Vermont Association of Hospitals and Health Systems

Issue Brief: Federal and State Regulatory Flexibility- August 28, 2020
VAHHS link to document

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Federal Regulatory Flexibility

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In effect as of 3/1/20 for Vermont without further action.

NOTE: AHA Announced on April 24, 2020 that Secretary Azar had renewed the declaration of emergency for another 90 days, which is one of the conditions for keeping the 1135 waivers in effect.

The information provided below is from the following:

- COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers **updated 8/20/20**
- Hospitals: CMS Flexibilities to Fight COVID-19
- Section 1135 Waiver Flexibilities—Vermont Coronavirus Disease of 2019
- Interim Final Rule—Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

NOTE: VAHHS has and will continue to submit multiple waivers on behalf of our hospitals and health systems, nursing homes, home health and hospice agencies, and health care providers. If you have provisions you need in the waiver, please contact devon@vahhs.org.

Hospitals, Psychiatric Hospitals, and Critical Access Hospitals

CONTROLLED SUBSTANCES

DEA worked in consultation with HHS to allow DEA-registered practitioners to begin issuing prescriptions for controlled substances to patients for whom they have not conducted an in-person medical evaluation. DEA-registered practitioners may continue this telemedicine practice for as long as the designation is in effect, if all required conditions are met:

The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice

The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system.

The practitioner is acting in accordance with applicable Federal and State law.

Provided the practitioner satisfies these requirements, the practitioner may issue the prescription using any of the methods of prescribing currently available adhering to DEA regulations, including issuing a prescription electronically or by calling in a prescription to the pharmacy.

Substance Abuse and Mental Health Services Administration (SAMHSA) guidance allowing states and provider to request exceptions to SAMHSA's limits on amounts of take-home medication for treatment of opioid use disorder.

DISCHARGE PLANNING

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. 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. 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:

- §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.

DME

DME: contractors can waive face-to-face requirement, new physician's order, and/or new medical necessity documentation

Flexibility for Respiratory Related Devices, Oxygen and Oxygen Equipment, Home Infusion Pumps and Home Anticoagulation Therapy: Clinicians now have maximum flexibility in determining patient needs for respiratory related devices and equipment and the flexibility for more patients to manage their treatments at home. The current NCDs and LCDs that restrict coverage of these devices and services to patients with certain clinical characteristics do not apply during the public health emergency

EMTALA[1]

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 (CAHs) to screen patients at a location offsite from the hospital's campus
to prevent the spread of COVID-19, so long as it is not inconsistent with a state's emergency preparedness or pandemic plan.

FACILITY REQUIREMENTS

Physical Environment. CMS is waiving certain requirements under the Medicare conditions of participation at 42 CFR §482.41 and §485.623 to allow for flexibilities during hospital, psychiatric hospital, and CAH surges. CMS will permit non-hospital buildings/space to be used for patient care and quarantine sites, provided that the location is approved by the state (ensuring that safety and comfort for patients and staff are sufficiently addressed) and so long as it is not inconsistent with a state's emergency preparedness or pandemic plan. This allows for increased capacity and promotes appropriate cohorting of COVID-19 patients. States are still under subject to the obligations under the integration mandate of the Americans with Disabilities Act, to avoid subjecting persons with disabilities to unjustified institutionalization or segregation.

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 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

[1] Memo with detailed information on EMTALA.

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) so 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.

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 under the Inpatient Psychiatric Facility Prospective Payment System for these patients and annotate the medical record to indicate the patient is a psychiatric inpatient being cared for in an acute care bed because of capacity or other exigent circumstances related to the COVID-19 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.

Acute Care Patients in the IRF or Inpatient Psychiatric Facility. 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.

Inpatient Rehab Unit Patients in Acute Care Unit. 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 under the inpatient rehabilitation facility prospective payment system for these patients and annotate the medical record to indicate the patient is a rehabilitation inpatient being cared for in an acute care bed because of capacity or other exigent circumstances related to the disaster or emergency. This waiver may be utilized where the hospital's acute care beds are appropriate for providing care to rehabilitation patients and such patients continue to receive intensive rehabilitation services.

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

classification as an IRF.

Ambulance: Medicare covering ambulance transportation to all destinations, from any point of origin, that are equipped to treat the condition of the patient.[2]

HIPAA

HIPAA[3] is not enforcing the following for hospitals with disaster protocols in effect:

- Requirement to obtain patient consent to speak with family members or friends
- Patients right to request privacy restrictions or confidential communications

QUALITY REPORTING

Quality Reporting Relief: Memo on exceptions and extensions for quality reporting

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 priorities for the program's performance improvement activities, and integrated Quality Assurance & Performance Improvement programs (for hospitals that are part of a hospital system). These flexibilities, which apply to both hospitals and CAHs, may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan. We expect any improvements to the plan to focus on the Public Health Emergency (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.

REGULATORY AND REPORTING REQUIREMENTS

Prior Authorization for Medicaid. Waiver available to suspend prior authorizations under 42 C.F.R. § 440.230(d).

Pre-existing authorizations previously received by the beneficiary are extended. Services approved prior to March 1, 2020 can continue to be provided without a new or renewed prior authorization through the public health emergency.

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:

[2] https://www.cms.gov/files/document/covid-ambulances.pdf
[3] OCR is not imposing penalties for noncompliance with the regulatory requirements under the HIPAA Rules against covered health care providers in connection with the good faith provision of telehealth during the COVID-19 nationwide public health emergency

- §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.

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, which 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 so long as they are not inconsistent 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.

Soft Wrist Restraint 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 for hospitals that are located in a state which has widespread confirmed cases (i.e., 51 or more confirmed cases*) Vermont meets this

requirement.[4] Vermont hospitals 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.

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 so long as they are not inconsistent 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 for staff to more efficiently deliver care to a larger number of patients.

Extension for Inpatient Prospective Payment System (IPPS) Wage Index Occupational Mix Survey Submission. CMS is currently granting an extension for hospitals nationwide affected by COVID-19 until August 3, 2020. If hospitals encounter difficulty meeting this extended deadline date, hospitals should communicate their concerns to CMS via their MAC, and CMS may consider an additional extension if CMS determines it is warranted.

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

[4] Note: as updated on the CDC website, CDC States Reporting Cases of COVID-19, at https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html

flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.

Emergency Preparedness Policies and Procedures. CMS is waiving 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.

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 so long as they are not inconsistent 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.

STARK LAW[5]

CMS issued 18 waivers from sanctions under the Stark/Physician self-referral law that address a wide array of specific types of transactions or referrals related to the COVID-19 outbreak in the United States. In waiving the sanctions, CMS makes clear that items and services delivered on the basis of a referral permitted under the waivers are reimbursable under the program. CMS also provided 19 concrete examples of situations to which the waivers would apply. The remuneration and referrals described in the blanket waivers must be solely related to "COVID-19 Purposes."

SWING-BEDS

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:

[5] For more information, go here: https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf

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

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

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

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

TELEHEALTH[6]

Audio-only covered: Allowing the provision of evaluation and management services and behavioral health service via audio-only phones. (see designated codes https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes)

Eligible Practitioners: CMS is waiving the requirements of section 1834(m)(4)(E) of the Act and 42 CFR § 410.78 (b)(2). 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

Provider's Home: Practitioners can provide telehealth services from their home, without reporting their home address on their Medicare enrollment, while continuing to bill from their currently enrolled location.

[6] For more information, including CPT codes, go here: https://www.cms.gov/files/document/covid-19-physicians-and-practitioners.pdf

Telehealth Service Expansion: Paying for more than 80 additional services when furnished via telehealth, including emergency department visits.

Virtual check-ins: Allowing "virtual check-ins" with physicians to be provided to new, as well as established patients.

Remote Patient Monitoring: Allowing clinicians to provide remote patient monitoring services for acute conditions, whether for COVID-19 or for another condition.

Homebound Determination via Telehealth: Allowing a physician determination that a Medicare beneficiary should not leave home because of a medical reason or COVID-19 to satisfy the home health "homebound" requirement.

Hospice Recerts: Allowing hospice recertifications to be completed via telehealth, rather than a face-to-face visit.

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.

WORKFORCE

Provider Enrollment: Non-Waiver CMS Action: CMS has a toll-free hotline for physicians and non-physician practitioners and Part A certified providers and suppliers establishing isolation facilities to enroll and receive temporary Medicare billing privileges.

- Waive the following screening requirements:
  - Application Fee - (to the extent applicable).
  - Criminal background checks associated with fingerprint-based criminal background checks (FCBC) (to the extent applicable) - 42 CFR §424.518.
  - Site visits (to the extent applicable) - 42 CFR §424.517.
- Postpone all revalidation actions. •Allow licensed providers to render services outside of their state of enrollment.
- Expedite any pending or new applications from providers.
- Allow physicians and other 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.

- Allow opted-out physicians and non-physician practitioners to terminate their opt-out status early and enroll in Medicare to provide care to more patients.

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.

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 so long as it is not inconsistent with a state's emergency preparedness or pandemic plan. This allows hospitals to use other practitioners to the fullest extent possible.

CRNA Supervision/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 so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.

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 allows for the provision of nursing care to an increased number of patients. In addition, we expect that hospitals will need relief for the provision of inpatient services and as a result, the requirement to establish nursing-related policies and procedures for outpatient departments is likely of lower priority. These flexibilities apply to both hospitals and CAHs §485.635(d)(4), and may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.

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 so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.

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.

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.

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, which 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 so long as they are not inconsistent 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.

Academic Medical Center Direct Supervision through Telecommunications. Amending the teaching physician regulations to allow the requirement for the presence of a teaching physician to be met, at a minimum, through direct supervision by interactive telecommunications technology, including when the medical resident is quarantined at home.

Academic Medical Center GME Regulations: Amending graduate medical education (GME) regulations to allow a hospital to continue to claim a resident for indirect medical education (IME) and direct GME purposes when, during an emergency situation, the resident is performing approved residency patient care duties from home or from a patient's home.[7]

OTHER

340B audits—not flexible right now - HRSA is conducting 340B Program audits remotely (virtually). If a covered entity has specific questions regarding an audit once they have been engaged, please contact the Bizzell Group (the 340B audit contractor) at *340baudit@thebizzellgroup.com* who will coordinate with HRSA based on the specifics of the request.

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 anapplication to the Medicare Geographic Classification Review Board (MGCRB) for FY 2022 reclassifications. These provisions require applications to be filed through OH CDMS(https://www.cms.gov/Regulations-and-Guidance/Review-Boards/MGCRB/Electronic-Filing)not later than the first day of the 13-month period preceding the Federal fiscal year for which reclassification is requested. Due to the COVID-19 Public Health Emergency (PHE), under the authority of section 1135(b)(5)of the Act, CMS is postponing the September 1 deadline until 15 days after the public display date of the FY 2021 IPPS/LTCH final rule by the Office of the Federal Register.

Critical Access Hospitals

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 so long as they are not inconsistent 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.

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

[7] https://www.cms.gov/files/document/covid-final-ifc.pdf

§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 so long as they are not inconsistent 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 so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.

Responsibilities of physicians in critical access hospitals (CAHs). 42 C.F.R. § 485.631(b)(2). CMS is waiving the requirement for CAHs that a doctor of medicine or osteopathy be physically present to provide medical direction, consultation, and supervision for the services provided in the CAH at § 485.631(b)(2). CMS is retaining the regulatory language in the second part of the requirement at § 485.631(b)(2) that a physician be available "through direct radio or telephone communication, or electronic communication for consultation, assistance with medical emergencies, or patient referral."

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.

Medicare-Dependent, Small Rural Hospitals (MDHs)

For hospitals classified as MDHs prior to the PHE, CMS is waiving the eligibility requirement at 42 CFR § 412.108(a)(1)(ii) that the hospital has 100 or fewer beds during the cost reporting period, and the eligibility requirement at 42 CFR § 412.108(a)(1)(iv)(C) that at least 60 percent of the hospital's inpatient days or discharges were attributable to individuals entitled to Medicare Part A benefits during the specified hospital cost reporting periods. CMS is waiving these requirements for the duration of the PHE to allow these hospitals to meet the needs of the communities they serve during the PHE, such as to provide for increased capacity and promote appropriate cohorting of COVID-19 patients. MACs will resume their standard practice for evaluation of all eligibility requirements after the conclusion of the PHE pe

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

Certain staffing requirements. 42 C.F.R. 491.8(a)(6). CMS is waiving the requirement in the second sentence of § 491.8(a)(6) that a nurse practitioner, physician assistant, or certified nurse-midwife be available to furnish patient care services at least 50 percent of the time the RHC and FQHC operates. CMS is not waiving the first sentence of § 491.8(a)(6) that 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 PH

Physician supervision of NPs in RHCs and FQHCs. 42 C.F.R. 491.8(b)(1). We are eliminating the requirement that physicians must provide medical direction for nurse practitioners, and only to the extent permitted by state law (VT has waived collaboration agreement requirement). Physicians must provide direction to other staff either in-person or remotely.

Temporary Expansion Locations. CMS is waiving the requirements at 42 CFR §491.5(a)(3)(iii) which require RHCs and FQHCs 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 services locations to meet the needs of Medicare beneficiaries. This flexibility includes areas which 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.

Long-Term Care Facilities/Skilled Nursing Facilities (SNFs)/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.

~~**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 states and nursing homes to suspend these assessments for new residents for 30 days. After 30 days, new patients admitted to nursing homes with a mental illness (MI) or intellectual disability (ID) should be referred to State PASARR program for Level 2 Resident Review.

Physical Environment. CMS is waiving requirements related at 42 CFR 483.90, specifically the following:

> 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 ofCOVID-19.

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.

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.

Resident roommates and grouping. CMS is waiving the requirements in 42 CFR 483.10(e) (5), (6), 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), (c)(5)(i) and (iv), (c)(9), and (d); and **§** 483.21(a)(1)(i), (a)(2)(i), and (b) (2)(i) (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:

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;

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

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), (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.
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 not inconsistent 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.

Expanding availability of ESRD to Nursing Home Residents. 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 in the nursing home or skilled nursing facility. CMS continues to require that services provided to these nursing home 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: furnish all dialysis care and services, provide all equipment and supplies necessary, maintain equipment and supplies in the nursing home, 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.

Physician Services. CMS is providing relief to long-term care facilities related to provision of physician services throughthe 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 ofpractice 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.

- **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.
- **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.

Quality Assurance and Performance Improvement (QAPI). (New since 4/21 Release) CMS is modifying certain requirements in 42 CFR §483.75, which requires 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.

In-Service Training. (New since 4/21 Release) 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.

Detailed Information Sharing for Discharge Planning for Long-Term Care (LTC) Facilities. (New since 4/21 Release) 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.

Clinical Records. (New since 4/21 Release) 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.

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).

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 and Homebound Status. 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.

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) to perform initial and comprehensive assessment for all patients. 42 C.F.R. 484.55(a)(2) and 484.55(b)(3). CMS is waiving the requirement that OTs may only perform the initial and comprehensive assessment if occupational therapy is the service that establishes eligibility for the patient to be receiving home health care. This temporary blanket modification allows OTs 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 occupational therapy is the service that establishes eligibility. The existing regulations at § 484.55(a) and (b)(2) would continue to apply that OTs and other therapists would not be permitted to perform assessments in nursing only case

12-hour Annual In-Service Training Requirement for Home Health Aides. (New since 4/21 Release) CMS is modifying the requirement at 42 C.F.R. §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 17 04/29/2020
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. (New since 4/21 Release) 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: (New since 4/21 Release) In accordance with section 1135(b)(5) of the Act, CMS is extending 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 will allow HHAs ten business days to provide a

patient's clinical record, instead of four.

Home Health Agencies and Hospice

Training and Assessment of Aides: (New since 4/21 Release) CMS is 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.

Quality Assurance and Performance Improvement (QAPI). (New since 4/21 Release) 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 C.F.R. 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 C.F.R. 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. (New since 4/21 Release) 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

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, 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, §485.623(b) for CAH, §418.110(c)(2)(iv) for inpatient hospice, §483.470(j) for ICF/IID; and §483.90 for SNFs/NFs 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, §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 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, §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 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.

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.

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 3 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 so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.

Expanding availability of ESRD to Nursing Home Residents. 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 in the nursing home or skilled nursing facility. CMS continues to require that services provided to these nursing home 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: furnish all dialysis care and services, provide all equipment and supplies necessary, maintain equipment and supplies in the nursing home, 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.

Vermont Association of Hospitals and Health Systems

Issue Brief: Federal and State Regulatory Flexibility- May 16, 2020

State Regulatory Flexibility

RESOURCES FOR PROVIDERS: For state resources for providers, go here.

RESUMING NON-URGENT CARE: An executive order on 5/4/2020 allows for non-urgent out-patient care and procedures can resume if facilities take environmental precautions, have a reliable supply of PPE, and perform patient and staff screening and testing. For the administration's guidelines, go here.

LIABILITY/MALPRACTICE: Governor's latest executive order limits liability for health care providers and health care facilities who are providing COVID-19-related care except in cases of gross negligence or willful misconduct. This includes cancelling or denying non-essential care and reduced record-keeping. The Governor's office assured VAHHS that this language should take care of any barriers that malpractice insurers are posing.

MEDICAID: For all information, go here. Provider-related waivers are included, above. For a full list, go here.

PROVIDER LICENSING:

- For a chart outlining COVID-19 licensure flexibilities, go here.
- Board of Medical Practice
- Office of Professional Regulation

TELEHEALTH INFORMATION: go her e for comprehensive information on the latest policies and practical advice for telehealth expansion.

HOSPITAL LICENSING EMERGENCY RULES, VDH 3/27: Go here. VDH will apply federal flexibilities at the state level.

SUSPENSION OF INSURER CREDENTIALING VERIFICATION PRACTICE, DFR 3/20: Go here. The purpose of this emergency rule is to relax provider credentialing requirements in order to facilitate the reimbursement through commercial insurance during the State of Emergency for health care services provided by physicians or other health care professionals who hold an equivalent license in another State.

PRESCRIPTION DRUG REFILLS: Insurers must cover at least 30 days supply. More information here.

SUMMARY OF ACT 91 AND ACT 140

For Act 91, go here. For the official summary, go here. For Act 140, go here.

Financial Assistance

- Modify or postpone hospital provider tax –
- Medicaid testified to the mechanisms they already have to financially support the health care system
    - Suspend provider tax

  - Exploring payment to health care providers in absence of claims or utilization due to COVID-19
  - Potential advantageous change in payment methodology to FQHCs and Rural Health Clinics, if necessary
- Medicaid-funded facilities providing 24-hour per day services, such as long-term care facilities may be reimbursed by AHS for bed-hold days.

Regulatory Flexibility

- Variance in state regulatory standards through March 31, 2021, including:
  - Hospital licensing
  - Hospital reporting
  - Nursing home licensing and operations
  - Home health licensing and operations
  - Child care licensing regulations
  - Public assistance program regulations
  - Other rules and standards under AHS
- Green Mountain Care Board has the authority to waive statutes or rules pertaining to
  - Hospital budget review
  - Certificate of Need
  - Health insurance rate review
  - ACO certification and budget review
- To the extent permitted under federal law, documentation or reporting requirements for involuntary treatment is waived for voluntary and involuntary patients
- Quarantine is not considered involuntary seclusion or restraint if the patient has been exposed to COVID-19

Workforce Flexibility

- Relaxed provider credentialing for Medicaid and commercial insurance until last of Vermont state of emergency, federal public health emergency, or declared national emergency
- Until March 31, 2021, Automatic licensure of providers licensed in other jurisdictions in good standing as well as providers who have retired in the last 3 years as long as practice is through telehealth or they are working at a health care facility. Those who are part of a facility must submit name, contact information, and location to BOM or OPR. Temporary licenses for those who are not with a facility.
- Waiver of supervision requirement for PAs now in effect. Practice agreement required. BOM may also waive supervision and scope of practice requirements for PAs, including documentation of relationship between a PA and physician through March 31, 2021.
- Waiver of transition to practice requirements for APRNs
- Until March 31, 2021, temporary licenses to those licensed who have retired 4-10 years ago in good standing and a graduate of a program who is unable to obtain a license because exams are not reasonably available
- All fees waived

Prescription Drugs

- Pharmacies can re-fill maintenance medications in 30-day supplies and physicians prescribing buprenorphine for treatment of SUD can renew the prescription without an office visit, to the extent federal law requires
- Pharmacist, with patient consent, can substitute an available prescription drug for an unavailable one
- Health care professional can authorize renewal of an existing buprenorphine prescription without an office visit

Telehealth Expansion

- DFR to consider adopting audio-only until July 1, 2021
- Same reimbursement as in-person visit for a telehealth visit
- Store and forward expansion in effect regardless of emergency
- Until March 31, 2021, waiver of HIPAA compliant connections if not practicable
- Until March 31, 2021, waiver of documented patient consent if not practicable

COVID-19 EXECUTIVE ORDERS: go here