Exhibit 342

COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers

https://www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf

COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers

The Administration is taking aggressive actions and exercising regulatory flexibilities to help healthcare providers contain the spread of 2019 Novel Coronavirus Disease (COVID-19). CMS is empowered to take proactive steps through 1135 waivers as well as, where applicable, authority granted under section 1812(f) of the Social Security Act (the Act) and rapidly expand the Administration's aggressive efforts against COVID-19. As a result, the following blanket waivers are in effect, with a retroactive effective date of March 1, 2020, through the end of the emergency declaration. For general information about waivers, see Attachment A to this document. **These waivers DO NOT require a request to be sent to the 1135waiver@cms.hhs.gov mailbox or that notification be made to any of CMS' regional offices.**

Unless otherwise noted, these waivers will terminate at the end of the COVID-19 public health emergency (PHE).

Flexibility for Medicare Telehealth Services

- **Eligible Practitioners.** Pursuant to authority granted under the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) that broadens the waiver authority under section 1135 of the Social Security Act, the Secretary has authorized additional telehealth waivers. CMS is waiving the requirements of section 1834(m)(4)(E) of the Act and 42 CFR § 410.78 (b)(2), which specify the types of practitioners that may bill for their services when furnished as Medicare telehealth services from the distant site. The waiver of these requirements expands the types of health care professionals who can furnish distant site telehealth services to include all those who are eligible to bill Medicare for their professional services. This allows health care professionals who were previously ineligible to furnish and bill for Medicare telehealth services, including physical therapists, occupational therapists, speech language pathologists, and others, to receive payment for Medicare telehealth services. **This waiver will end 151 days after the conclusion of the PHE.**

- **Audio-Only Telehealth for Certain Services.** Pursuant to authority granted under the CARES Act, CMS is waiving the requirements of section 1834(m)(1) of the Act and 42 CFR § 410.78(a)(3) for use of interactive telecommunications systems to furnish telehealth services, to the extent they require use of video technology, for certain services. This waiver allows the use of audio-only equipment to furnish services described by the codes for audio-only telephone evaluation and management services, and behavioral health counseling and educational services (see designated codes https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes). Unless provided otherwise, other services included on the Medicare telehealth services list must be furnished using, at a minimum,

audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner**. This waiver will end 151 days after the conclusion of the PHE.**

Hospitals, Psychiatric Hospitals, and Critical Access Hospitals (CAHs), including Cancer Centers and Long-Term Care Hospitals (LTCHs)

- **Emergency Medical Treatment & Labor Act (EMTALA).** CMS is waiving the enforcement of section 1867(a) of the Act. This will allow hospitals, psychiatric hospitals, and critical access hospitals (CAujHs) to screen patients at a location offsite from the hospital's campus to prevent the spread of COVID-19, as long as it is consistent with a state's emergency preparedness or pandemic plan.

- **Verbal Orders.** CMS is waiving the requirements of 42 CFR §482.23, §482.24 and §485.635(d)(3) to provide additional flexibility related to verbal orders where read-back verification is required but authentication may occur later than 48 hours. This will allow more efficient treatment of patients in surge situations. Specifically, the following requirements are waived:
    - §482.23(c)(3)(i) — If verbal orders are used for the use of drugs and biologicals (except immunizations), they are to be used infrequently.
    - §482.24(c)(2) — All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner or by another practitioner who is responsible for the care of the patient.
    - §482.24(c)(3) — Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders. This would include all subparts at §482.24(c)(3).
    - §485.635(d)(3) — Although the regulation requires that medication administration be based on a written, signed order, this does not preclude the CAH from using verbal orders. A practitioner responsible for the care of the patient must authenticate the order in writing as soon as possible after the fact.

- **Reporting Requirements**. CMS is waiving the requirements at 42 CFR §482.13(g) (1)(i)-(ii), which require that hospitals report patients in an intensive care unit whose death is caused by their disease, but who required soft wrist restraints to prevent pulling tubes/IVs, no later than the close of business on the next business day. Due to current hospital surge, CMS is waiving this requirement to ensure that hospitals are focusing on increased patient care demands and increased patient census, provided any death where the restraint may have contributed is still reported within standard time limits (i.e., close of business on the next business day following knowledge of the patient's death).

- **Patient Rights.** CMS is waiving requirements under 42 CFR §482.13 **only for hospitals that are considered to be impacted by a widespread outbreak of COVID-19**. Hospitals that are located in a state that has widespread confirmed cases (i.e., 51 or more confirmed cases*), as updated on the CDC website at, CDC States Reporting Cases of COVID-19, would not be required to meet the following requirements:
    - §482.13(d)(2) — With respect to timeframes in providing a copy of a medical record.
    - §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.
    - §482.13(e)(1)(ii) — Regarding seclusion.

  *The waiver flexibility is based on the number of confirmed cases as reported by CDC and will be assessed accordingly when COVID-19 confirmed cases decrease.

- **Sterile Compounding.** CMS is waiving requirements (also outlined in USP797) at 42 CFR §482.25(b)(1) and §485.635(a)(3) in order to allow used face masks to be removed and retained in the compounding area to be re-donned and reused during the same work shift in the compounding area only. This will conserve scarce face mask supplies. CMS will not review the use and storage of face masks under these requirements.

- **Detailed Information Sharing for Discharge Planning for Hospitals and CAHs.** CMS is waiving the requirement 42 CFR §482.43(a)(8), §482.61(e), and §485.642(a)(8) to provide detailed information regarding discharge planning, described below:
    - 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) quality measures and resource use measures. The hospital must ensure that the post-acute care data on quality measures and resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.
    - CMS is maintaining the discharge planning requirements that ensure a patient is discharged to an appropriate setting with the necessary medical information and goals of care as described in 42 CFR §482.43(a)(1)-(7) and (b).

- **Limiting Detailed Discharge Planning for Hospitals.** During the PHE**,** CMS is waiving all the requirements and subparts at 42 CFR §482.43(c) related to post-acute care services so as to expedite the safe discharge and movement of patients among care settings and to be responsive to fluid situations in various areas of the country. CMS is maintaining the discharge planning requirements that ensure a patient is discharged to an appropriate setting with the necessary medical information and goals of care as described in 42 CFR §482.43(a)(1)-(7) and

(b). CMS is waiving the more detailed requirement that, for patients discharged home and referred for HHA services, transferred to a SNF for post-hospital extended care services, or transferred to an IRF or LTCH for specialized hospital services, hospitals must:

  - §482.43(c)(1): Include in the discharge plan a list of HHAs, SNFs, IRFs, or LTCHs that are available to the patient.
  - §482.43(c)(2): Inform the patient or the patient's representative of their freedom to choose among participating Medicare providers and suppliers of post-discharge services.
  - §482.43(c)(3): Identify in the discharge plan any HHA or SNF to which the patient is referred in which the hospital has a disclosable financial interest, as specified by the Secretary, and any HHA or SNF that has a disclosable financial interest in a hospital under Medicare.

- **Medical Staff.** CMS is waiving requirements under 42 CFR §482.22(a)(1)-(4) to allow for physicians whose privileges will expire to continue practicing at the hospital and for new physicians to be able to practice before full medical staff/governing body review and approval to address workforce concerns related to COVID-19. CMS is waiving §482.22(a) (1)-(4) regarding details of the credentialing and privileging process. **(Please also refer to Practitioner Locations Blanket Waiver listed below.)**

- **Medical Records.** CMS is waiving requirements under 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, and these flexibilities may be implemented as long as they are consistent with a state's emergency preparedness or pandemic plan. CMS is waiving §482.24(c)(4)(viii) related to medical records to allow flexibility in completion of medical records within 30 days following discharge from a hospital. This flexibility will allow clinicians to focus on the patient care at the bedside during the pandemic.

- **Flexibility in Patient Self Determination Act Requirements (Advance Directives).** CMS is waiving the requirements at sections 1902(a)(58) and 1902(w)(1)(A) of the Act (for Medicaid); 1852(i) of the Act (for Medicare Advantage); and 1866(f) of the Act and 42 CFR §489.102 (for Medicare), which require hospitals and CAHs to provide information about their advance directive policies to patients. CMS is waiving this requirement to allow staff to more efficiently deliver care to a larger number of patients.

- **Physical Environment.** CMS is waiving certain physical environment requirements under the Medicare conditions of participation at 42 CFR §482.41 and 42 CFR §485.623 to allow for increased flexibilities for surge capacity and patient quarantine at hospitals, psychiatric hospitals, and critical access hospitals (CAHs) as a result of COVID-19. CMS will permit facility

and non-facility space that is not normally used for patient care to be utilized for patient care or quarantine, provided the location is approved by the state (ensuring that safety and comfort for patients and staff are sufficiently addressed) and is consistent with the state's emergency preparedness or pandemic plan. This allows for increased capacity and promotes appropriate cohorting of COVID-19 patients. States are still subject to obligations under the integration mandate of the Americans with Disabilities Act, to avoid subjecting persons with disabilities to unjustified institutionalization or segregation[1].

- **Telemedicine.** CMS is waiving the provisions related to telemedicine at 42 CFR §482.12(a) (8)–(9) for hospitals and §485.616(c) for CAHs, 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 PHE.**

- **Physician Services.** CMS is waiving requirements under 42 CFR §482.12(c)(1)–(2) and §482.12(c)(4), which requires that Medicare patients be under the care of a physician. This waiver may be implemented as long as it is consistent with a state's emergency preparedness or pandemic plan. This allows hospitals to use other practitioners to the fullest extent possible.

- **Anesthesia Services.** CMS is waiving requirements under 42 CFR §482.52(a)(5), §485.639(c) (2), and §416.42 (b)(2) that a certified registered nurse anesthetist (CRNA) is under the supervision of a physician in paragraphs §482.52(a)(5) and §485.639(c)(2). CRNA supervision will be at the discretion of the hospital and state law. This waiver applies to hospitals, CAHs, and Ambulatory Surgical Centers (ASCs). These waivers will allow CRNAs to function to the fullest extent of their licensure, and may be implemented as long as they are consistent with a state's emergency preparedness or pandemic plan.

- **Utilization Review.** CMS is waiving certain requirements under 42 CFR §482.1(a)(3) and 42 CFR §482.30, which address the statutory basis for hospitals and includes the requirement that hospitals participating in Medicare and Medicaid must have a utilization review plan that meets specified requirements.
    - CMS is waiving the entire utilization review condition of participation: Utilization Review (UR), at §482.30, requires that a hospital must have a UR plan with a UR committee that provides for a 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 may be implemented as long as they are

[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 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.

consistent with a state's emergency preparedness or pandemic plan. Removing these administrative requirements will allow hospitals to focus more resources on providing direct patient care.

- **Written Policies and Procedures for Appraisal of Emergencies at Off Campus Hospital Departments**. CMS is waiving 42 CFR §482.12(f)(3), emergency services, with respect to surge facilities **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 may be implemented as long as they are consistent with a state's emergency preparedness or pandemic plan.

- **Emergency Preparedness Policies and Procedures.** CMS is waiving 42 CFR §482.15(b) and §485.625(b), which requires the hospital and CAH to develop and implement emergency preparedness policies and procedures, and §482.15(c)(1)–(5) and §485.625(c)(1)–(5), which requires that the emergency preparedness communication plans for hospitals and CAHs to contain specified elements with respect to the surge site. The requirement under the communication plan requires hospitals and CAHs to have specific contact information for staff, entities providing services under arrangement, patients' physicians, other hospitals and CAHs, and volunteers. This would not be an expectation for the surge site. This waiver applies to both hospitals and CAHs, and removes the burden on facilities to establish these policies and procedures for their surge facilities or surge sites.

- **Quality Assessment and Performance Improvement Program.** CMS is waiving 42 CFR §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 Quality Assurance & Performance Improvement (QAPI) programs (for hospitals that are part of a hospital system). These flexibilities, which apply to both hospitals and CAHs, may be implemented as long as they are consistent with a state's emergency preparedness or pandemic plan. We expect any improvements to the plan to focus on the Public Health Emergency (PHE). 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.

- **Nursing Services.** CMS is waiving the requirements at 42 CFR §482.23(b)(4), which requires the nursing staff to develop and keep current a nursing care plan for each patient, and §482.23(b)(7), which 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 expect

that hospitals will need relief for the provision of inpatient services and, as a result, the requirement to establish nursing-related policies and procedures for outpatient departments is likely of lower priority. These flexibilities apply to both hospitals and CAHs §485.635(d)(4), and may be implemented as long as they are consistent with a state's emergency preparedness or pandemic plan.

- **Food and Dietetic Services.** CMS is waiving the requirement at paragraph 42 CFR §482.28(b)(3), which requires providers 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 may be implemented as long as they are consistent with a state's emergency preparedness or pandemic plan. Removing these administrative requirements will allow hospitals to focus more resources on providing direct patient care.

- **Respiratory Care Services.** CMS is waiving the requirements at 42 CFR §482.57(b)(1) that require hospitals to designate in writing the personnel qualified to perform specific respiratory care procedures and the amount of supervision required for personnel to carry out specific procedures. These flexibilities may be implemented as long as they are consistent with a state's emergency preparedness or pandemic plan. Not being required to designate these professionals in writing will allow qualified professionals to operate to the fullest extent of their licensure and training in providing patient care.

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

  In order to qualify for this waiver, hospitals must:

  - Not use SNF swing beds for acute level care.
  - Comply with all other hospital conditions of participation and those SNF provisions set out at 42 CFR 482.58(b) to the extent not waived.
  - Be consistent with the state's emergency preparedness or pandemic plan.

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

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

- **Medicare Graduate Medical Education (GME) Affiliation Agreement:** Due to the COVID-19 Public Health Emergency (PHE), under the authority of section 1135(b)(5) of the Social Security Act (the Act), extended the submission deadline for both new Medicare GME affiliation agreements and amendments to existing Medicare GME affiliation agreements to January 1, 2022. CMS previously 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. **This waiver is no longer applicable**.
- **CAH Personnel Qualifications.** CMS is waiving the minimum personnel qualifications for clinical nurse specialists at paragraph 42 CFR §485.604(a)(2), nurse practitioners, at paragraph

§485.604(b)(1)–(3), and physician assistants at paragraph §485.604(c)(1)–(3). Removing these federal personnel requirements will allow CAHs to employ individuals in these roles who meet state licensure requirements and provide maximum staffing flexibility. These flexibilities should be implemented as long as they are consistent with a state's emergency preparedness or pandemic plan.

- **CAH Staff Licensure.** CMS is deferring to staff licensure, certification, or registration to state law by waiving 42 CFR §485.608(d) regarding the requirement that staff of the CAH be licensed, certified, or registered in accordance with applicable federal, state, and local laws and regulations. This waiver will provide maximum flexibility for CAHs to use all available clinicians. These flexibilities may be implemented as long as they are consistent with a state's emergency preparedness or pandemic plan.

- **CAH Status and Location.** CMS is waiving the requirement at 42 CFR §485.610(b) that the CAH be located in a rural area or an area being treated as being rural, allowing the CAH flexibility in the establishment of surge site locations. CMS is also waiving the requirement at §485.610(e) regarding the CAH's off-campus and co-location requirements, allowing the CAH flexibility in establishing temporary off-site locations. In an effort to facilitate the establishment of CAHs without walls, these waivers will suspend restrictions on CAHs regarding their rural location and their location relative to other hospitals and CAHs. These flexibilities may be implemented as long as they are consistent with a state's emergency preparedness or pandemic plan.

- **CAH Length of Stay.** CMS is waiving the requirements that 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 for number of beds and length of stay at 42 CFR §485.620.

- **Temporary Expansion Locations:** For the duration of the PHE related to COVID-19, CMS is waiving certain requirements, under the Medicare conditions of participation at 42 CFR §482.41 and §485.623 (as noted elsewhere in this waiver document) and the provider-based department requirements at §413.65, to allow hospitals to establish and operate as part of the hospital any location meeting those conditions of participation, for hospitals that continue to apply during the PHE. This waiver also allows hospitals to change the status of their current provider-based department locations to the extent necessary to address the needs of hospital patients as part of the state or local pandemic plan. This extends to any entity operating as a hospital (whether a current hospital establishing a new location or an Ambulatory Surgical Center (ASC) enrolling as a hospital during the PHE, pursuant to a streamlined enrollment and survey and certification process), as long as the relevant location meets the conditions of participation and other requirements not waived by CMS. This waiver will enable hospitals to meet the needs of Medicare beneficiaries.

- **Responsibilities of Physicians in Critical Access Hospitals (CAHs).** 42 CFR § 485.631(b)(2). CMS is waiving the requirement for CAHs that a doctor of medicine or osteopathy be physically

present to provide medical direction, consultation, and supervision for the services provided in the CAH at § 485.631(b)(2). CMS is retaining the regulatory language in the second part of the requirement at § 485.631(b)(2) that a physician be available "through direct radio or telephone communication, or electronic communication for consultation, assistance with medical emergencies, or patient referral." Retaining this longstanding CMS policy, and related longstanding subregulatory guidance that further described communication between CAHs and physicians, will assure an appropriate level of physician direction and supervision for the services provided by the CAH. This will allow the physician to perform responsibilities remotely, as appropriate. This also allows CAHs to use nurse practitioners and physician assistants to the fullest extent possible, while ensuring necessary consultation and support as needed.

- **Postponement of Application Deadline to the Medicare Geographic Classification Review Board *(New since 7/29 Release).*** Per requirements at section 1886(d)(10)(C)(ii), of the Social Security Act (the Act), and 42 CFR 412.256(a)(2), September 1, 2020 is the deadline to submit an application to the Medicare Geographic Classification Review Board (MGCRB) for FY 2022 reclassifications. These provisions require applications to be filed through OH CDMS (https://www.cms.gov/Regulations-and-Guidance/Review-Boards/MGCRB/Electronic-Filing) not later than the first day of the 13-month period preceding the federal fiscal year for which reclassification is requested.

  Due to the COVID-19 Public Health Emergency (PHE), under the authority of section 1135(b)(5) of the Act, CMS 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 September 1, 2021 deadline for submission of applications for FY 2023 reclassifications to the MGCRB due to the COVID-19 PHE. Similarly, the deadline for submission of applications for FY 2024 reclassifications to the MGCRB is expected to be September 1, 2022, consistent with the existing requirements.

- **Long-Term Care Hospitals — Site Neutral Payment Rate Provisions.** Also as required by section 3711(b) of the CARES Act, during the Public Health Emergency (PHE) due to COVID-19, the Secretary has waived section 1886(m)(6) of the Social Security Act relating to certain site neutral payment rate provisions for long-term care hospitals (LTCHs).
    - Section 3711(b)(1) of the CARES Act waives the payment adjustment under section 1886(m)(6)(C)(ii) of the Act for LTCHs that do not have a discharge payment percentage (DPP) for the period that is at least 50% during the COVID-19 public health emergency period. Under this provision, for the purposes of calculating an LTCH's DPP, all admissions during the COVID-19 public health emergency period will be counted in the numerator of the calculation, that is, LTCH cases that were admitted during the COVID-19 public health emergency period will be counted as discharges paid the LTCH PPS standard federal payment rate.

- Section 3711(b)(2) of the CARES Act provides a waiver of the application of the site neutral payment rate under section 1886(m)(6)(A)(i) of the Act for those LTCH admissions that are in response to the public health emergency and occur during the COVID-19 public health emergency (PHE) period. Under this provision, all LTCH cases admitted during the COVID-19 public health emergency period (that is, admissions occurring on or after January 27, 2020 through the duration of the COVID-19 PHE) were paid the relatively higher LTCH PPS standard federal rate. When the PHE ends, all LTCH admissions, except those that meet the requirements for exclusion from the site neutral rate, are subject to the site neutral payment rate under section 1886(m)(6)(A)(i) of the Act.

- **Conditions of Participation (CoP) for COVID-19 Vaccinations.** ***(New since 12/1/20 Release).*** Under the authority afforded by Section 1135 of the Social Security Act, for the duration of the Public Health Emergency, CMS is modifying the following regulation:

  § 482.23 Condition of participation: Nursing services.

  (c) Standard: Preparation and administration of drugs.

  (3) With the exception of influenza and pneumococcal vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with state law and hospital policy, and who is responsible for the care of the patient.

  To allow for hospital and community administration of COVID-19 vaccines, the following highlighted language is being incorporated into this regulation for the duration of the PHE:

  § 482.23 Condition of participation: Nursing services.

  (c) Standard: Preparation and administration of drugs.

  (3) With the exception of influenza, pneumococcal, and COVID-19 vaccines (either currently approved by the FDA or authorized under an FDA Emergency Use Authorization), which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with state law and hospital policy, and who is responsible for the care of the patient.

Hospitals Classified as Sole Community Hospitals (SCHs)

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

Hospitals Classified as Medicare-Dependent, Small Rural Hospitals (MDHs) (updated 10/7/21)

- **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 percent of the hospital's inpatient days or discharges were attributable to individuals entitled to Medicare Part A benefits during the specified hospital cost reporting periods. CMS 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 PHE ends, MACs will resume their standard practice for evaluation of all eligibility requirements.

Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

- **Certain staffing requirements***:* CMS has been waiving the requirement in the second sentence of 42 CFR §491.8(a)(6) that a nurse practitioner, physician assistant, or certified nurse-midwife be available to furnish patient care services at least 50% of the time the RHC and FQHC operates. CMS is not waiving the first sentence of §491.8(a)(6), which requires a physician, nurse practitioner, physician assistant, certified nurse-midwife, clinical social worker, or clinical psychologist to be available to furnish patient care services at all times the clinic or center operates. This will assist in addressing potential staffing shortages by increasing flexibility regarding staffing mixes during the PHE. CMS is exploring options to make this flexibility permanent.

- **Physician Supervision of NPs in RHCs and FQHCs.** 42 CFR 491.8(b)(1). We are modifying the requirement that physicians must provide medical direction for the clinic's or center's health

care activities and consultation for, and medical supervision of, the health care staff, only with respect to medical supervision of nurse practitioners, and only to the extent permitted by state law. The physician, either in person or through telehealth and other remote communications, continues to be responsible for providing medical direction for the clinic or center's health care activities and consultation for the health care staff, and medical supervision of the remaining health care staff. This allows RHCs and FQHCs to use nurse practitioners to the fullest extent possible and allows physicians to direct their time to more critical tasks. **This flexibility is currently set to return to pre-PHE rules at the end of the calendar year that the PHE ends. CMS is exploring options to make this flexibility permanent**.

- **Temporary Expansion Locations.** CMS is waiving the requirements at 42 CFR §491.5(a)(3)(iii), which require RHCs and FQHCs to be independently considered for Medicare approval if services are furnished in more than one permanent location. Due to the current PHE, CMS is temporarily waiving this requirement, removing the location restrictions to allow flexibility for existing RHCs/FQHCs to expand service locations to meet the needs of Medicare beneficiaries. This flexibility includes areas that may be outside of the location requirements 42 CFR §491.5(a)(1) and (2), but will end when the HHS Secretary determines there is no longer a PHE due to COVID-19.

Housing Acute Care Patients in the IRF or Inpatient Psychiatric Facility (IPF) Excluded Distinct Part Units

- CMS is waiving requirements to allow acute care hospitals to house acute care inpatients in excluded distinct part units, such as excluded distinct part unit IRFs or IPFs, where the distinct part unit's beds are appropriate for acute care inpatients. The Inpatient Prospective Payment System (IPPS) hospital should bill for the care and annotate the patient's medical record to indicate the patient is an acute care inpatient being housed in the excluded unit because of capacity issues related to the disaster or emergency.

Care for Excluded Inpatient Psychiatric Unit Patients in the Acute Care Unit of a Hospital

- CMS is allowing acute care hospitals, with excluded distinct part inpatient psychiatric units, to relocate inpatients from the excluded distinct part psychiatric unit to an acute care bed and unit, as a result of a disaster or emergency. The hospital should continue to bill for inpatient psychiatric services for these patients, under the Inpatient Psychiatric Facility Prospective Payment System, 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 emergency. This waiver may be utilized where the hospital's acute care beds are appropriate for psychiatric patients and the staff and

environment are conducive to safe care. For psychiatric patients, this includes assessment of the acute care bed and unit location to ensure those patients at risk of harm to self and others are safely cared for.

Care for Excluded Inpatient Rehabilitation Unit Patients in the Acute Care Unit of a Hospital

- CMS is allowing 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 as a result of this PHE. The hospital should continue to bill for inpatient rehabilitation services for these patients, under the inpatient rehabilitation facility prospective payment system, and annotate the medical record to indicate the patient is a rehabilitation inpatient being cared for in an acute care bed, because of capacity or other exigent circumstances related to the disaster or emergency. This waiver may be utilized where the hospital's acute care beds are appropriate for providing care to rehabilitation patients, and such patients continue to receive intensive rehabilitation services. When the 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.

Flexibility for Inpatient Rehabilitation Facilities Regarding the "60% Rule"

- CMS is allowing IRFs to exclude patients from the freestanding hospital's or excluded distinct part unit's inpatient population for purposes of calculating the applicable thresholds associated with the requirements to receive payment as an IRF (commonly referred to as the "60% rule") if an IRF admits a patient solely to respond to the emergency and the patient's medical record properly identifies the patient as such. In addition, during the applicable waiver time period, we would also apply the exception to facilities not yet classified as IRFs, but that are attempting to obtain classification as an IRF. When the PHE ends, all inpatients will again be included in the freestanding hospital's or excluded distinct part unit's inpatient population for purposes of calculating the applicable thresholds associated with the requirements to receive payment as an IRF (commonly referred to as the "60% rule").

Inpatient Rehabilitation Facility – Intensity of Therapy Requirement ("3-Hour Rule")

- As required by section 3711(a) of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, during the COVID-19 public health emergency, the Secretary has waived 42 CFR § 412.622(a)(3)(ii), which provides that payment generally requires that patients of an inpatient rehabilitation facility receive at least 15 hours of therapy per week. This waiver clarifies information provided in "Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (CMS-1744-IFC). (85 Federal

Register 19252, 19287, April 6, 2020). The information in that rulemaking (CMS-1744-IFC) about Inpatient Rehabilitation Facilities was contemplated prior to the passage of the CARES Act.

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. Completed 2019 Occupational Mix Surveys, Hospital Reporting Form CMS-10079, for the Wage Index Beginning FY 2022, were initially due to the Medicare Administrative Contractors (MACs) on the Excel hospital reporting form available at **https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html** by July 1, 2020. CMS granted an extension for hospitals nationwide affected by COVID-19 until August 3, 2020. Due to continued COVID related concerns from hospitals about meeting this deadline, CMS is further extending this deadline to September 3, 2020. Hospitals must submit their occupational mix surveys along with complete supporting documentation to their MACs by no later than September 3, 2020. Hospitals may then submit revisions to their occupational mix surveys to their MACs, if needed, by no later than September 10, 2020. The next collection of the wage index occupational mix survey data (based on 2022 data) is expected to be collected in Summer 2023.

Supporting Care for Patients in Long-Term Care Acute Hospitals (LTCHs)

- CMS determined it was appropriate to issue a blanket waiver to long-term care hospitals (LTCHs) where an LTCH admits or discharges patients in order to meet the demands of the emergency from the 25-day average length of stay requirement at § 412.23(e)(2), which allows these hospitals to participate in the LTCH PPS. In addition, during the applicable waiver time period, CMS determined it is appropriate to issue a blanket waiver to hospitals not yet classified as LTCHs, but seeking classification as an LTCH, to exclude patient stays where the hospital admits or discharges patients in order to meet the demands of the emergency from the 25-day average length of stay requirement, which must be met in order for these hospitals to be eligible to participate in the LTCH PPS. Hospitals should add the "DR" condition code to applicable claims.

Care for Patients in Extended Neoplastic Disease Care Hospitals

- CMS is allowing extended neoplastic disease care hospitals to exclude inpatient stays where the hospital admits or discharges patients in order to meet the demands of the emergency from the greater than 20-day average length of stay requirement, which allows these facilities to be excluded from the hospital inpatient prospective payment system and paid an adjusted payment for Medicare inpatient operating and capital-related costs under the reasonable cost-based reimbursement rules as authorized under Section 1886(d)(1)(B)(vi) of the Act and §42

CFR 412.22(i). At the end of the PHE, Extended Neoplastic Disease Care Hospitals must comply with the 20-day average length of stay requirement at § 412.23(i)(1).

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

We are modifying the participant hospital deadlines to permit the participant hospital 120 calendar days after the reconciliation report is issued to appeal a determination that such hospital owes repayment to CMS, or upon request, to appeal a determination that such hospital is eligible for a reconciliation payment. If a notice of calculation error is received by CMS within the 120-day period, then consistent with the existing regulation, CMS responds in writing within 30 calendar days to either confirm that there was an error in the calculation or verify that the calculation is correct, although CMS reserves the right to an extension upon written notice to the participant hospital.

Hospitals receiving a reconciliation payment that do not request a 120-day appeal period have 45 days to provide a notice of calculation error. Unless the participant hospital provides written notice of the calculation error, CMS deems the CJR reconciliation report to be final 45 calendar days after it is issued, and proceeds with the payment. **This waiver was no longer applicable after 10/7/2020.**

Long-Term Care Facilities and Skilled Nursing Facilities (SNFs) and/or Nursing Facilities (NFs)

- **3-Day Prior Hospitalization.** Using the authority under Section 1812(f) of the Act, CMS is waiving the requirement for a 3-day prior hospitalization for coverage of a SNF stay, which provides temporary emergency coverage of SNF services without a qualifying hospital stay, for those people who experience dislocations, or are otherwise affected by COVID-19. In addition, for certain beneficiaries who recently exhausted their SNF benefits, it authorizes renewed SNF coverage without first having to start a new benefit period (this waiver will apply only for those

beneficiaries who have been delayed or prevented by the emergency itself from commencing or completing the process of ending their current benefit period and renewing their SNF benefits that would have occurred under normal circumstances).

- ~~**Reporting Minimum Data Set.** CMS is waiving 42 CFR 483.20 to provide relief to SNFs on the timeframe requirements for Minimum Data Set assessments and transmission.~~ **~~(Terminated effective 5/10/21 per QSO-21-17-NH)~~**

- ~~**Staffing Data Submission.** CMS is waiving 42 CFR 483.70(q) to provide relief to long-term care facilities on the requirements for submitting staffing data through the Payroll-Based Journal system.~~ **~~(Terminated effective 6/25/2020)~~**

- **Waive Pre-Admission Screening and Annual Resident Review (PASARR).** CMS is waiving 42 CFR 483.20(k), allowing nursing homes to admit new residents who have not received Level one or Level two Preadmission Screening. Level one assessments may be performed post-admission. On or before the 30th day of admission, new patients admitted to nursing homes with a mental illness (MI) or intellectual disability (ID) should be referred promptly by the nursing home to state PASARR program for Level two Resident Review.

- ~~**Physical Environment.** CMS is waiving requirements related at 42 CFR 483.90, specifically the following:~~ ***~~(Terminated on 6-6-2022 per QSO-22-15-NH & NLTC & LSC)~~***
    - ~~Provided that the state has approved the location as one that sufficiently addresses safety and comfort for patients and staff, CMS is waiving requirements under § 483.90 to allow for a non-SNF building to be temporarily certified and available for use by a SNF in the event there are needs for isolation processes for COVID-19 positive residents, which may not be feasible in the existing SNF structure to ensure care and services during treatment for COVID-19 are available while protecting other vulnerable adults.~~
    - ~~CMS believes this will also provide another measure that will free up inpatient care beds at hospitals for the most acute patients while providing beds for those still in need of care. CMS will waive certain conditions of participation and certification requirements for opening a NF if the state determines there is a need to quickly stand up a temporary COVID-19 isolation and treatment location.~~
    - ~~CMS is also waiving requirements under 42 CFR 483.90 to temporarily allow for rooms in a long-term care facility not normally used as a resident's room, to be used to accommodate beds and residents for resident care in emergencies and situations needed to help with surge capacity. Rooms that may be used for this purpose include activity rooms, meeting/conference rooms, dining rooms, or other rooms, as long as residents can be kept safe, comfortable, and other applicable requirements for participation are met. This can be done so long as it is not inconsistent with a state's emergency preparedness or pandemic plan, or as directed by the local or state health~~

~~department.~~

- ~~**Resident Groups.** CMS is waiving the requirements at 42 CFR 483.10(f)(5), which ensure residents can participate in-person in resident groups. This waiver would only permit the facility to restrict in-person meetings during the national emergency given the recommendations of social distancing and limiting gatherings of more than ten people. Refraining from in-person gatherings will help prevent the spread of COVID-19.~~ ***(Terminated on 5-7-2022 per QSO-22-15-NH & NLTC & LSC)***

- ~~**Training and Certification of Nurse Aides.** CMS is waiving the requirements at 42 CFR 483.35(d) (with the exception of 42 CFR 483.35(d)(1)(i)), which require that a SNF and NF may not employ anyone for longer than four months unless they met the training and certification requirements under § 483.35(d). CMS is waiving these requirements to assist in potential staffing shortages seen with the COVID-19 pandemic. To ensure the health and safety of nursing home residents, CMS is not waiving 42 CFR § 483.35(d)(1)(i), which requires facilities to not use any individual working as a nurse aide for more than four months, on a full-time basis, unless that individual is competent to provide nursing and nursing related services. We further note that we are not waiving § 483.35(c), which requires facilities to ensure that nurse aides are able to demonstrate competency in skills and techniques necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.~~ ***(Terminated on 06-06-2022 per QSO-22-15-NH&NLTC&LSC; Nurse aides hired under the current waiver (on or before June 6, 2022) have until October 6, 2022 to complete a NATCEP).***

- ~~**Physician Visits in Skilled Nursing Facilities/Nursing Facilities.** CMS is waiving the requirement in 42 CFR 483.30 for physicians and non-physician practitioners to perform in- person visits for nursing home residents and allow visits to be conducted, as appropriate, via telehealth options.~~ ***(Terminated on 5-7-2022 per QSO-22-15-NH & NLTC & LSC)***

- **Resident Roommates and Grouping.** CMS is waiving the requirements in 42 CFR 483.10(e) (5), ~~(6)~~ **(Terminated on 05/10/2021 per QSO-21-17)**, and (7) solely for the purposes of grouping or cohorting residents with respiratory illness symptoms and/or residents with a confirmed diagnosis of COVID-19, and separating them from residents who are asymptomatic or tested negative for COVID-19. This action waives a facility's requirements, under 42 CFR 483.10, to provide for a resident to share a room with his or her roommate of choice in certain circumstances, ~~to provide notice and rationale for changing a resident's room,~~ and to provide for a resident's refusal a transfer to another room in the facility. This aligns with CDC guidance to preferably place residents in locations designed to care for COVID-19 residents, to prevent the transmission of COVID-19 to other residents.

- **Resident Transfer and Discharge.** CMS is waiving requirements in 42 CFR 483.10(c)(5); 483.15(c)(3)~~, (c)(4)(ii)~~ **(Terminated on 05/10/2021 per QSO-21-17)**, (c)(5)(i) and (iv), (c)(9), and (d); and ~~§ 483.21(a)(1)(i), (a)(2)(i), and (b) (2)(i)~~ **(Terminated on 05/10/2021 per QSO-21-17)**

(with some exceptions) to allow a long-term care (LTC) facility to transfer or discharge residents to another LTC facility solely for the following cohorting purposes:

1. Transferring residents with symptoms of a respiratory infection or confirmed diagnosis of COVID-19 to another facility that agrees to accept each specific resident, and is dedicated to the care of such residents;

2. Transferring residents without symptoms of a respiratory infection or confirmed to not have COVID-19 to another facility that agrees to accept each specific resident, and is dedicated to the care of such residents to prevent them from acquiring COVID-19; or

3. Transferring residents without symptoms of a respiratory infection to another facility that agrees to accept each specific resident to observe for any signs or symptoms of a respiratory infection over 14 days.

Exceptions:

- These requirements are **only** waived in cases where the transferring facility receives confirmation that the receiving facility agrees to accept the resident to be transferred or discharged. Confirmation may be in writing or verbal. If verbal, the transferring facility needs to document the date, time, and person that the receiving facility communicated agreement.

- In § 483.10, we are only waiving the requirement, under § 483.10(c)(5), that a facility provide advance notification of options relating to the transfer or discharge to another facility. Otherwise, all requirements related to § 483.10 are not waived. Similarly, in § 483.15, we are only waiving the requirement, under § 483.15(c)(3)~~, (c)(4)(ii)~~ **(Terminated on 05/10/2021 per QSO-21-17)**, (c)(5)(i) and (iv), and (d), for the written notice of transfer or discharge to be provided before the transfer or discharge. This notice must be provided as soon as practicable.

- ~~In § 483.21, we are only waiving the timeframes for certain care planning requirements for residents who are transferred or discharged for the purposes explained in 1–3 above. Receiving facilities should complete the required care plans as soon as practicable, and we expect receiving facilities to review and use the care plans for residents from the transferring facility, and adjust as necessary to protect the health and safety of the residents the apply to.~~ **(Terminated on 05/10/2021 per QSO-21-17)**

- These requirements are also waived when the transferring residents to another facility, such as a COVID-19 isolation and treatment location, with the provision of services "under arrangements," as long as it is consistent with a state's emergency preparedness or pandemic plan, or as directed by the local or state health department.

In these cases, the transferring LTC facility need not issue a formal discharge, as it is still considered the provider and should bill Medicare normally for each day of care. The transferring LTC facility is then responsible for reimbursing the other provider that accepted its resident(s) during the emergency period.

- If the LTC facility does not intend to provide services under arrangement, the COVID-19 isolation and treatment facility is the responsible entity for Medicare billing purposes. The LTC facility should follow the procedures described in 40.3.4 of the Medicare Claims Processing Manual (**https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c06.pdf**) to submit a discharge bill to Medicare. The COVID-19 isolation and treatment facility should then bill Medicare appropriately for the type of care it is providing for the beneficiary. If the COVID-19 isolation and treatment facility is not yet an enrolled provider, the facility should enroll through the provider enrollment hotline for the Medicare Administrative Contractor that services their geographic area to establish temporary Medicare billing privileges.

We remind LTC facilities that they are responsible for ensuring that any transfers (either within a facility, or to another facility) are conducted in a safe and orderly manner, and that each resident's health and safety is protected.

We also remind states that under 42 CFR 488.426(a)(1), in an emergency, the state has the authority to transfer Medicaid and Medicare residents to another facility.

- ~~**Physician Services.** CMS is providing relief to long-term care facilities related to provision of physician services through the following actions:~~

  - ~~**Physician Delegation of Tasks in SNFs.** 42 CFR 483.30(e)(4). CMS is waiving the requirement in § 483.30(e)(4) that prevents a physician from delegating a task when the regulations specify that the physician must perform it personally. This waiver gives physicians the ability to delegate any tasks to a physician assistant, nurse practitioner, or clinical nurse specialist who meets the applicable definition in 42 CFR 491.2 or, in the case of a clinical nurse specialist, is licensed as such by the State and is acting within the scope of practice laws as defined by State law. We are temporarily modifying this regulation to specify that any task delegated under this waiver must continue to be under the supervision of the physician. This waiver does not include the provision of § 483.30(e)(4) that prohibits a physician from delegating a task when the delegation is prohibited under State law or by the facility's own policy.~~ ***(Terminated on 5-7-2022 per QSO-22-15-NH & NLTC & LSC)***

  - ~~**Physician Visits.** 42 CFR 483.30(c)(3). CMS is waiving the requirement at § 483.30(c)(3) that all required physician visits (not already exempted in § 483.30(c)(4) and (f)) must be made by the physician personally. We are modifying this provision to permit~~

physicians to delegate any required physician visit to a nurse practitioner (NPs), physician assistant, or clinical nurse specialist who is not an employee of the facility, who is working in collaboration with a physician, and who is licensed by the State and performing within the state's scope of practice laws. ***(Terminated on 5-7-2022 per QSO-22-15-NH & NLTC & LSC)***

- **Note to Facilities.** These actions will assist in potential staffing shortages, maximize the use of medical personnel, and protect the health and safety of residents during the PHE. We note that we are not waiving the requirements for the frequency of required physician visits at § 483.30(c)(1). As set out above, we have only modified the requirement to allow for the requirement to be met by an NP, physician assistant, or clinical nurse specialist, and via telehealth or other remote communication options, as appropriate. In addition, we note that we are not waiving our requirements for physician supervision in § 483.30(a)(1), and the requirement at § 483.30(d)(3) for the facility to provide or arrange for the provision of physician services 24 hours a day, in case of an emergency. It is important that the physician be available for consultation regarding a resident's care. ***(Terminated on 5-7-2022 per QSO-22-15-NH & NLTC & LSC)***

- **Quality Assurance and Performance Improvement (QAPI).** CMS is modifying certain requirements in 42 CFR §483.75, which require long-term care facilities to develop, implement, evaluate, and maintain an effective, comprehensive, data-driven QAPI program. Specifically, CMS is modifying §483.75(b)–(d) and (e)(3) to the extent necessary to narrow the scope of the QAPI program to focus on adverse events and infection control. This will help ensure facilities focus on aspects of care delivery most closely associated with COVID-19 during the PHE. ***(Terminated on 5-7-2022 per QSO-22-15-NH & NLTC & LSC)***

- **In-Service Training:** CMS is modifying the nurse aide training requirements at §483.95(g)(1) for SNFs and NFs, which requires the nursing assistant to receive at least 12 hours of in-service training annually. In accordance with section 1135(b)(5) of the Act, we are postponing the deadline for completing this requirement throughout the COVID-19 PHE until the end of the first full quarter after the declaration of the PHE concludes. ***(Terminated on 06-06-2022 per QSO-22-15-NH&NLTC&LSC; Nurse aides hired prior to and under the current waiver (on or before June 6, 2022) will have 12 months from this date to complete the required annual training.)***

- **Detailed Information Sharing for Discharge Planning for Long-Term Care (LTC) Facilities.** CMS is waiving the discharge planning requirement in §483.21(c)(1)(viii), which requires LTC facilities to assist residents and their representatives in selecting a post-acute care provider using data, such as standardized patient assessment data, quality measures and resource use. This temporary waiver is to provide facilities the ability to expedite discharge and movement of residents among care settings. CMS is maintaining all other discharge

planning requirements, such as but not limited to, ensuring that the discharge needs of each resident are identified and result in the development of a discharge plan for each resident; involving the interdisciplinary team, as defined at 42 CFR §483.21(b)(2)(ii), in the ongoing process of developing the discharge plan address the resident's goals of care and treatment preferences. ***(Terminated on 5-7-2022 per QSO-22-15-NH & NLTC & LSC)***

- **Clinical Records.** Pursuant to section 1135(b)(5) of the Act, CMS is modifying the requirement at 42 CFR §483.10(g)(2)(ii) which requires long-term care (LTC) facilities to provide a resident a copy of their records within two working days (when requested by the resident). Specifically, CMS is modifying the timeframe requirements to allow LTC facilities ten working days to provide a resident's record rather than two working days. ***(Terminated on 5-7-2022 per QSO-22-15-NH & NLTC & LSC)***

- **Paid Feeding Assistants.** CMS is modifying the requirements at 42 CFR §§ 483.60(h)(1)(i) and 483.160(a) regarding required training of paid feeding assistants. Specifically, CMS is modifying the minimum timeframe requirements in these sections, which require this training to be a minimum of 8 hours. CMS is modifying to allow that the training can be a minimum of 1 hour in length. CMS is not waiving any other requirements under 42 CFR §483.60(h) related to paid feeding assistants or the required training content at 42 CFR §483.160(a)(1)-(8), which contains infection control training and other elements. Additionally, CMS is also not waiving or modifying the requirements at 42 CFR §483.60(h)(2)(i), which requires that a feeding assistant must work under the supervision of a registered nurse (RN) or licensed practical nurse (LPN). ***(Terminated on 6-6-2022 per QSO-22-15-NH & NLTC & LSC)***

- **Director of Food and Nutrition Services (New as of 11/26/21).** CMS is issuing an 1135 waiver for 42 CFR 483.60(a)(1) and 483.60(a)(2) that requires dietitians hired or contracted with prior to November 28, 2016, to meet the specified requirements no later than five years after November 28, 2016 or as required by state law and to designate a person to serve as the director of food and nutrition services who, for designations prior to November 28, 2016, meets the specified requirements no later than five years after November 28, 2016, or no later than one year after November 28, 2016 for designations after November 28, 2016. The specified requirements involve specialized education or training in food service management and safety resulting in an associate's or higher degree in hospitality or food service management, a bachelor's or higher degree granted by a regionally accredited college or university in the United States, a certified dietary manager, or a certified food service manager. These educational and training requirements range in length, at a minimum, of 18 months to four years. It has been unusually challenging for these requirements to be met due to the COVID-19 Public Health Emergency (PHE). Therefore, CMS is waiving this requirement due to the inability for individuals to enroll in, attend, or complete a certification program due to circumstances related to the COVID-19 PHE. *(Terminated on 10-01-2022 per Fiscal Year*

(FY) 2023 Skilled Nursing Facility (SNF) Prospective Payment System (PPS) Final Rule (CMS 1765-F)).

Home Health Agencies (HHAs)

- **Requests for Anticipated Payment (RAPs).** CMS is allowing Medicare Administrative Contractors (MACs) to extend the auto-cancellation date of Requests for Anticipated Payment (RAPs) during emergencies.

- **Reporting.** CMS is providing relief to HHAs on the timeframes related to OASIS Transmission through the following actions below:
    - Extending the 5-day completion requirement for the comprehensive assessment to 30 days.
    - Waiving the 30-day OASIS submission requirement. Delayed submission is permitted during the PHE.

- **Initial Assessments.** CMS is waiving the requirements at 42 CFR §484.55(a) to allow HHAs to perform Medicare-covered initial assessments and determine patients' homebound status remotely or by record review. This will allow patients to be cared for in the best environment for them while supporting infection control and reducing impact on acute care and long-term care facilities. This will allow for maximizing coverage by already scarce physician, and advanced practice clinicians, and allow those clinicians to focus on caring for patients with the greatest acuity.

- **Waive Onsite Visits for HHA Aide Supervision.** CMS is waiving the requirements at 42 CFR §484.80(h), which require a nurse to conduct an onsite visit every two weeks. This would include waiving the requirements for a nurse or other professional to conduct an onsite visit every two weeks to evaluate if aides are providing care consistent with the care plan, as this may not be physically possible for a period of time. This waiver is also temporarily suspending the 2-week aide supervision by a registered nurse for home health agencies requirement at §484.80(h)(1), but virtual supervision is encouraged during the period of the waiver.

- **Allow Occupational Therapists (OTs), Physical Therapists (PTs), and Speech Language Pathologists (SLPs) to Perform Initial and Comprehensive Assessment for all Patients.** CMS is waiving the requirements in 42 CFR § 484.55(a)(2) and § 484.55(b)(3) that rehabilitation skilled professionals may only perform the initial and comprehensive assessment when only therapy services are ordered. This temporary blanket modification allows any rehabilitation professional (OT, PT, or SLP) to perform the initial and comprehensive assessment for all patients receiving therapy services as part of the plan of care, to the extent permitted under state law, regardless of whether or not the service establishes eligibility for the patient to be receiving home care. The existing regulations at § 484.55(a) and (b)(2) would continue to apply;

rehabilitation skilled professionals would not be permitted to perform assessments in nursing-only cases. We would continue to expect HHAs to match the appropriate discipline that performs the assessment to the needs of the patient to the greatest extent possible. Therapists must act within their state scope of practice laws when performing initial and comprehensive assessments, and access a registered nurse or other professional to complete sections of the assessment that are beyond their scope of practice. Expanding the category of therapists who may perform initial and comprehensive assessments provides HHAs with additional flexibility that may decrease patient wait times for the initiation of home health services. This waiver was made permanent in the Consolidated Appropriations Act of 2021 (CAA, 2021).

- **12-hour Annual In-service Training Requirement for Home Health Aides.** CMS is modifying the requirement at 42 CFR §484.80(d) that home health agencies must assure that each home health aide receives 12 hours of in-service training in a 12-month period. In accordance with section 1135(b)(5) of the Act, we are postponing the deadline for completing this requirement throughout the COVID-19 PHE until the end of the first full quarter after the declaration of the PHE concludes. This will allow aides and the registered nurses (RNs) who teach in-service training to spend more time delivering direct patient care and additional time for staff to complete this requirement.

- **Detailed Information Sharing for Discharge Planning for Home Health Agencies.** CMS is waiving the requirements of 42 CFR §484.58(a) to provide detailed information regarding discharge planning, to patients and their caregivers, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, (another) home health agency (HHA), skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), and long-term care hospital (LTCH) quality measures and resource use measures.

    - This temporary waiver provides facilities the ability to expedite discharge and movement of residents among care settings. CMS is maintaining all other discharge planning requirements.

- **Clinical Records:** In accordance with section 1135(b)(5) of the Act, CMS extended the deadline for completion of the requirement at 42 CFR §484.110(e), which requires HHAs to provide a patient a copy of their medical record at no cost during the next visit or within four business days (when requested by the patient). Specifically, CMS has allowed HHAs ten business days to provide a patient's clinical record, instead of four.

Home Health Agencies (HHAs) and Hospice

- **Training and Assessment of Aides:** CMS has been waiving the requirement at 42 CFR §418.76(h)(2) for Hospice and 42 CFR §484.80(h)(1)(iii) for HHAs, which require a registered nurse, or in the case of an HHA a registered nurse or other appropriate skilled professional

(physical therapist/occupational therapist, speech language pathologist) to make an annual onsite supervisory visit (direct observation) for each aide that provides services on behalf of the agency. In accordance with section 1135(b)(5) of the Act, we are postponing completion of these visits. All postponed onsite assessments must be completed by these professionals no later than 60 days after the expiration of the PHE. CMS will end this waiver at the conclusion of the PHE.

- **Quality Assurance and Performance Improvement (QAPI).** CMS is modifying the requirement at 42 CFR §418.58 for Hospice and §484.65 for HHAs, which requires these providers to develop, implement, evaluate, and maintain an effective, ongoing, hospice/HHA-wide, data-driven QAPI program. Specifically, CMS is modifying the requirements at §418.58(a)–(d) and §484.65(a)–(d) to narrow the scope of the QAPI program to concentrate on infection control issues, while retaining the requirement that remaining activities should continue to focus on adverse events. This modification decreases burden associated with the development and maintenance of a broad-based QAPI program, allowing the providers to focus efforts on aspects of care delivery most closely associated with COVID-19, and tracking adverse events during the PHE. The requirement that HHAs and hospices maintain an effective, ongoing, agency-wide, data-driven quality assessment and performance improvement program will remain.

Hospice

- **Waive Requirement for Hospices to Use Volunteers**. CMS is waiving the requirement at 42 CFR §418.78(e) that hospices are required to use volunteers (including at least 5% of patient care hours). It is anticipated that hospice volunteer availability and use will be reduced related to COVID-19 surge and potential quarantine.

- **Comprehensive Assessments.** CMS is waiving certain requirements at 42 CFR §418.54 related to updating comprehensive assessments of patients. This waiver applies the timeframes for updates to the comprehensive assessment found at §418.54(d). Hospices must continue to complete the required assessments and updates; however, the timeframes for updating the assessment may be extended from 15 to 21 days.

- **Waive Non-Core Services.** CMS is waiving the requirement for hospices to provide certain non-core hospice services during the national emergency, including the requirements at 42 CFR §418.72 for physical therapy, occupational therapy, and speech-language pathology.

- **Waived Onsite Visits for Hospice Aide Supervision.** CMS is waiving the requirements at 42 CFR §418.76(h), which require a nurse to conduct an onsite supervisory visit every two weeks. This would include waiving the requirements for a nurse or other professional to conduct an onsite visit every two weeks to evaluate if aides are providing care consistent with the care plan, as

this may not be physically possible for a period of time.

- **Hospice Aide Competency Testing Allow Use of Pseudo Patients.** 42 CFR 418.76(c)(1). CMS is temporarily modifying the requirement in § 418.76(c)(1) that a hospice aide must be evaluated by observing an aide's performance of certain tasks with a patient. This modification allows hospices to utilize pseudo patients such as a person trained to participate in a role-play situation or a computer-based mannequin device, instead of actual patients, in the competency testing of hospice aides for those tasks that must be observed being performed on a patient. This increases the speed of performing competency testing and allows new aides to begin serving patients more quickly without affecting patient health and safety during the public health emergency (PHE).

- **12 hour Annual In-service Training Requirement for Hospice Aides.** 42 CFR 418.76(d). CMS is waiving the requirement that hospices must assure that each hospice aide receives 12 hours of in-service training in a 12 month period. This allows aides and the registered nurses (RNs) who teach in-service training to spend more time delivering direct patient care.

- **Annual Training.** CMS is modifying the requirement at 42 CFR §418.100(g)(3), which requires hospices to annually assess the skills and competence of all individuals furnishing care and provide in-service training and education programs where required. Pursuant to section 1135(b)(5) of the Act, we are postponing the deadline for completing this requirement throughout the COVID-19 PHE until the end of the first full quarter after the declaration of the PHE concludes. This does not alter the minimum personnel requirements at 42 CFR §418.114. Selected hospice staff must complete training and have their competency evaluated in accordance with unwaived provisions of 42 CFR Part 418.

End-Stage Renal Dialysis (ESRD) Facilities

- **Training Program and Periodic Audits.** CMS is waiving the requirement at 42 CFR §494.40(a) related to the condition on Water & Dialysate Quality, specifically that on-time periodic audits for operators of the water/dialysate equipment are waived to allow for flexibilities.

- ~~**Defer Equipment Maintenance & Fire Safety Inspections.** CMS is waiving the requirement at 42 CFR §494.60(b) for on-time preventive maintenance of dialysis machines and ancillary dialysis equipment. Additionally, CMS is also waiving the requirements under §494.60(d) which requires ESRD facilities to conduct on-time fire inspections. These waivers are intended to ensure that dialysis facilities are able to focus on the operations related to the Public Health Emergency.~~ ***(Terminated on 6-6-2022 per QSO-22-15-NH & NLTC & LSC)***

  Emergency Preparedness. CMS is waiving the requirements at 42 CFR §494.62(d)(1)(iv), which requires ESRD facilities to demonstrate as part of their Emergency Preparedness Training and Testing Program, that staff can demonstrate that, at a minimum, its patient care staff maintains

current CPR certification. CMS is waiving the requirement for maintenance of CPR certification during the COVID-19 emergency due to the limited availability of CPR classes.

- **Ability to Delay Some Patient Assessments.** CMS is not waiving subsections (a) or (c) of 42 CFR §494.80, but is waiving the following requirements at 42 CFR §494.80(b) related to the frequency of assessments for patients admitted to the dialysis facility. CMS is waiving the "on-time" requirements for the initial and follow up comprehensive assessments within the specified timeframes as noted below. This waiver applies to assessments conducted by members of the interdisciplinary team, including: a registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian. These waivers are intended to ensure that dialysis facilities are able to focus on the operations related to the Public Health Emergency. Specifically, CMS is waiving:
    - §494.80(b)(1): An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session.
    - §494.80(b)(2): A follow up comprehensive reassessment must occur within three months after the completion of the initial assessment to provide information to adjust the patient's plan of care specified in §494.90.

- **Time Period for Initiation of Care Planning and Monthly Physician Visits.** CMS is modifying two requirements related to care planning, specifically:
    - 42 CFR §494.90(b)(2): CMS is modifying the requirement that requires the dialysis facility to implement the initial plan of care within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. This modification will also apply to the requirement for monthly or annual updates of the plan of care within 15 days of the completion of the additional patient assessments.
    - §494.90(b)(4): CMS is modifying the requirement that requires the ESRD dialysis facility to ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist, or physician's assistant providing ESRD care at least monthly, and periodically while the hemodialysis patient is receiving in-facility dialysis. CMS is waiving the requirement for a monthly in-person visit if the patient is considered stable and also recommends exercising telehealth flexibilities; e.g., phone calls to ensure patient safety.

- **Dialysis Home Visits to Assess Adaptation and Home Dialysis Machine Designation.** CMS is waiving the requirement at 42 CFR §494.100(c)(1)(i), which requires the periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel. For more information on existing flexibilities for in-center dialysis patients to receive their dialysis treatments in the home, or long-term care facility, reference QSO-20-19-ESRD.

- **Home Dialysis Machine Designation — Clarification.** The ESRD Conditions for Coverage (CFCs) do not explicitly require that each home dialysis patient have their own designated home dialysis machine. The dialysis facility is required to follow FDA labeling and manufacturer's directions for use to ensure appropriate operation of the dialysis machine and ancillary equipment. Dialysis machines must be properly cleaned and disinfected to minimize the risk of infection based on the requirements at 42 CFR §494.30 Condition: Infection Control if used to treat multiple patients.

- **Special Purpose Renal Dialysis Facilities (SPRDF) Designation Expanded.** CMS authorizes the establishment of SPRDFs under 42 CFR §494.120 to address access to care issues due to COVID-19 and the need to mitigate transmission among this vulnerable population. This will not include the normal determination regarding lack of access to care at §494.120(b) as this standard has been met during the period of the national emergency. Approval as a Special Purpose Renal Dialysis Facility related to COVID-19 does not require federal survey prior to providing services.

- **Dialysis Patient Care Technician (PCT) Certification.** CMS is modifying the requirement at 42 CFR §494.140(e)(4) for dialysis PCTs that requires certification under a state certification program or a national commercially available certification program within 18 months of being hired as a dialysis PCT for newly employed patient care technicians. CMS is aware of the challenges that PCTs are facing with the limited availability and closures of testing sites during the time of this crisis. CMS will allow PCTs to continue working even if they have not achieved certification within 18 months or have not met on time renewals.

- **Transferability of Physician Credentialing.** CMS is modifying the requirement at 42 CFR §494.180(c)(1), which requires that all medical staff appointments and credentialing are in accordance with state law, including attending physicians, physician assistants, nurse practitioners, and clinical nurse specialists. These waivers will allow physicians that are appropriately credentialed at a certified dialysis facility to function to the fullest extent of their licensure to provide care at designated isolation locations without separate credentialing at that facility, and may be implemented as long as they are consistent with a state's emergency preparedness or pandemic plan**.**

- **Expanding Availability of Renal Dialysis Services to ESRD Patients.** CMS is waiving the following requirements related to Nursing Home residents:

    - **Furnishing Dialysis Services on the Main Premises:** ESRD requirements at 42 CFR §494.180(d) require dialysis facilities to provide services directly on its main premises or on other premises that are contiguous with the main premises. CMS is waiving this requirement to allow dialysis facilities to provide service to its patients who reside in the nursing homes, long-term care facilities, assisted living facilities and similar types of facilities, as licensed by the state (if applicable). CMS continues to require that services

provided to these patients or residents are under the direction of the same governing body and professional staff as the resident's usual Medicare-certified dialysis facility. Further, in order to ensure that care is safe, effective and is provided by trained and qualified personnel, CMS requires that the dialysis facility staff: 1) furnish all dialysis care and services; 2) provide all equipment and supplies necessary; 3) maintain equipment and supplies in off-premises location; 4) and complete all equipment maintenance, cleaning and disinfection using appropriate infection control procedures and manufacturer's instructions for use.

- **Clarification for Billing Procedures**. Typically, ESRD beneficiaries are transported from a SNF/NF to an ESRD facility to receive renal dialysis services. In an effort to keep patients in their SNF/NF and decrease their risk of being exposed to COVID-19, ESRD facilities may temporarily furnish renal dialysis services to ESRD beneficiaries in the SNF/NF instead of the offsite ESRD facility. The in-center dialysis center should bill Medicare using Condition Code 71 (Full care unit. Billing for a patient who received staff-assisted dialysis services in a hospital or renal dialysis facility). The in-center dialysis center should also apply condition code DR to claims if all the treatments billed on the claim meet this condition or modifier CR on the line level to identify individual treatments meeting this condition. The ESRD provider would need to have their trained personnel administer the treatment in the SNF/ NF. In addition, the provider must follow the CFCs. In particular, under the CFCs is the requirement that to use a dialysis machine, the FDA-approved labeling must be adhered to § 494.100 and it must be maintained and operated in accordance with the manufacturer's recommendations (§ 494.60) and follow infection control requirements at § 494.30.

Physical Environment for Multiple Providers/Suppliers

Inspection, Testing & Maintenance (ITM) under the Physical Environment Conditions of Participation: CMS is waiving certain physical environment requirements for Hospitals, and CAHs, ~~inpatient hospice, ICF/IIDs, and SNFs/NFs~~ to reduce disruption of patient care and potential exposure/transmission of COVID-19. The physical environment regulations require that facilities and equipment be maintained to ensure an acceptable level of safety and quality.

CMS will permit facilities to adjust scheduled inspection, testing and maintenance (ITM) frequencies and activities for facility and medical equipment.

- **Specific Physical Environment Waiver Information:**
    - 42 CFR §482.41(d) for hospitals, *and* §485.623(b) for CAHs, ~~§418.110(c)(2)(iv) for inpatient hospice, §483.470(j) for ICF/IID; and §483.90 for SNFs/NFs~~ ***(Terminated waivers at 418.110(c)(2)(iv) for inpatient hospice, 483.470(j) for ICF/IID and 483.90(a)(1) and (b) for SNFs/NF on 6-6-2022 per QSO-22-15-NH & NLTC & LSC)*** all require these facilities and their equipment to be maintained to ensure an acceptable

level of safety and quality. CMS is temporarily modifying these requirements to the extent necessary to permit these facilities to adjust scheduled inspection, testing and maintenance (ITM) frequencies and activities for facility and medical equipment.

- 42 CFR §482.41(b)(1)(i) and (c) for hospitals, *and* §485.623(c)(1)(i) and (d) for CAHs, ~~§482.41(d)(1)(i) and (e) for inpatient hospices, §483.470(j)(1)(i) and (5)(v) for ICF/IIDs, and §483.90(a)(1)(i) and (b) for SNFs/NFs~~ ***(Terminated waivers at 482.41(d)(1)(i) and (e) for inpatient hospices, §483.470(j)(1)(i) and (5)(v) for ICF/IIDs, and §483.90(a)(1)(i) and (b) for SNFs/NFs on 6-6-2022 per QSO-22-15-NH & NLTC & LSC)*** require these facilities to be in compliance with the Life Safety Code (LSC) and Health Care Facilities Code (HCFC). CMS is temporarily modifying these provisions to the extent necessary to permit these facilities to adjust scheduled ITM frequencies and activities required by the LSC and HCFC. The following LSC and HCFC ITM are considered critical are not included in this waiver:
    - Sprinkler system monthly electric motor-driven and weekly diesel engine-driven fire pump testing.
    - Portable fire extinguisher monthly inspection.
    - Elevators with firefighters' emergency operations monthly testing.
    - Emergency generator 30 continuous minute monthly testing and associated transfer switch monthly testing.
    - Means of egress daily inspection in areas that have undergone construction, repair, alterations, or additions to ensure its ability to be used instantly in case of emergency.
- 42 CFR §482.41(b)(9) for hospitals, *and* §485.623(c)(7) for CAHs, ~~§418.110(d)(6) for inpatient hospices, §483.470(e)(1)(i) for ICF/IIDs, and §483.90(a)(7) for SNFs/NFs~~ ***(Terminated waivers at §418.110(d)(6) for inpatient hospice, §483.470(e)(1)(i) for ICF/IID and §483.90(a)(7) for SNFs/NFs on 6-6-2022 per QSO-22-15-NH & NLTC & LSC)*** require these facilities to have an outside window or outside door in every sleeping room. CMS will permit a waiver of these outside window and outside door requirements to permit these providers to utilize facility and non-facility space that is not normally used for patient care to be utilized for temporary patient care or quarantine.

Specific Life Safety Code (LSC) for Multiple Providers - Waiver Information:

CMS is waiving and modifying particular waivers under 42 CFR §482.41(b) for hospitals; §485.623(c) for CAHs; §418.110(d) for inpatient hospice; §483.470(j) for ICF/IIDs and §483.90(a) for SNF/NFs. Specifically, CMS is modifying these requirements as follows:

- **Alcohol-based Hand-Rub (ABHR) Dispensers:** We are waiving the prescriptive requirements for the placement of alcohol based hand rub (ABHR) dispensers for use by staff and others due

to the need for the increased use of ABHR in infection control. However, ABHRs contain ethyl alcohol, which is considered a flammable liquid, and there are restrictions on the storage and location of the containers. This includes restricting access by certain patient/resident population to prevent accidental ingestion. Due to the increased fire risk for bulk containers (over five gallons) those will still need to be stored in a protected hazardous materials area.

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; §485.623(c)(5) for CAHs; §418.110(d)(4) for inpatient hospice; §483.470(j)(5)(ii) for ICF/IIDs and §483.90(a)(4) for SNF/NFs.

- **Fire Drills:** Due to the inadvisability of quarterly fire drills that move and mass staff together, we will instead permit a documented orientation training program related to the current fire plan, which considers current facility conditions. The training will instruct employees, including existing, new or temporary employees, on their current duties, life safety procedures and the fire protection devices in their assigned area. ***(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).***

  Refer to: 2012 LSC, sections 18/19.7.1.6.

- **Temporary Construction:** CMS is waiving requirements that would otherwise not permit temporary walls and barriers between patients. ***(Terminated waivers for temporary construction at §418.110(d) for inpatient hospice; §483.470(j) for ICF/IIDs; and §483.90(a) for SNF/NFs on 6-6-2022 per QSO-22-15-NH & NLTC & LSC).***

  Refer to: 2012 LSC, sections 18/19.3.3.2.

Intermediate Care Facility for Individuals with Intellectual Disabilities

- **Staffing Flexibilities.** CMS is waiving the requirements at 42 CFR §483.430(c)(4), which requires the facility to provide sufficient Direct Support Staff (DSS) so that Direct Care Staff (DCS) are not required to perform support services that interfere with direct client care. DSS perform activities such as cleaning of the facility, cooking, and laundry services. DSC perform activities such as teaching clients appropriate hygiene, budgeting, or effective communication and socialization skills. During the time of this waiver, DCS may be needed to conduct some of the activities normally performed by the DSS. This will allow facilities to adjust staffing patterns, while maintaining the minimum staffing ratios required at §483.430(d)(3).

- **Suspension of Community Outings.** CMS is waiving the requirements at 42 CFR §483.420(a)(11), which requires clients have the opportunity to participate in social, religious, and community group activities. The federal and/or state emergency restrictions will dictate

the level of restriction from the community based on whether it is for social, religious, or medical purposes. States may have also imposed more restrictive limitations. CMS is authorizing the facility to implement social distancing precautions with respect to on and off-campus movement. State and federal restrictive measures should be made in the context of competent, person-centered planning for each client.

- **Suspend Mandatory Training Requirements.** CMS is waiving, in-part, the requirements at 42 CFR §483.430(e)(1) related to routine staff training programs unrelated to the public health emergency. CMS is not waiving 42 CFR §483.430(e)(2)-(4), which requires focusing on the clients' developmental, behavioral and health needs and being able to demonstrate skills related to interventions for inappropriate behavior and implementing individual plans. We are not waiving these requirements as we believe the staff ability to develop and implement the skills necessary to effectively address clients' developmental, behavioral and health needs are essential functions for an ICF/IID. CMS is also not waiving initial training for new staff hires or training for staff around prevention and care for the infection control of COVID-19. It is critical that new staff gain the necessary skills and understanding of how to effectively perform their role as they work with this complex client population and that staff understand how to prevent and care for clients with COVID-19.

- **Modification of Adult Training Programs and Active Treatment.** CMS recognizes that during the public health emergency, active treatment will need to be modified. The requirements at 42 CFR §483.440(a)(1) require that each client must receive a continuous active treatment program, which includes consistent implementation of a program of specialized and generic training, treatment, health services and related services.

  CMS is waiving those components of beneficiaries' active treatment programs and training that would violate current state and local requirements for social distancing, staying at home, and traveling for essential services only. For example, although day habilitation programs and supported employment are important opportunities for training and socialization of clients at intermediate care facilities for individuals with developmental disabilities, these programs pose too high of a risk to staff and clients for exposure to a person with suspected or confirmed COVID-19. In accordance with §483.440(c)(1), any modification to a client's Individual Program Plan (IPP) in response to treatment changes associated with the COVID-19 crisis requires the approval of the interdisciplinary team. For facilities that have interdisciplinary team members who are unavailable due to the COVID-19, CMS would allow for a retroactive review of the IPP under 483.440(f)(2) in order to allow IPPs to receive modifications as necessary based on the impact of the COVID-19 crisis.

Ambulatory Surgical Centers (ASCs)

- **Medical Staff.** 42 CFR 416.45(b). CMS is waiving the requirement at § 416.45(b) that medical staff privileges must be periodically reappraised, and the scope of procedures performed in

the ASC must be periodically reviewed. This will allow for physicians whose privileges will expire to continue practicing at the ambulatory surgical center, without the need for reappraisal, and for ASCs to continue operations without performing these administrative tasks during the PHE. This waiver will improve the ability of ASCs to maintain their current workforce during the PHE.

- **Nursing Services.** 42 CFR 42 CFR §482.23(b)(1). For ASCs enrolling as hospitals during the PHE as part of the Hospitals Without Walls Program, CMS is waiving the particular requirement at 42 CFR §482.23(b)(1), which requires the hospital to have a licensed practical nurse or registered nurse on duty at all times. This waiver will only require ASCs enrolled as hospitals to provide 24-hour nursing services when there is a patient in the facility. This flexibility will allow ASCs enrolled as hospitals to provide nursing services on demand with a 24-7 on call service in the event a surgeon requests to admit a patient for a required surgical procedure. Waiver authority applies only to federal requirements and does not supersede state requirements for licensure.

Community Mental Health Clinics (CMHCs)

- **Quality assessment and performance improvement (QAPI).** 42 CFR 485.917(a)-(d) We are modifying the requirements for CMHC's quality assessment and performance improvement (QAPI). Specifically, we are retaining the overall requirement that CMHC's maintain an effective, ongoing, CMHC-wide, data-driven QAPI program, while providing flexibility for CMHCs to use their QAPI resources to focus on challenges and opportunities for improvement related to the PHE by waiving the specific detailed requirements for the QAPI program's organization and content at § 485.917(a)-(d). Waiving the requirements related to the details of the QAPI program's organization and content will make it easier for CMHCs to reconfigure their QAPI programs, as needed, to adapt to specific needs and circumstances that arise during the PHE. These flexibilities may be implemented as long as they are consistent with a state's emergency preparedness or pandemic plan.

- **Provision of Services.** 42 CFR 485.918(b)(1)(iii). We are 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 recent regulatory changes (https://www.federalregister.gov/documents/2020/05/08/2020-09608/medicare-and-medicaid-programs-basic-health-program-and-exchanges-additional-policy-and-regulatory) that clarify how CMHCs should bill for services provided in an individual's home, and how such services should be documented in the medical record. While this waiver will now allow CMHCs to furnish services in client homes, including through the use of 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.

- **40 Percent Rule.** 42 CFR 485.918(b)(1)(v) We are waiving the requirement at § 485.918(b)(1)(v) that a CMHC provides at least 40 percent of its items and services to individuals who are not eligible for Medicare benefits. Waiving the 40 percent requirement will facilitate appropriate timely discharge from inpatient psychiatric units and prevent admissions to these facilities because CMHCs will be able to provide PHP services to Medicare beneficiaries without restrictions on the proportion of Medicare beneficiaries that they are permitted to treat at a time. This will allow communities greater access to health services, including mental health services.

Ambulance Services

- **Medicare Ground Ambulance Data Collection System *(Modified since 11/25 Release).*** CMS is modifying the data collection period and data reporting period, as defined at 42 CFR § 414.626(a), for ground ambulance organizations (as defined at 42 CFR § 414.605) that were selected by CMS under 42 CFR § 414.626(c) to collect data beginning between January 1, 2020 and December 31, 2020 (year 1) and for ground ambulance organizations that were selected to collect data beginning between January 1, 2021 and December 31, 2021 (year 2) for purposes of complying with the data reporting requirements described at 42 CFR § 414.626. Under this modification, these ground ambulance organizations can select a new continuous 12-month data collection period that begins between January 1, 2022 and December 31, 2022, to collect data necessary to complete the Medicare Ground Ambulance Data Collection Instrument during their selected data collection period, and submit a completed Medicare Ground Ambulance Data Collection Instrument during the data reporting period that corresponds to their selected data collection period. CMS is modifying this data collection and reporting period to increase flexibilities for ground ambulance organizations that would otherwise be required to collect data in 2020-2021 so that they can focus on their operations and patient care.

- **Ambulance Treat in Place (New 5/5/2021).** Pursuant to authority granted under section 9832 of the American Rescue Plan Act of 2021, CMS is waiving the requirements under section 1861(s)(7) and section 1834(l) of the Act that an ambulance service include the transport of an individual to the extent necessary to allow payment for ground ambulance services furnished in response to a 911 call (or the equivalent in areas without a 911 call system) in cases in which an individual would have been transported to a destination permitted under Medicare regulations (as described in section 410.40 to title 42, Code of Federal Regulations (or successor regulations)) but such transport did not occur as a result of community-wide

emergency medical service (EMS) protocols due to the public health emergency described in subsection (g)(1)(B).

For purposes of this waiver, community-wide EMS protocols are those established by state, local, or municipal authorities (including by a hospital, but only where a hospital has the requisite legal authority) in response to the COVID-19 PHE that govern the provision of ambulance services, and that require or allow, with patient consent, an ambulance provider or supplier to "treat in place" a patient who otherwise, but for the COVID-19 PHE, would have been transported to a Medicare covered destination (such as a hospital). Such protocols were/will be issued in written format, and such format that may have included, but is not limited to: state or local agency and official correspondence or electronic platforms that provided just-in-time updates to standard operative procedure or protocols. However, to the extent that a verbal protocol (such as from an individual hospital in a remote area) was/is in effect at the time of transport, we expect the verbal protocol to be fully documented. CMS will pay for treatment in place under this waiver in cases where the individual that would have been transported would have met the Medicare criteria for a medically necessary ground ambulance transport to the nearest appropriate facility that could have treated the patient's condition, but such transport did not occur as a result of community-wide EMS protocols due to the COVID-19 PHE. The beneficiary's condition must have required both the ambulance transportation itself and the level of service provided in order for the billed service to be considered medically necessary.

Under this waiver, ground ambulance services will be paid at the base rate that would have been paid under the fee schedule established under 1834(l) (excluding any mileage payment) if the individual had been so transported and, with respect to ambulance services furnished by a critical access hospital or an entity described in paragraph (8) of such section, at the amount that otherwise would be paid under such paragraph. Claims shall be submitted consistent with instructions, including the use of appropriate modifiers, and documentation to support medical necessity and the presence of a qualifying community-wide EMS protocol must be maintained and provided to CMS contractors for medical review upon request.

The deadline to submit claims for services that were furnished under this waiver between March 1, 2020 and May 5, 2021 is also modified. The deadline to submit such claims is May 5, 2022.

Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

- When DMEPOS is lost, destroyed, irreparably damaged, or otherwise rendered unusable, CMS is allowing DME Medicare Administrative Contractors (MACs) to have the flexibility to waive replacements requirements such that the face-to-face requirement, a new physician's order, and new medical necessity documentation are not required. Suppliers must still include a

narrative description on the claim explaining the reason why the equipment must be replaced

and are reminded to maintain documentation indicating that the DMEPOS was lost, destroyed, irreparably damaged, or otherwise rendered unusable or unavailable as a result of the emergency.

Practitioner Locations

CMS is temporarily waiving requirements that out-of-state practitioners be licensed in the state where they are providing services when they are licensed in another state. CMS will waive the physician or non-physician practitioner licensing requirements when the following four conditions are met: 1) must be enrolled as such in the Medicare program; 2) must possess a valid license to practice in the state, which relates to his or her Medicare enrollment; 3) is furnishing services — whether in person or via telehealth — in a state in which the emergency is occurring in order to contribute to relief efforts in his or her professional capacity; and, 4) is not affirmatively excluded from practice in the state or any other state that is part of the 1135 emergency area.

- In addition to the statutory limitations that apply to 1135-based licensure waivers, an 1135 waiver, when granted by CMS, does not have the effect of waiving state or local licensure requirements or any requirement specified by the state or a local government as a condition for waiving its licensure requirements. Those requirements would continue to apply unless waived by the state. Therefore, in order for the physician or non-physician practitioner to avail him or herself of the 1135 waiver under the conditions described above, the state also would have to waive its licensure requirements, either individually or categorically, for the type of practice for which the physician or non-physician practitioner is licensed in his or her home state. **When the PHE ends, current regulations will continue to allow for a deferral to state law.**

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 06-06-20202 and MACs resumed all provider enrollment site visits per TDL-200540.)***
    - *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 C.F.R. § 424.518, resumed requesting fingerprints for all newly enrolling high risk providers and suppliers per TDL-210506.)***

- *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 C.F.R. § 424.514, resumed collecting application fees per TDL-210506.)***

- *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 October 2021 with due dates in early 2022 per TDL-210506.)***
- *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:* 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, practitioners will be required to resume reporting their home address on the Medicare enrollment.
- *State Licensure:* CMS allowed licensed providers to render services outside of their state of enrollment when enrolled in Medicare, in possession of a valid license in the state of Medicare enrollment, furnishing services (either in person or via telehealth) to contribute to relief efforts in their professional capacity, and not affirmatively excluded from practice in the state or any other state that is part of the 1135 emergency area. Also, CMS waived the board certification requirement for new PAs and NPs wherever states have likewise waived the requirement.

Modification of 60-Day Limit for Substitute Billing Arrangements (Locum Tenens)

CMS is modifying the 60-day limit in section 1842(b)(6)(D)(iii) of the Social Security Act to allow a physician or physical therapist to use the same substitute for the entire time he or she is unavailable to provide services during the COVID-19 emergency plus an additional period of no more than 60 continuous days after the public health emergency expires. On the 61st day after the public health

emergency ends (or earlier if desired), the regular physician or physical therapist must use a different substitute or return to work in his or her practice for at least one day in order to reset the 60-day clock. Without this flexibility, the regular physician or physical therapist generally could not use a single substitute for a continuous period of longer than 60 days, and would instead be required to secure a series of substitutes to cover sequential 60-day periods. The modified timetable applies to both types of substitute billing arrangements under Medicare fee-for-service (i.e., reciprocal billing arrangements and fee-for-time compensation arrangements (formerly known as locum tenens)).

Notes: Under the Medicare statute, only 1) physicians and 2) physical therapists who furnish outpatient physical therapy services in a health professional shortage area (HPSA), a medically underserved area (MUA), or a rural area can receive Medicare fee-for-service payment for services furnished by a substitute under a substitute billing arrangement. In addition, Medicare can pay for services under a substitute billing arrangement only when the regular physician or physical therapist is unavailable to provide the services. Finally, as provided by law, a regular physician or physical therapist who has been called or ordered to active duty as a member of a reserve component of the Armed Forces may continue to use the same substitute for an unlimited time even after the emergency ends.

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 using 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 will continue to apply, consistent with existing regulatory authority.

Medicaid and CHIP (as of 3/13/2020)

States and territories can request approval that certain statutes and implementing regulations be waived by CMS, pursuant to section 1135 of the Act. To assist states in this process, CMS released an 1135 Waiver Checklist to make it easier for states to receive federal waivers and implement flexibilities in their Medicaid and CHIP programs. States' use of this 1135 checklist will expedite their ability to apply for and receive approval for 1135 waivers that are now available under the President's national emergency declaration.

States and territories may submit a Section 1135 waiver request directly to their Center for Medicaid & CHIP Services (CMCS) state lead or Jackie Glaze, Acting Director, Medicaid & CHIP Operations Group, Center for Medicaid & CHIP Services at CMS by e-mail (**Jackie.Glaze@cms.hhs.gov**) or letter.

The following are examples of flexibilities that states and territories may seek through a Section 1135 waiver request:

- Waive prior authorization requirements in fee-for-service programs.

- Permits providers located out of state/territory to provide care to another state's Medicaid enrollee impacted by the emergency.
- Temporarily suspend certain provider enrollment and revalidation requirements to increase access to care.
- Temporarily suspend requirements for certain pre-admission and annual screenings for nursing home residents.

States and territories are encouraged to assess their needs and request these available flexibilities, which are more completely outlined in the Medicaid and CHIP Disaster Response Toolkit. For more information and to access the toolkit and the **1135 waiver checklist**, visit: **https://www.medicaid.gov/state-resource-center/disaster-response-toolkit/index.html**.

ATTACHMENT A

Blanket Waivers of Sanctions under the Physician Self-Referral Law (also known as the "Stark Law")

CMS has issued blanket waivers of sanctions under section 1877(g) of the Act. The blanket waivers may be used now without notifying CMS. Individual waivers of sanctions under section 1877(g) of the Act may be granted upon request. For more information, visit: **https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Spotlight**

For resources and additional information on 1135 Waivers, please also visit:

- **https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page**
- **https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf**

For questions, please email: **1135waiver@cms.hhs.gov**

Blanket Waivers: Stafford Act, Public Health Emergency (PHE) and Section 1135 Waivers

Background

On March 13, 2020, the President issued an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5207 (the "Stafford Act") to declare a national health emergency. The Secretary of the Department of Health and Human Services (the Secretary) is authorized to waive certain Medicare, Medicaid and Children's Health Insurance Program (CHIP) program requirements and conditions of participation under Section 1135 of the Social Security Act once the President has declared an emergency through the Stafford Act[2] and the Secretary has declared a Public Health Emergency (PHE). The Secretary issued a PHE on January 31, 2020[3]. As a result of this authority, CMS can grant waivers that will ease certain requirements for affected providers as stated under Section 1135 of the Social Security Act[4].

CMS can issue two types of waivers: blanket waivers and provider/supplier requested waivers. Specifics about the two types of waivers are outlined in detail below. Examples of these 1135 waivers or modifications include:

- Conditions of participation or other certification requirements
- Program participation and similar requirements
- Preapproval requirements
- Requirements that physicians and other health care professionals be licensed in the state in which they are providing services, as long as they have equivalent licensing in another state (this waiver is for purposes of Medicare, Medicaid, and CHIP reimbursement only – state law governs whether a non-Federal provider is authorized to provide services in the state without state licensure)
- Emergency Medical Treatment and Labor Act (EMTALA)
- Sanctions under the physician self-referral law (also known as the "Stark Law")
- Performance deadlines and timetables may be adjusted (but not waived)
- Limitations on payment for health care items and services furnished to Medicare Advantage enrollees by non-network providers

[2] https://www.whitehouse.gov/wp-content/uploads/2020/03/LetterFromThePresident.pdf

[3] https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx

[4] https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx

Waivers under Section 1135 of the Social Security Act typically end no later than the termination of the emergency period, or 60 days from the date the waiver or modification is first published. The Secretary can extend the waiver by notice for additional periods of up to 60 days, up to the end of the emergency period.

The 1135 waiver authority applies **only** to federal requirements and **does not apply** to state requirements for licensure or conditions of participation.

In addition to the 1135 waiver authority, Section 1812(f) of the Social Security Act (the Act) authorizes the Secretary to provide for Skilled Nursing Facilities (SNF) coverage in the absence of a qualifying hospital stay, as long as this action does not increase overall program payments and does not alter the SNF benefit's "acute care nature" (that is, its orientation toward relatively short-term and intensive care).

Federally certified/approved providers must continue to operate under normal rules and regulations, unless they have sought and have been granted modifications under the waiver authority from specific requirements.

In addition, the Coronavirus Preparedness and Response Supplemental Appropriations Act, as signed into law by the President on March 6, 2020, includes a provision allowing the Secretary to waive certain Medicare telehealth payment requirements during the PHE the Secretary declared on January 31, 2020 to allow beneficiaries in all areas of the country to receive telehealth services, including at their home. Under the waiver, limitations on where Medicare patients are eligible for telehealth will be removed during the emergency. In particular, patients outside of rural areas, and patients in their homes will be eligible for telehealth services, effective for services starting March 6, 2020.[5] **This waiver will end 151 days after the conclusion of the PHE.**

[5] **https://edit.cms.gov/files/document/medicare-telehealth-frequently-asked-questions-faqs-31720.pdf**

CMS Section 1135 Waiver Authority: Blanket Waivers, Provider/Supplier Individual Waivers, Medicaid and Special Waivers

Medicare Blanket Waivers

- **Approval:** CMS implements specific waivers or modifications under the 1135 authority on a "blanket" basis when a determination has been made that all similarly situated providers in the emergency area need such a waiver or modification. These waivers prevent gaps in access to care for beneficiaries impacted by the emergency. **Once approved these waivers apply automatically to all applicable providers and suppliers. Providers and suppliers do not need to apply for an individual waiver if a blanket waiver is issued by CMS.**

- **Claims Submission for Blanket Waivers:** When submitting claims covered by the blanket waivers, the "DR" (disaster-related) condition code should be used for institutional billing (i.e., claims submitted using the ASC X12 837 institutional claims format or paper Form CMS-1450). The "CR" (catastrophe/disaster-related) modifier should be used for Part B billing, both institutional and non-institutional (i.e., claims submitted using the ASC X12 837 professional claim format or paper Form CMS-1500 or, for pharmacies, in the NCPDP format). This requirement does not apply for purposes of compliance with waivers (blanket or individual) of sanctions under the physician self-referral law.

Medicare Provider/Supplier Individual Waivers

- **Approval:** Providers and suppliers can submit requests for individual 1135 waivers. These requests must include a justification for the waiver and expected duration of the modification requested. The State Survey Agency and CMS Survey Operations Group will review the provider's request and make appropriate decisions, usually on a case-by-case basis. Providers and suppliers should keep careful records of beneficiaries to whom they provide services, in order to ensure that proper payment may be made. Providers are expected to come into compliance with any waived requirements prior to the end of the emergency period.

- With the exception of physician self-referral law waivers, the process for requesting an 1135 waiver is managed through the Survey Operations Group, and CMS locations, previously known as the CMS Regional Offices. More information on the process is located at **https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers**. The website includes contact information for each CMS location. Facilities should ensure to review the process and identify the appropriate contact based on the location of the facility.

Examples of Individual Requests for 1135 Waivers

An individual hospital may request a waiver of COPs related to doubling of single occupancy patient rooms or a waiver of the requirement to discharge to a specified location or situation.

Waiver Request Process

You **do not** have to make a request for a blanket waiver that has already been issued, and you **do not** have to notify CMS if you are taking action in accordance with a waiver during the time period in which the waiver is valid. If you are requesting an 1135 waiver outside of those outlined in this document or are already available at the CMS **Current Emergencies** page, please send your request or questions about a request to **1135waiver@cms.hhs.gov**.

Medicaid Waivers

Approval

CMS works with the states and territories to respond to public health emergencies and disasters. States and territories have multiple strategies available to support Medicaid and CHIP Operations and enrollees in times of crisis. Some of these strategies are available without needing approval from CMS while some disaster-related and Public Health Emergency legal authorities include:

- Medicaid State Plan Amendments;
- CHIP Disaster Relief State Plan Amendments;
- Verification Plans;
- 1915(c) Waivers Appendix K;
- 1135 Waivers; and
- 1115 Demonstrations.

In Medicaid and CHIP, 1135 waivers can be used to implement a range of flexibilities. Some of these include: provider enrollment and participation; Medicaid prior authorization requirements; pre-admission screening and annual resident review (PASARR) Level I and Level II Assessments for 30 days; extend minimum data set authorizations for nursing facility and SNF residents; state fair hearing and appeal process timelines; and reporting and oversight. Under 1135 waivers, states also have flexibility on public notice, tribal consultation, and the effective dates of state plan amendment (SPA) submissions. For public notice, Section 1135 authority can be used to provide flexibility related to the need and timing for public notice associated with cost sharing, Alternative Benefit Plan (ABP) benefit and payment SPAs. Section 1135 authority can be used to provide flexibility related to the timing of tribal consultation including shortening consultation or conducting tribal consultation after submission of the SPA. For SPA submission dates, Section 1135 authority can be utilized to effectively permit states to submit a Medicaid SPA after the end of this quarter and still have an effective date retroactive to the date of the declaration by the Secretary of a Public Health Emergency.

In the event of a disaster or public health emergency, state Medicaid agencies should contact CMS for questions and waiver requests. More information on this process is located at: **https://www.medicaid.gov/state-resource-center/disaster-response-toolkit/index.html**

Special Waivers

EMTALA:

Only two aspects of the EMTALA requirements can be waived under 1135 Waiver Authority: 1) Transfer of an individual who has not been stabilized, if the transfer arises out of an emergency or, 2) Redirection to another location (offsite alternate screening location) to receive a medical screening exam under a state emergency preparedness or pandemic plan. A waiver of EMTALA sanctions is effective only if actions under the waiver do not discriminate as to source of payment or ability to pay. Hospitals are generally able to manage the separation and flow of potentially infectious patients through alternate screening locations on the hospital campus.

Therefore, waivers to provide Medical Screening Examinations at an offsite alternate screening location not owned or operated by the hospital will be reviewed on a case-by-case basis. Please note, there is no waiver authority available for any other EMTALA requirement.

For the duration of the COVID-19 national emergency, CMS is waiving the enforcement of section 1867(a) of the Social Security Act (the Emergency Medical Treatment and Active Labor Act, or EMTALA). This will allow hospitals, psychiatric hospitals, and CAHs to screen patients at a location offsite from the hospital's campus to prevent the spread of COVID-19, in accordance with the state emergency preparedness or pandemic plan.

Individual Physician Self-Referral Law Waiver Requests:

CMS has issued blanket waivers of sanctions under the physician self-referral law. The blanket waivers may be used now without notifying CMS. For more information, visit: **https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Spotlight**.

Unlike other 1135 waiver requests, any requests for individual waivers of sanctions under the physician self-referral law related to COVID-19 will be handled by CMS Baltimore. Please send your request to **1877CallCenter@cms.hhs.gov** and include the words "Request for 1877(g) Waiver" in the subject line of the email. All requests should include the following minimum information:

- Name and address of requesting entity;
- Name, phone number and email address of person designated to represent the entity;
- CMS Certification Number (CCN) or Taxpayer Identification Number (TIN);
- Nature of request.

Individual waivers may be granted only upon request and on a case-by-case basis and require specific details concerning the actual or proposed financial relationship between the referring physician(s) and the referred-to entity. Unless and until a waiver of sanctions under the physician self-referral law (i.e., a waiver of section 1877(g) of the Social Security Act) is granted to the requesting party(ies), such party(ies) must comply with section 1877 of the Social Security Act and the regulations at 42 CFR §411.350 et seq.

Helpful Website Resources

- **Approved 1135 Waivers:** https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf
- **Approved Telehealth Waivers:** https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet
- **1135 Waiver Request Information:** https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers
- **Medicare Fee-For-Service Additional Emergency and Disaster-Related Policies and Procedures That May Be Implemented Only With an §1135 Waiver:** https://www. cms.gov/About-CMS/Agency-Information/Emergency/Downloads/MedicareFFS-EmergencyQsAs1135Waiver.pdf
- **Blanket Waivers – Claims Submission:** https://www.cms.gov/files/document/se20011.pdf
- **Frequently Asked Questions – 1135 Waivers:** https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/MedicareFFS-EmergencyQsAs1135Waiver.pdf
- **Frequently Asked Questions – non-1135 Waivers:** https://www.cms.gov/About-CMS/ Agency-Information/Emergency/Downloads/Consolidated_Medicare_FFS_Emergency_ QsAs.pdf
- **Medicaid Disaster Response Toolkit:** https://www.medicaid.gov/state-resource-center/ disaster-response-toolkit/index.html

CMS Oversight

CMS remains committed to ensuring continuity of oversight activities during a national public health emergency. We continue to work State Survey Agencies and accrediting organizations, charged with inspecting Medicare and Medicaid providers to ensure compliance with federal requirements, to ensure these activities are prioritized to allow providers to focus on current health and safety threats and provide needed care to beneficiaries. We will continue to monitor program operations to support proper enrollment and accurate billing practices. CMS will coordinate our oversight activities with the OIG and GAO.