

Teaching Hospitals, Teaching Physicians and Medical Residents: 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 that the PHE ends, 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 PHE

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/COV-IDOTCtestsProvider>. **This program will end at the end of the COVID-19 public health emergency.**

Workforce

- *Application of Teaching Physician Regulations:* Under current rules, Medicare payment is made for services furnished by a teaching physician involving residents only if the physician is physically present for the key portion of the service or procedure, and immediately available to furnish services during the entire procedure, where applicable. During the COVID-19 PHE, teaching physicians may use audio/video real time communications technology to interact with the resident through virtual means, which would meet the requirement that they be present for the key portion of the service, including when the teaching physician involves the resident in furnishing Medicare Telehealth services. After the PHE, CMS is exercising enforcement discretion to allow teaching physicians in all teaching settings to be present virtually, through audio/video real-time communications technology, for purposes of billing under the PFS for services they furnish involving resident physicians. We are exercising this enforcement discretion through December 31, 2023, as we anticipate considering our policy for services

involving teaching physicians and residents further through our rulemaking process. These flexibilities do not apply in the case of surgical, high risk, interventional, or other complex procedures, services performed through an endoscope, and anesthesia services. This allows teaching hospitals to maximize their workforce to safely take care of patients.

- Teaching physicians involving residents in providing care at certain primary care centers can provide the necessary direction, management, and review for services furnished by up to four residents at a time using audio/video real-time communications technology. After the PHE, CMS is exercising enforcement discretion to allow teaching physicians in all teaching settings to be present virtually, through audio/video real-time communications technology, for purposes of billing under the PFS for services they furnish involving resident physicians. We are exercising this enforcement discretion through December 31, 2023, as we anticipate considering our policy for services

involving teaching physicians and residents further through our rulemaking process. During the PHE, teaching physicians can oversee and bill for an expanded scope of care furnished by up to four residents at a time in certain primary care centers, including all levels of an office/outpatient evaluation and management (E/M) visit, telephone E/M, care management, and communication technology-based services. After the PHE, teaching physicians cannot bill for levels 4-5 of an office/outpatient evaluation and management (E/M) visit furnished by residents in these primary care centers in any location.

- *Resident Moonlighting:* Under our permanent policy, Medicare considers the services of residents that are not related to their approved graduate medical education programs and performed in the outpatient department or the emergency department of a hospital as the resident's separately billable physicians' services. Medicare also considers the services of residents that are not related to their approved GME programs and furnished to inpatients of a hospital in which they have their training program as separately billable physicians' services. **This is unchanged and will continue after the PHE.**
- *Counting of Resident Time at Alternate Locations:* Existing regulations have specific rules on when a hospital may count a resident for purposes of Medicare direct graduate medical education (DGME) payments or indirect medical education (IME) payments. Normally, if the resident is performing activities within the scope of his/her approved program in his/her own home, or a patient's home, the hospital may not count the resident. During the COVID-19 PHE, a hospital that is paying the resident's salary and fringe benefits for the time that the resident is at home or in a patient's home, but

performing duties within the scope of the approved residency program and meeting appropriate physician supervision requirements, could claim that resident for IME and DGME purposes. This allowed medical residents to perform their duties in alternative locations, including their own home or a patient's home, as long as such activities meet appropriate physician supervision requirements. When the COVID-19 PHE ends, a hospital may not count a resident for purposes of Medicare DGME payments or IME payments if the resident is performing activities within the scope of his/her approved program in his/her own home, or a patient's home.

- *Graduate Medical Education (GME) Residents' Training in Other Hospitals:* During the COVID-19 PHE, a teaching hospital that sends residents to other hospitals has been able to continue to claim those residents in the teaching hospital's IME and DGME FTE resident counts, if certain requirements are met. Those requirements include that 1) the teaching hospital sends the resident to the other hospital in response to the COVID-19 pandemic; 2) the time spent by the resident training at the other hospital is in lieu of time that would have been spent training at the sending hospital; and 3) the time that

the resident spent training immediately prior to and/or subsequent to the time frame that the COVID-19 PHE has been in effect has been included in the FTE count for the sending hospital. Moreover, the presence of residents in non-teaching hospitals has not triggered establishment of IME and/or DGME FTE resident caps at those non-teaching hospitals. Specifically, for DGME, the presence of residents in non-teaching hospitals has not triggered establishment of PRAs at those non-teaching hospitals. When the COVID-19 PHE ends, a teaching hospital that sends residents to other hospitals cannot claim those residents in its IME and DGME FTE resident counts. Also, when the COVID-19 PHE ends, the presence of residents in non-teaching hospitals will trigger establishment of IME and/or DGME FTE resident caps at those non-teaching hospitals (and for DGME, it will trigger establishment of PRAs at those non-teaching hospitals).

- *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.

- *IME Payments Held Harmless for Temporary Increase in Beds:* During the COVID-19 PHE, CMS has held teaching hospitals harmless from a reduction in IME payments due to beds temporarily added during the COVID-19 PHE, by not considering such beds when determining IME payments. **When the COVID-19 PHE ends, any added beds will be considered in determining the hospital's IME payments.**
- *Inpatient Psychiatric Facilities (IPFs) and Inpatient Rehabilitation Facilities (IRFs) Teaching Status Adjustment Payments:* To ensure that teaching IPFs and IRFs can alleviate bed capacity issues by taking patients from the inpatient acute care hospitals without being penalized by lower teaching status adjustments, we have been freezing the IPFs' and IRFs' teaching status adjustment payments at their values prior to the PHE.

For the duration of the COVID-19 PHE, a teaching IPF's and a teaching IRF's teaching status adjustment payments have been the same as they were on the day before the COVID-19 PHE was declared. **When the COVID-19 PHE ends, any change to a teaching IPF's or a teaching IRF's average daily census will be considered in determining its teaching status adjustment payments.**

- *Sterile Compounding:* CMS has been waiving hospital sterile compounding requirements 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. **This waiver will end 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. **This waiver will end 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 and that a physician be

on call at all times. This allows hospitals to use other practitioners, such as physician's assistants and nurse practitioners, to the fullest extent possible. These waivers have been implemented while remaining consistent with a state's emergency preparedness or pandemic plan. **These waivers will end 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. **This will expire at the end of the COVID-19 public health emergency.**
- *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 will expire at the end of the COVID-19 public health emergency.**
- *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 C.F.R 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. **This will expire at the end of the COVID-19 public health emergency.**
- *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. **CMS will end this waiver at the conclusion of the COVID-19 PHE.**

CMS Hospitals Without Walls (Temporary Expansion Sites)

- *Hospitals Able to Provide Inpatient Care in Temporary Expansion Sites:* As part of the CMS Hospital Without Walls initiative, during the PHE hospitals could provide hospital services in other health care facilities and sites not otherwise considered to be part of a health care facility, or 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 or sites not considered part of a health care facility, such as hotels or community facilities. This flexibility allows 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 PHE, CMS allowed hospitals to screen patients at offsite locations and furnish inpatient and outpatient services at temporary expansion sites. Hospitals have still been expected to control and oversee the services provided at an alternative location. **When the COVID-19 PHE ends, hospitals will be required to provide services to patients within their hospital departments.**
- *Relaxing Conditions of Participation.* Under an additional initiative, CMS has been relaxing certain conditions of participation (CoPs) for hospital operations to maximize hospitals' ability to focus on patient care. The same initiative has also allowed 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 freestanding emergency departments (IFEDs), could pursue enrolling as an ASC and then pursue converting their enrollment to hospital during the PHE. As of December 1, 2021, no new ASC or new IFED requests to temporarily enroll as hospitals have been accepted. Refer to <https://www.cms.gov/files/document/qso-22-03-asc-hospital.pdf> for more information. **When the PHE ends, ASCs can only be paid under the ASC payment system for services on the ASC Covered Procedures List. When the COVID-19 PHE ends, IFEDs cannot bill Medicare for services as their temporary Medicare certification would end.**
- *Off Site Patient Screening:* CMS has been waiving the enforcement of section 1867(a) of the Social Security Act (the Emergency Medical Treatment and Labor Act, or EMTALA). This has been allowing 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 consistent with the state emergency preparedness or pandemic plan. **This waiver will terminate at the end of the COVID-19 PHE.**

- *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 have:

- Not used SNF swing beds for acute level care.
- Complied with all other hospital conditions of participation and those SNF provisions set out at 42 CFR 482.58(b) to the extent not waived.
- Been 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.
- 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) consistent 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. **This waiver will terminate at the end of the COVID-19 PHE.**

- *Paperwork Requirements:* CMS has been waiving certain specific paperwork requirements only for hospitals that are considered to be impacted by a widespread outbreak of COVID-19. This allows hospitals to establish COVID-19 specific areas. This waiver will terminate at the end of the PHE. 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 has been 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 has been permitting 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. **This waiver will terminate at the end of the COVID-19 PHE.**

- *Critical Access Hospital 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 will expire at the end of the COVID-19 public health emergency.**
- *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 allows the CAH flexibility in establishing off-site locations. In an effort to facilitate the establishment of CAHs without walls, these waivers remove restrictions on CAHs regarding their rural location and their location relative to other hospitals and CAHs. These flexibilities have been implemented while consistent with state or emergency or pandemic plan. **CMS will end this waiver at the conclusion of the COVID-19 PHE.**
- *Housing Acute Care Patients in Excluded Distinct Part Units:* 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 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. At the end of the PHE, acute care hospitals cannot bill for acute care inpatients housed in excluded distinct part units.
- *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

²Please 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.

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 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. **At the end of the PHE, 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.**

- *Care for Excluded Inpatient Rehabilitation 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 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. **At the end of the PHE, 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.**
- *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. **CMS will end this waiver at the conclusion of the COVID-19 PHE.**

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:

- o 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.
- o 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.
- o 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.
- o 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.
- o 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.
 - o 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.
 - o 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 allows for more efficient treatment of patients in a surge situation. **CMS will end this waiver at the conclusion of the PHE.**
 - *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. **CMS will end this waiver at the conclusion of the PHE.**
 - *Limit Discharge Planning for Hospital and CAHs*: To allow hospitals and CAHs more time to focus on increasing care demands, discharge planning has focused 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). 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. The hospital 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. **CMS will end this waiver at the conclusion of the PHE.**

- *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 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 need 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 these requirements under 42 CFR §482.24(c)(4)(viii) and §485.638(a)(4)(iii) 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 has allowed 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 their 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 that deadline, CMS further extended this deadline to September 3, 2020. Hospitals could submit 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.**
- *Extension of Comprehensive Care for Joint Replacement (CJR) Model Year 5:* In the IFC issued October 28, 2020, CMS extended Performance Year (PY) five of the Comprehensive Care for Joint Replacement (CJR) model an additional 6 months, so that PY five ended September 30, 2021. To accommodate the extension of PY 5, CMS performed 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, expired on March 31, 2021. Beginning on April 1, 2021 through the end of the model, the extreme and uncontrollable circumstances policy for COVID-19 has been episode based, where 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.
- *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 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 deadlines 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 these requirements at 42 CFR §482.1(a)(3) and 42 C.F.R §482.30 that require 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 allow hospitals to focus more resources on providing direct patient care. **CMS will end this waiver at the conclusion of the PHE.**
- *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 of 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 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. This waiver applies to both hospitals and CAHs. **CMS will end this waiver at the conclusion of the PHE.**
- *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 require 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 has been 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 have not needed 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 allow 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 require 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 has not been an expectation for a temporary expansion site. These waivers remove the burden on facilities to establish these policies and procedures for their surge facilities or surge sites. **CMS will end these waivers at the conclusion of the PHE.**

- **Signature Requirements:** CMS has been waiving 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 have been documenting 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.**

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>.

- Providers that 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.**
- *Opt-Out Enrollment:* CMS allowed practitioners to cancel their opt-out status early and enroll in Medicare to provide care to more patients. CMS also allowed MACs to accept opt-out cancellation requests via email, fax, or phone call to the hotline. CMS allowed a provider to submit an application (an 855-I or 855-R for example) to cancel their opt-out. Providers were not required to submit a written notification to cancel their opt-out status. **When the PHE ends, this waiver will terminate and opted-out practitioners will not be able to cancel their opt-out statuses earlier than the applicable regulation at 42 CFR 405.445 allows for.**
- *Reporting Home Address:* During the PHE, CMS allowed practitioners to render telehealth services from their home without reporting their home address on their Medicare enrollment while continuing to bill from their currently enrolled location. **When the PHE ends, the waiver will continue through December 31, 2024.**
- *State Licensure:* During the PHE, CMS allowed licensed physicians and other practitioners to bill Medicare for services provided outside of their state of enrollment. **CMS has determined that, when the PHE ends, CMS regulations will continue to allow for a total deferral to state law.** Thus, there is no CMS-based requirement that a provider must be licensed in its state of enrollment.

Payment for Innovative COVID-19 Therapies

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 as applicable) 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.**

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 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 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.**

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 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>.

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>