76 per dose to administer COVID-19 vaccines in the home for certain Medicare patients through calendar year 2023. **The additional payment is not affected by the end of the PHE.**

More information: COVID-19 vaccine toolkits

- Providers
  - Payment
  - Billing
  - Coding
- Health & Drug Plans
- State Medicaid programs

COVID-19 Monoclonal Antibodies

There are currently no COVID-19 monoclonal antibodies approved or authorized for use against the dominant strains of COVID-19 in the United States.

The FDA issued emergency use authorizations (EUA) for monoclonal antibody therapies used for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients with positive COVID-19 test results who are at high risk for progressing to severe COVID-19 and/or hospitalization. The FDA also issued an EUA for a monoclonal antibody product used as a pre-exposure prophylaxis of COVID-19 in adults and pediatric patients with certain conditions.

During the EUA declaration for drugs and biologicals with respect to COVID-19, CMS covers and pays for these infusions or injections the same way it covers and pays for COVID-19 vaccines when furnished consistent with the EUA. There's also no beneficiary cost sharing and no deductible for COVID-19 monoclonal antibody products when providers administer them. In the event these products become approved or authorized for use, they will continue to be covered and paid under the Medicare Part B preventive vaccine benefit until the end of the calendar year in which the Secretary ends the EUA declaration. This coverage and payment will continue even if the PHE ends.

CMS doesn't pay for the COVID-19 monoclonal antibody product when a health care setting has received it for free. If a health care setting purchased the product from the manufacturer, Medicare pays the reasonable cost or 95% of the average wholesale price.

More information: COVID-19 Monoclonal Antibodies

Payment After the End of the PHE

Effective January 1 of the year following the year in which the Secretary ends the EUA declaration for drugs and biologicals with respect to COVID-19, CMS will pay for monoclonal antibodies used for the treatment or for post-exposure prophylaxis of COVID-19:

- As we pay for biological products under Section 1847A of the Social Security Act.

- Through the applicable payment system, using the appropriate coding and payment rates, similar to the way we pay for administering other complex biological products.

Monoclonal antibodies that are used for pre-exposure prophylaxis prevention of COVID-19 will continue to be paid under the Part B preventive vaccine benefit if they meet applicable coverage requirements.

COVID-19 VEKLURY™ (remdesivir)

As of April 25, 2022, VEKLURY™ (remdesivir) is approved for the treatment of COVID-19. The federal government didn't purchase a supply of remdesivir. Medicare Part B provides payment for the drug and its administration under the applicable Medicare Part B payment policy when a facility or practitioner provides it in the outpatient setting, according to the FDA approval. In most cases, the Medicare patient's yearly Part B deductible and 20% co-insurance apply.

Medicare Coverage for Over-the-Counter COVID-19 Tests. On April 4, 2022, Medicare implemented a demonstration program to allow people with Medicare to receive up to eight tests per calendar month at no cost. This is the first time that Medicare has covered an over-the-counter, self-administered, test. This new initiative enables people with Medicare Part B, including those enrolled in a Medicare Advantage plan, to receive tests at no cost from providers and suppliers who are eligible to participate. Pharmacies and other health care providers interested in participating in this initiative can get more information here: https://www.cms.gov/COVIDOTCtestsProvider. **This program will end at the end of the COVID-19 public health emergency.**

Telehealth

*Hospital Originating Site Facility Fee for Professional Services Furnished Via Telehealth***:** When a physician or nonphysician practitioner, who typically furnishes professional services in the hospital outpatient department, furnishes telehealth services to the patient's home during the COVID-19 PHE as a "distant site" practitioner, 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. The hospital may bill under the OPPS 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 during the PHE, hospitals could provide hospital services in other hospitals and sites that otherwise would not have been considered part of a healthcare facility, or could set up temporary expansion sites to help address the urgent need to increase capacity to care for patients. During the PHE, CMS provided additional flexibilities for hospitals to create surge capacity by allowing them to provide room and board, nursing, and other hospital services at remote locations, such as hotels or community facilities. During the PHE, hospitals are expected to control and oversee the services provided at an alternative location. **When the PHE ends, hospitals and CAHs will be required to provide services to patients within their hospital departments, pursuant to Hospital and CAH conditions of participation at 42 CFR part 482 and part 485, Subpart F, respectively.**

- *Under the Hospitals Without Walls initiative*: CMS permitted ambulatory surgical centers (ASCs) to temporarily reenroll 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, freestanding, emergency departments (IFEDs), could pursue temporarily enrolling as a hospital during the PHE. (As of December 1, 2021, no new ASC or new IFED requests to temporarily enroll as hospitals were being accepted.) See https://www.cms.gov/files/document/provider-enrollment-relief-faqs-covid-19.pdf for additional information. **When the PHE ends, ASCs must decide either to meet the certification standards for hospitals at 42 CFR part 482, or return to ASC status.** If they choose to return to ASC status, they can only be paid under the ASC payment system for services on the ASC Covered Procedures List. **When the PHE ends, IFEDs cannot bill Medicare for services as their temporary Medicare certification would end.**

Voluntary Termination of ASC's Temporary Hospital Status

The temporarily enrolled ASC must submit a notification of intent to convert back to an ASC to the applicable CMS Survey and Operations Group (SOG) location on or before the conclusion of the PHE via email or mailed letter. Once the CMS SOG location receives the notification from the temporary hospital of their desire to convert back to an ASC, the location will terminate the temporary hospital CMS Certification Number (CCN) and send a tie-out notice to the applicable Medicare Administrative Contractor (MAC). The MAC will deactivate the temporary hospital billing privileges and reinstate the original ASC billing privileges. Once the temporary hospital enrollment is terminated, the ASC must come back into compliance immediately with all applicable ASC federal participation requirements, including the Conditions for Coverage.

If the ASC wishes to participate as a hospital, it must undergo the hospital enrollment process by submitting a form CMS-855A to begin the process of enrollment and initial certification as a hospital on or before the conclusion of the PHE. An initial survey, either done by the State Agency (SA) or Accreditation Organization (AO), will be conducted to determine compliance with all applicable hospital Conditions of Participation (CoPs) before CMS issues a final determination letter for Medicare participation.

- *Off Site Patient Screening*: CMS has been partially waiving the enforcement of section 1867(a) of the Social Security Act (the Emergency Medical Treatment and Active Labor Act, or EMTALA). This has allowed 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, while remaining consistent with the state emergency preparedness or pandemic plan. **This will expire at the end of the COVID-19 public health emergency.**

- *Paperwork Requirements*: CMS has been waiving certain specific paperwork requirements under this section only for hospitals that are considered to be impacted by a widespread outbreak of COVID-19, as determined by CDC guidelines. Hospitals that are located in a state that has widespread confirmed cases have not been required to meet the following requirements. **This will expire at the end of the COVID-19 public health emergency.**

    - 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*: As noted above, CMS has been waving 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 CAHs as a result of COVID-19. CMS has permitted 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 has allowed for increased capacity and has promoted 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 segregation[1].

- *Specific Life Safety Code (LSC) for Hospitals and CAHs:* CMS has been waiving and modifying particular waivers under 42 CFR §482.41(b) for hospitals and §485.623(c) for CAHs. Specifically, CMS has temporarily modified these requirements as follows:

    - Alcohol-Based Hand-Rub (ABHR) Dispensers: We have been 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 populations to prevent accidental ingestion. Due to the increased fire risk for bulk containers (over five gallons) those still need to be stored in a protected hazardous materials area.

    - 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. **This will expire at the end of the COVID-19 public health emergency.**

    - Fire Drills: Due to the inadvisability of quarterly fire drills that move and mass staff together, we have instead permitted a documented orientation training program related to the current fire plan, which considers current facility conditions. The training instructs 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. **(Terminated waivers for fire drills at §418.110(d) for inpatient hospice; §483.470(j) for ICF/IIDs; and §483.90(a) for SNF/NFs terminated on 6-6-2022 per QSO-22-15-NH & NLTC & LSC).**

    - Temporary Construction: CMS has been waiving requirements that would otherwise not permit temporary walls and barriers between patients. Refer to: 2012 LSC, sections 18/19.3.3.2.

[1]Please note that consistent with the integration mandate of Title II of the ADA and the *Olmstead vs LC* decision, states are obligated to make available 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.

- *Hospital Outpatient: Use of Provider-Based Departments as Temporary Expansion Sites*: For the duration of the PHE related to COVID-19, CMS has been 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 creating new, or relocating existing, provider-based departments. These waivers were intended to 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 made several changes to support hospitals so they can more effectively respond to the COVID-19 PHE. During the 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 prior extraordinary relocation exception policy, only relocating off-campus PBDs were 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.

- The temporary extraordinary circumstances relocation policy established in the May 8, 2020 IFC (85 FR 27567 through 27568) will end following the end of the COVID-19 PHE. We anticipate that most, if not all, PBDs that relocated during the COVID-19 PHE will relocate back to their original location prior to, or soon after, the end of the COVID-19 PHE. PBDs that hospitals choose to permanently relocate off-campus would be considered new off-campus PBDs billing after November 2, 2015, and, therefore, would be required to bill using the "PN" modifier for hospital outpatient services furnished from that PBD location and would be paid the PFS-equivalent rate once the COVID-19 PHE ends.

- Following the COVID-19 PHE, hospitals may seek an extraordinary circumstances relocation exception for excepted off-campus locations that have permanently relocated, but these hospitals would need to follow the standard extraordinary circumstances application process we adopted in CY 2017 and file an updated CMS-855A enrollment form to reflect the new address(es) of the PBD(s).

    - We note that our standard relocation exception policy only applies to excepted off-campus PBDs that relocate; on-campus PBDs that wish to permanently relocate off-campus will not be able to receive an extraordinary circumstances relocation exception under the standard extraordinary circumstances relocation request process after the conclusion of the COVID-19 PHE.
    - We also note that hospitals should not rely on having relocated the off-campus PBD during the COVID-19 PHE as the reason the off-campus PBD should be permanently excepted following the end of the COVID-19 PHE. In other words, the fact that the off-campus PBD relocated in response to the pandemic will not, by itself, be considered an "extraordinary circumstance" for purposes of a permanent relocation exception, although CMS Regional Offices will continue to have discretion to approve or deny relocation requests for hospitals that apply after the COVID-19 PHE, depending on whether the relocation request meets the requirements for the extraordinary circumstances' exception.
    - Following the COVID-19 PHE, if temporarily relocated off-campus PBDs do not go back to their original location, they will be considered to be non-excepted PBDs and paid the PFS-equivalent rate.

Provider-Based Department (PBD) Type	Non-PHE Payment Policy Before Relocation	Non-PHE Payment Policy if PBD Relocates Off-Campus (Absent Extraordinary Circumstance Relocation Approval)	Payment Policy During PHE Following Off-Campus Relocation
On-Campus PBD	Full OPPS	PFS-equivalent (treated as new location)	OPPS** (if extraordinary circumstance relocation request is approved)
Excepted* Off-Campus PBD	OPPS**	PFS-equivalent (treated as new location)	OPPS** (if extraordinary circumstance relocation request is approved)
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.
**While all other services provided at an excepted off-campus provider-based department would be paid at the OPPS rate, we note that the clinic visit service is paid at the PFS-equivalent rate when performed at an off-campus provider-based department, regardless of whether that department is excepted.

After the PHE ends, these waivers will end:

- *Hospital-Only Remote Outpatient Therapy and Education Services*: Consistent with the CMS Hospitals without Walls Initiative, during the PHE, hospitals may provide behavioral

health and education services furnished by hospital-employed counselors or other professionals who 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 as 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 at List of Hospital Outpatient Services and List of Partial Hospitalization Program Services Accompanying the 04/30/2020 IFC .

- 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 as 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, as 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.

- **After the PHE, *other than the following exceptions,* these services will no longer be able to be paid when provided in the patient's home.**

  - **In the Calendar Year 2023 OPPS/ASC Final Rule CMS finalized OPPS payment after the PHE ends for behavioral health services furnished remotely by clinical staff of hospital outpatient departments.** This flexibility does not depend on considering the beneficiary's home to be a part of the hospital. Additionally, CMS clarified that

these services will not be recognized as partial hospitalization services, but will be available to beneficiaries in a partial hospitalization program.

- **Through the end of CY 2023, hospital and other providers of physical therapy, occupational therapy, speech-language pathology, diabetes self-management training and medical nutrition therapy services that remain on the telehealth list, can continue to bill for these services when furnished remotely in the same way they have been during the PHE, except that** beneficiaries' homes will no longer need to be registered as provider-based departments of the hospital to allow for hospitals to bill for these services. We note that we are exercising enforcement discretion in reviewing the telehealth practitioner status of the clinical staff personally providing any part of a remotely furnished DSMT service, so long as the practitioner is otherwise qualified to provide the service.

- *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 has been 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 not able to take patients because of the COVID-19 public health emergency (PHE).

- The hospital meets all waiver eligibility requirements.

- 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, while consistent with the state's emergency preparedness or pandemic plan. The hospital cannot 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 will terminate at the end of the COVID-19 PHE.**

- *Critical Access Hospital Bed Count and Length of Stay*: CMS has been 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. This waiver will terminate at the end of the COVID-19 PHE.

- *CAH Status and location*: CMS has been 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 allow the CAH flexibility in establishing off-site locations. In an effort to facilitate the establishment of CAHs without walls, these waivers have removed restrictions on CAHs regarding their rural location and their location relative to other hospitals and CAHs. These flexibilities have been implemented, remaining consistent with state or emergency or pandemic plans. **This will expire at the end of the COVID-19 public health emergency.**

- *Hospitals Classified as Sole Community Hospitals (SCHs):* During the PHE, CMS waived certain eligibility requirements at 42 CFR § 412.92(a) for hospitals classified as SCHs prior to the beginning of the emergency period. Specifically, during the PHE, CMS has been waiving the requirements at paragraphs (a), (a)(1), (a)(2), and (a)(3) of 42 CFR § 412.92, and also waiving the "market share" and bed requirements (as applicable) at 42 CFR § 412.92(a)(1)(i) and (ii). CMS has been 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. When the COVID-19 PHE ends, MACs will resume their standard practice for evaluation of all eligibility requirements.

- *Hospitals Classified as Medicare-Dependent, Small Rural Hospitals (MDHs):* During the PHE, for hospitals classified as MDHs prior to the beginning of the emergency period, and hospitals that became newly classified as MDHs during the PHE without the application

of this wavier, CMS has been 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% 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 has been 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. When the COVID-19 PHE ends, MACs will resume their standard practice for evaluation of all eligibility requirements.

- *Housing Acute Care Patients in Excluded Distinct Part Unit*s: During the PHE, CMS has been 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. **When the COVID-19 PHE ends, acute care hospitals under the IPPS cannot bill for acute care inpatients housed in excluded distinct part units. This waiver will terminate at the end of the COVID-19 PHE.**

- *Care for Excluded Inpatient Psychiatric Unit Patients in the Acute Care Unit of a Hospital:* During the PHE, CMS has been 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 PHE. This waiver could 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. **When the PHE ends, inpatients receiving psychiatric services paid under the IPF PPS and furnished by the excluded distinct part psychiatric unit of an acute care hospital cannot be housed in an acute care bed and unit. This will expire at the end of the COVID-19 public health emergency.**

- *Care for Excluded Inpatient Rehabilitation Unit Patients in the Acute Care Unit of a Hospital*: CMS has been 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 could 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. When the COVID-19 PHE ends, inpatients receiving rehabilitation services, paid under the IRF PPS and furnished by the excluded distinct part rehabilitation unit of an acute care hospital, cannot be housed in an acute care bed and unit. **This waiver will terminate at the end of the COVID-19 PHE.**

- *Flexibility for Inpatient Rehabilitation Facilities Regarding the 60% Rule:* During the PHE, CMS has been allowing IRFs to exclude patients from the freestanding hospitals, 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% 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, this exception has also applied to facilities not yet classified as IRFs, but have attempted to obtain classification as an IRF. **When the PHE ends, all inpatients will again be included in the freestanding hospitals, 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 (the 60% rule). This waiver will terminate at the end of the COVID-19 PHE.**

- *Telemedicine***:** CMS has been 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. **This waiver will terminate at the end of the COVID-19 PHE.**

- *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 separate professional claim for these services. During the PHE:

    - The beneficiary's home would be considered a provider-based department of the hospital for purposes of receiving these 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).

- These services require an order by a physician or qualified NPP and must be supervised by a physician or other NPP appropriate for supervising the service, given their hospital admitting privileges, state licensing, and scope of practice consistent with the requirements in 42 CFR § 410.27.

- The hospital could bill for these services as hospital outpatient services and be paid for them under the OPPS, rather than at the lower PFS-equivalent rate under the PFS, provided the PBD is an on campus or excepted off-campus PBD that relocated to the patient's home, applied, and was approved for an extraordinary circumstances relocation exception.

After the COVID-19 PHE, these flexibilities will end.

Enhanced Payment for 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 and to minimize any potential payment disruption immediately following the end of the PHE, effective for discharges occurring on or after November 2, 2020, and through the end of the FY in which the COVID-19 PHE ends, the Medicare program has provided an enhanced payment for eligible inpatient cases that involve use of certain new products authorized or approved to treat COVID-19 (86 FR 45162). The enhanced payment is equal to the lesser of: 1) 65% of the operating outlier threshold for the claim; or 2) 65% of the costs of the case beyond the operating Medicare payment (including the 20% add-on payment under section 3710 of the CARES Act) for eligible cases.

- *Separate Medicare Payment for New COVID-19 Treatments: Hospital Outpatient Departments*: To mitigate potential financial disincentives for hospitals to provide new COVID-19 treatments in a hospital outpatient setting during the COVID-19 PHE, CMS has excluded FDA-authorized or approved drugs and biologicals (including blood products) authorized or approved to treat COVID-19 (and for which the FDA authorization or approval does not limit use to the inpatient setting) 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 has been paying for these drugs and biologicals separately for the duration of the PHE. **After the PHE, payment for these treatments will be packaged into the payment for a C-APC when these services are billed on the same outpatient claim.**

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 are to make public the cash price for such tests on their websites. Providers without websites have been 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. **After the PHE, in accordance with the CARES Act, this special price transparency requirement will terminate. Price transparency requirements under other laws and regulations will continue to apply.**

- During the PHE, hospital outpatient departments could 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 OPPS. This approach heled hospitals to operate testing sites during the PHE. Medicare paid a national rate of roughly $25 for HCPCS code C9803 when it is not billed with a separately payable hospital outpatient service. HCPCS code C9803 is a temporary code that was created to support increased testing during the COVID-19 PHE. After the PHE, HCPCS code C9803 remains active and payable under the OPPS for the remainder of Calendar Year (CY) 2023. The status of HCPCS code C9803 for CY 2024 will be addressed in the CY 2024 OPPS/ASC rulemaking process.
- *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. **At the end of the PHE, coverage is at the Medicare Administrative contractor discretion.**

Reducing Administrative Burden

- *"Stark Law" Waivers:* The physician self-referral law (also known as the "Stark Law") 1) prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless the requirements of an applicable exception are satisfied; and 2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for any improperly referred designated health services. On March 30, 2020, CMS issued blanket waivers of certain provisions of the Stark Law. These blanket waivers applied 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. During the PHE, CMS permitted certain referrals and the submission of related claims that would otherwise violate the Stark Law, if all requirements of the waivers were met. **When the COVID-19 PHE ends, the waivers will terminate and physicians and entities must immediately comply with all provisions of the Stark Law.**

Flexibilities under the "Stark Law" waivers have included:

- Hospitals and other health care providers could pay above or below fair market value for the personal services of a physician (or an immediate family member of a physician), and parties could pay below fair market value to rent equipment or purchase items or services. For example, a physician practice could rent or sell needed equipment to a hospital at a price below what the practice could charge another party. Or, a hospital could provide space on hospital grounds at no charge to a physician who is willing to treat patients who sought care at the hospital but were not appropriate for emergency department or inpatient care.
- Health care providers could support each other financially to ensure continuity of health care operations. For example, a physician owner of a hospital could make a personal loan to the hospital without charging interest at a fair market rate so that the hospital could make payroll or pay its vendors.
- Hospitals could provide benefits to their medical staff, such as multiple daily meals, laundry service to launder soiled personal clothing, or child care services while the physicians were at the hospital and engaging in activities that benefited the hospital and its patients.
- Health care providers could offer certain items and services that were 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 could provide continuing medical education to physicians in the community on the latest care protocols for homebound patients with COVID-19, or a hospital could 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 could 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 could 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 could furnish medically necessary designated health services (DHS) in a patient's home were loosened. For

example, any physician in the group could order medically necessary DHS that were furnished to a patient by one of the group's technicians or nurses in the patient's home contemporaneously with a physician service that was furnished via telehealth by the physician who ordered the DHS.
  - Group practices could furnish medically necessary MRIs, CT scans, or clinical laboratory services from locations like mobile vans in parking lots that the group practice rented on a part-time basis.

- *Verbal Orders*: CMS has been 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 has allowed for more efficient treatment of patients in a surge situation. **This will expire at the end of the COVID-19 public health emergency.**

- *Reporting Requirements*: CMS has been 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. **This will expire at the end of the COVID-19 public health emergency.**

- *Limit Discharge Planning for Hospital and CAHs:* To allow hospitals and CAHs more time to focus on increasing care demands, discharge planning has been focusing on ensuring that patients are discharged to an appropriate setting with the necessary medical information and goals of care. CMS has been 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). After the expiration of the PHE hospital, the CAH assists 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. **This will expire at the end of the COVID-19 public health emergency.**

- *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 has been 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 has been 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. **CMS will end this waiver at the conclusion of the PHE.**

- *Medical Records*: CMS has been 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 has been 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 allows clinicians to focus on the patient care at the bedside during the pandemic. **CMS will end this waiver at the conclusion of the PHE.**

- *Flexibility in Patient Self Determination Act Requirements (Advance Directives)*: CMS has been 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. This waiver will terminate at the end of the COVID-19 PHE.

- *Extension for Inpatient Prospective Payment System (IPPS) Wage Index Occupational Mix Survey Submission***:** CMS collects data every three years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. During the PHE, 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 further extended that deadline to September 3, 2020. Hospitals must have submitted their occupational mix surveys along with complete supporting documentation to their MACs by no later than September 3, 2020. Hospitals could then submit revisions to their occupational mix surveys to their MACs, if needed, by no later than September 10, 2020. The next

collection of the wage index occupational mix survey data (based on 2022 data) is expected to be collected in Summer 2023.

- *Postponement of Application Deadline to the Medicare Geographic Classification Review:* 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 was 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 postponed 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.

  CMS did not modify the respective September 1st deadline for submission of applications for FY 2023 or FY 2024 reclassifications to the MGCRB due to the COVID-19 PHE.

- *Utilization review:* CMS has been 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 has been 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 have been implemented while remaining consistent with a state or pandemic/emergency plan. Removing these administrative requirements allows hospitals to focus more resources on providing direct patient care. **This will expire at the end of the COVID-19 public health emergency.**

- *Quality assessment and performance improvement program*: CMS has been 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, have been implemented while remaining consistent with a state's emergency preparedness or pandemic plan. We expect any improvements to the program 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 remains. **This will expire at the end of the COVID-19 public health emergency.**

- *Nursing services*: CMS has been 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 meet the clinical care needs of each patient and allow for the provision of nursing care to an increased number of patients. In addition, we have expected that hospitals would need relief for the provision of inpatient services and, as a result, the requirement to establish nursing-related policies and procedures for outpatient departments likely would be unnecessary. These flexibilities apply to both hospitals and CAHs, and have been implemented while remaining consistent with a state or pandemic/emergency plan. **CMS will end this waiver at the conclusion of the PHE.**

- *Food and dietetic service*: CMS has been 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 have been implemented while remaining consistent with a state or pandemic/emergency plan. Removing these administrative requirements allows hospitals to focus more resources on providing direct patient care. CMS will end this waiver at the conclusion of the PHE.

- *Written policies and procedures for appraisal of emergencies at off campus hospital departments*: CMS has been 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 have been implemented while remaining consistent with a state's emergency preparedness or pandemic plan. **CMS will end this waiver at the conclusion of the PHE.**

- *Emergency preparedness policies and procedures*: CMS has been 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 require 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. **CMS will end this waiver at the conclusion of the PHE.**

- *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 COVID-19. 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. **After the PHE, signature and proof of delivery requirements will be reinstated.**

- *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 granted 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) for Hospitals and CAHs:* The policies in the CMS Interoperability and Patient Access final rule, published in the *Federal Register* on May 1, 2020 (https://www.federalregister.gov/d/2020-05050), had varied implementation dates. For the ADT notification CoP requirements, in light of the COVID-19 PHE at the time of the publication, CMS extended the implementation timeline by 12 months from the publication of the final rule. The ADT notification CoP requirements at 42 CFR Parts 482 and 485 have been in effect since June 1, 2021.

- *COVID-19 Accelerated and Advance Payments (CAAP):* For more information related to the CAAP Program please visit https://www.cms.gov/medicare/covid-19-accelerated-and-advance-payments

- *Comprehensive Care for Joint Replacement (CJR) Model:* CMS extended Performance Year (PY) five of CJR by an additional nine months, so that PY five ended on September 30, 2021. CMS also temporarily applied CJR's extreme and uncontrollable circumstances (EUC) policy, which caps episode spending for certain episodes at the quality adjusted target price for that episode, to all CJR episodes initiating between January 31, 2020 and March 31, 2021. Beginning on April 1, 2021 through the end of the CJR model, the EUC policy for COVID-19 has been episode based, where actual episode payments are

capped at the quality adjusted target price for episodes that include a claim with a COVID-19 diagnosis code. Questions about the CJR model can be submitted via email at CJRSupport@cms.hhs.gov.

- *Cost Reporting Deadlines*. Providers who continue to experience the impacts of the PHE and require additional time to file their cost report may submit a request to their MAC in accordance with our regulation at 42 CFR 413.24 (f)(2)(ii). The MAC has the authority to grant up to a 60-day extension of the due date for filing a cost report if the provider's operations are significantly adversely affected due to extraordinary circumstances over which the provider has no control, such as the PHE.

- *Provider Enrollment*: During the PHE, CMS has established toll-free hotlines for physicians, non-physician practitioners, and Part A certified providers and suppliers who have established isolation facilities to enroll and receive temporary Medicare billing privileges. **When the PHE ends, the hotlines will be shut down.** Additionally, CMS has provided the following flexibilities for provider enrollment:

  - *Screening requirements:*
    - Site Visits: CMS waived provider enrollment site visits for moderate and high-risk providers/suppliers. ***(This waiver terminated on 07-06-2020 and CMS, in accordance with 42 CFR §§ 424.517 and 424.518, resumed all provider enrollment site visits.)***

    - *Fingerprint-based criminal background checks:* CMS waived the requirement for fingerprint-based criminal background checks for 5% or greater owners of newly enrolling high-risk categories of providers and suppliers (e.g., newly-enrolling Home Health Agencies, DMEPOS suppliers, Medicare Diabetes Prevention Programs, Opioid Treatment Programs). ***(This waiver terminated on 10/31/2021 and CMS, in accordance with 42 CFR § 424.518, resumed requesting fingerprints for all newly enrolling high-risk providers and suppliers.)***

  - *Application Fees:* CMS waived the collection of application fees for institutional providers who are initially enrolling, revalidating, or adding a new practice location. ***(This waiver terminated on 10/31/2021 and CMS, in accordance with 42 CFR § 424.514, resumed collecting application fees.)***

  - *Revalidation:* CMS postponed all revalidation actions. This did not prevent a provider who wants to submit a revalidation application from doing so; MACs processed revalidation applications. ***(This waiver terminated on 10/31/2021 and CMS resumed a phased-in approach to revalidation activities; revalidation letters began being mailed again in November 2021 with due dates in early 2022.)***

- *Expedited Enrollment:* CMS expedited any pending or new applications from providers and suppliers, including physicians and non-physician practitioners received on or after March 1, 2020. **When the PHE ends, CMS will resume normal application processing times.**

- *Requirement for Hospitals and CAHs to Report Data for COVID-19 and Acute Respiratory Illness, including Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection:* Hospitals and CAHs are required 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. **Beginning after the PHE ends and continuing until April 30, 2024, unless the Secretary determines an earlier end date, hospitals and CAHs are required to report data for COVID-19 and seasonal influenza in a standardized format and frequency as specified by the Secretary.** CMS will notify regulated entities, stakeholders, and the public of the start date of necessary reporting, reporting frequency, and other requirements via sub regulatory guidance, following a model similar to that which we used to inform regulated entities at the beginning of the COVID-19 PHE.

Medicare appeals in Traditional Medicare, Medicare Advantage (MA) and Part D

- During the PHE, CMS has been allowing Medicare Administrative Contractors (MACs) and Qualified Independent Contractors (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 422.582 and 42 CFR 423.582), to allow extensions to file an appeal. Specifically, 42 CFR 422.582(c) and 42 CFR 423.582(c) allow a Part C or Part D plan to extend the timeframe for filing a request if there is good cause for the late filing. In addition, the Part D IRE may find good cause for late filing of a request for reconsideration. **When the PHE ends, these flexibilities will continue to apply consistent with existing authority and requests for appeals must meet the existing regulatory requirements.**

- During the PHE, CMS has been 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**.** In addition, under applicable regulations, 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), 42 CFR 422.572(b)(1) and 42 CFR 422.590(f)(1)). **When the PHE ends, these flexibilities will continue to apply consistent with existing authority, and requests for appeals must meet the existing regulatory requirements.**

- During the PHE, CMS has been allowing MACs and QICs in the FFS program (42 CFR 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 (see 42 CFR 422.561 and 42 CFR 423.560 for definitions of "representative"). However, any communication was sent only to the beneficiary. **When the PHE ends, this flexibility will continue to apply, consistent with existing guidance for the MACs and QIC in the FFS program. For MA and Part D plans, as well as the Part C and Part D IREs, this flexibility will no longer apply. The MA and Part D plans, as well as the Part C and D IREs, must process the appeals based on regulatory requirements (42 CFR 422.582(f)-(g), 42 CFR 423.582(e)-(f), 42 CFR 422.592(d)-(e), and 42 CFR 423.600(g)-(h)).**

- During the PHE, CMS has been 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, but instead use information that is available (42 CFR 422.562 and 42 CFR 423.562). **When the PHE ends, requests for appeals must meet the existing regulatory requirements.**

- During the PHE, CMS has been 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 utilize all flexibilities available in the appeal process as if good cause requirements are satisfied. **When the PHE ends, these flexibilities may only be provided consistent with existing regulatory authority.**

Workforce

- *Sterile Compounding*: CMS has been 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 conserves scarce face mask supplies. CMS has not been reviewing the use and storage of facemasks under these requirements. **CMS will end this waiver at the conclusion of the COVID-19 PHE.**

- *Medical Staff Requirements*: CMS has been waiving the Medical Staff requirements at 42 CFR § 482.22(a)(1)-(4) to allow for physicians, whose privileges would have expired, 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 has been waiving § 482.22(a) (1)-(4) regarding details of the credentialing and privileging process. **CMS will end this waiver at the conclusion of the COVID-19 PHE.**

- *Physician services:* CMS has been waiving § 482.12(c)(1)-(2) and § 482.12(c)(4), which require 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 has been implemented while remaining consistent with a state's emergency preparedness or pandemic plan. **CMS will end this waiver at the conclusion of the COVID-19 PHE.**

- *Anesthesia services:* CMS has been 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 has been at the discretion of the hospital or Ambulatory Surgical Center (ASC) and state law. This waiver applies to hospitals, CAHs, and ASCs. These waivers allow CRNAs to function to the fullest extent of their licensure and has been implemented while remaining consistent with a state or pandemic/emergency plan. **CMS will end this waiver at the conclusion of the COVID-19 PHE.**

- *Respiratory care services*: We have been 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. This flexibility has been implemented while remaining consistent with a state or pandemic/emergency plan. Not being required to designate these professionals in writing allows qualified professionals to operate to the fullest extent of their licensure and training in providing patient care for respiratory illnesses. **This waiver will end at the conclusion of the COVID-19 PHE.**

- *CAH Personnel qualifications*: CMS has been 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 CFR 485.604(c)(1)-(3). Clinical Nurse Specialists, Nurse Practitioners, and Physician Assistants still have to meet state requirements for licensure and scope of practice, but not additional federal requirements that may exceed state requirements. This gives states and facilities more flexibility in using clinicians in these roles to meet increased demand. These flexibilities have been implemented while remaining consistent with a state or pandemic/emergency plan. **CMS will end this waiver at the conclusion of the COVID-19 PHE.**

- *CAH staff licensure*: CMS has been 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 defers all licensure, certification, and registration requirements for CAH staff to the state, which adds flexibility where federal requirements are more stringent. This flexibility has been implemented while consistent with a state or pandemic/emergency plan. **This will expire at the end of the COVID-19 public health emergency.**

- *Responsibilities of physicians in CAHs:* 42 CFR § 485.631(b)(2). CMS has been 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 § (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 sub regulatory guidance that further describes communication between CAHs and physicians, assures an appropriate level of physician direction and supervision for the services provided by the CAH. This allows 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. **CMS will end this waiver at the conclusion of the PHE.**

- *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 waived 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 allowed hospitals to submit new and/or amended Medicare GME affiliation agreements as applicable to CMS and the MACs by January 1, 2021. Similarly, CMS allowed hospitals to submit new Medicare GME affiliation agreements by January 1, 2022 (for the academic year starting July 1, 2021) and allowed hospitals to submit amended Medicare GME affiliation agreements by January 1, 2022 (for the academic year ending

June 30, 2021). **CMS did not modify subsequent deadlines for hospitals to submit new and/or amended Medicare GME affiliation agreements (as applicable) to CMS and the MACs, and returned to the otherwise applicable July 1 and June 30 deadlines.**

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 has made 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 have been implemented while remaining consistent with a state's emergency preparedness or pandemic plan. **CMS will end this flexibility at the conclusion of the PHE**.

- *Provision of Services***:** CMS has been 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 now allows 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. **CMS will end this flexibility at the conclusion of the PHE.**

- *Partial Hospitalization Services*. For Partial Hospitalization Program services, during the PHE, 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, as 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 in furnished in an expanded CMHC. **When the PHE ends, these flexibilities will end as well.**

- *Forty percent rule***:** CMS has been waiving the requirement at § 485.918(b)(1)(v) that a CMHC provides at least 40% of its items and services to individuals who are not eligible for Medicare benefits. Waiving the 40% requirement facilitates appropriate timely discharge from inpatient psychiatric units and prevents admissions to these facilities, because CMHCs have been 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 allows communities greater access to health services, including mental health services. **This will expire at the end of the COVID-19 public health emergency.**

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.