Last Updated 4/13/2020

SUMMARY OF FEDERAL ACTIONS IN RESPONSE TO THE COVID-19 PANDEMIC

In response to the national emergency taking effect on March 1, 2020, and the public health emergency (PHE) taking effect on January 27, 2020, due to the COVID-19 pandemic, the legislature and various federal agencies have taken action to, among other purposes, offer health care providers, employers, business, and organizations certain flexibilities to ensure continued access to necessary health care and to relieve the financial burden on health care providers and other businesses to meet the increased demand for urgent health care.

The following is a summary of federal waivers, federal agency guidance, federal statutory provisions, and federal regulatory actions regarding changes to certain requirements applicable to health care providers, employers, and organizations enacted or implemented in response to the COVID-19 pandemic. The table below is organized by federal action and is also hyperlinked to the relevant source documents.

- Pages 2 – 34 describe the federal blanket waivers issued by federal agencies.
- Page 35 lists certain Medicare FFS flexibilities released by CMS.
- Pages 36–38 list the blanket waivers and flexibilities related to telemedicine.
- Pages 39 contains the relevant Stark Law blanket waiver.
- Pages 40–42 list certain statutory provisions.
- Pages 43–47 list the regulatory changes
- Pages 48–54 list guidance documents issued by CMS.
- Page 55–56 lists guidance documents issued by OIG.
- Pages 57–59 list guidance documents by the DEA
- Page 60–61 lists guidance documents by the FDA.
- Page 62 lists relevant guidance documents from various HHS sub-agencies and FEMA.
- Page 63 lists certain guidance from the IRS.
- Page 64–65 lists certain guidance from DOL.
- Page 66 lists guidance from The Joint Commission.

Please note this document captures the most relevant federal changes, but it is not exhaustive. This document was last updated on April 13, 2020. For additional information, please visit the Hall Render COVID-19 Resource Center at https://www.hallrender.com/coronavirus/ or contact John Williams at jwilliams@hallrender.com (202) 370-9585.

COVID-19 EMERGENCY DECLARATION BLANKET WAIVERS FOR HEALTH CARE PROVIDERS (Issued March 13, 2020 and Mach 17, 2020, Revised on March 20, 2020, and Updated on April 3, 2020 and April 9, 2020)				
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3/1/20	CMS/HHS	Hospitals, Psychiatric Hospitals, and CAHs	EMTALA Waiver	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.
3/1/20	CMS/HHS	Hospitals, Psychiatric Hospitals, and CAHs	Verbal Orders Waiver	CMS is waiving the requirements of §482.23, §482.24 and §485.635(d)(3) to allow for additional flexibilities related to verbal orders where read-back verification is still required but authentication may occur later than 48 hours. This will allow for more efficient treatment of patients in a surge situation.
3/1/20	CMS/HHS	Hospitals, Psychiatric Hospitals, and CAHs	Reporting Requirements Waiver	CMS is waiving the requirements at 42 C.F.R. §482.13(g)(1)(i)-(ii) which require hospitals to report patients in an intensive care unit whose death is caused by their disease process but who required soft wrist restraints to prevent pulling tubes/IVs may be reported later than close of business on the next business day, provided any death where the restraint may have contributed is continued to be reported within standard time limits. Due to current hospital surge, CMS is waiving this requirement to ensure hospitals are focusing on increased care demands and patient care.
3/1/20	CMS/HHS	Hospitals which are considered to be impacted by a widespread	Waiver re Certain Patient Rights Requirements	CMS is waiving requirements under this section only for hospitals which are considered to be impacted by a widespread outbreak of COVID-19. Hospitals that are located in a State which has widespread confirmed cases

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		outbreak of COVID-19 (i.e., 6-50 or more confirmed cases)		(i.e., 6-50 or more confirmed cases), as updated under the CDC States Reporting Cases of COVID- 19 to CDC
3/1/20	CMS/HHS	Hospitals, Psychiatric Hospitals, and CAHs	Sterile Compounding Waiver	CMS is waiving these requirements 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 which will help with the impending shortage of medications. While USP797 also outlines this, CMS will not be reviewing the use and storage of facemasks under these requirements.
3/1/20	CMS/HHS	Hospitals, Psychiatric Hospitals, and CAHs	Detailed Information Sharing for Discharge Planning for Hospitals and CAHs Waiver	CMS is waiving the requirement to provide detailed information regarding discharge planning as outlined in 42 C.F.R. §482.43(a)(8), §482.61(e), and 485.642(a)(8)
3/1/20	CMS/HHS	Hospitals, Psychiatric Hospitals, and CAHs	Limited Detailed Discharge Planning for Hospitals Waiver	CMS is waiving all the requirements and subparts 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.
3/1/20	CMS/HHS	Hospitals, Psychiatric Hospitals, and CAHs	Medical Staff Requirements Waiver	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

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				credentialing and privileging process. (Please also refer to Practitioner Locations Blanket Waiver listed below.)
3/1/20	CMS/HHS	Hospitals, Psychiatric Hospitals, and CAHs	Medical Records Timing Waiver	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.
3/1/20	CMS/HHS	Hospitals, Psychiatric Hospitals, and CAHs	Flexibility in Patient Self Determination Act Requirements (Advance Directives) Waiver	CMS is waiving the requirements at section 1902(a)(58) and 1902(w)(1)(A) for Medicaid, 1852(i) (for Medicare Advantage); and 1866(f) and 42 CFR 489.102 for Medicare, which require hospitals and CAHs to provide information about its advance directive policies to patients.
3/1/20	CMS/HHS	Hospitals, Psychiatric Hospitals, and CAHs	Physical Environment Requirements under 42 C.F.R. §482.41 and §485.623 Waiver	CMS is waiving certain requirements under the Medicare conditions at 42 C.F.R. §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 safety and comfort for patients and staff are sufficiently addressed).

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				This allows for increased capacity and promotes appropriate cohorting of COVID-19 patients.
3/1/20	CMS/HHS	Hospitals and CAHs	Telemedicine Requirements under 42 CFR §482.12(a) (8)–(9) for hospitals and §485.616(c) for CAHs Waivers	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.
3/1/20	CMS/HHS	Hospitals	Physician Services Requirements under 42 CFR §482.12(c)(1)–(2) and §482.12(c)(4) Waiver	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.
3/1/20	CMS/HHS	Hospitals, CAHs, and Ambulatory Surgical Centers (ASCs)	Anesthesia Services Requirements under 42 CFR §482.52(a)(5), §485.639(c)(2), and §416.42 (b)(2) Waiver	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. 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.
3/1/20	CMS/HHS	Hospitals	Utilization Review Requirements under 42	CMS is waiving certain requirements under 42 CFR §482.1(a)(3) and 42 CFR §482.30 which address the

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			CFR §482.1(a)(3) and 42 CFR §482.30 Waiver	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.
3/1/20	CMS/HHS	Surge Facilities	Written Policies and Procedures for Appraisal of Emergencies at Off Campus Hospital Departments Waiver	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 so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.
3/1/20	CMS/HHS	Hospitals and CAHs	Emergency Preparedness Policies and Procedures Waiver	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

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				removes the burden on facilities to establish these policies and procedures for their surge facilities or surge sites.
3/1/20	CMS/HHS	Hospitals and CAHs	Quality Assessment and Performance Improvement Program Waiver	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 (QAPI) 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.
3/1/20	CMS/HHS	Hospitals and CAHs	Nursing Services Requirements at 42 CFR §482.23(b)(4), §482.23(b)(7), and §485.635(d)(4)	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

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				provision of nursing care to an increased number of patients. In addition, CMS expects 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.
3/1/20	CMS/HHS	Hospitals	Food and Dietetic Services Requirements under 42 CFR §482.28(b)(3) Waiver	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.
3/1/20	CMS/HHS	Hospitals	Respiratory Care Services Requirements under 42 CFR §482.57(b)(1) Waiver	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. Not being required to designate these professionals in writing

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				will allow qualified professionals to operate to the fullest extent of their licensure and training in providing patient care.
3/1/20	CMS/HHS	CAHs	CAH Personnel Qualifications Waiver	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 so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.
3/1/20	CMS/HHS	CAHs	CAH Staff Licensure Waiver	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.
3/1/20	CMS/HHS	CAHs	CAH Status and Location Waiver	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

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				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.
3/1/20	CMS/HHS	CAHs	CAH Length of Stay Waiver	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.
3/1/20	CMS/HHS	Hospitals and CAHs	Temporary Expansion Locations Waiver	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 the 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) so long as the relevant

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				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.
3/1/20	CMS/HHS	CAHs	Responsibilities of physicians in critical access hospitals (CAHs) Waiver of Requirements under 42 C.F.R. § 485.631(b)(2)	CMS is waiving the requirement for CAHs that a doctor of medicine or osteopathy be physically present to provide medical direction, consultation, and supervision for the services provided in the CAH at § 485.631(b)(2). CMS is retaining the regulatory language in the second part of the requirement at § 485.631(b)(2) that a physician be available "through direct radio or telephone communication, or electronic communication for consultation, assistance with medical emergencies, or patient referral." Retaining this longstanding CMS policy and related longstanding subregulatory guidance that further described communication between CAHs and physicians will assure an appropriate level of physician direction and supervision for the services provided by the CAH. This will allow the physician to perform responsibilities remotely, as appropriate. This also allows CAHs to use nurse practitioners and physician assistants to the fullest extent possible, while ensuring necessary consultation and support as needed.
3/1/20	CMS/HHS	RHCs & FQHCs	Certain Staffing Requirements under 42 C.F.R. 491.8(a)(6) Waiver	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,

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				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.
3/1/20	CMS/HHS	RHCs & FQHCs	Physician supervision of NPs in RHCs and FQHCs Requirements under 42 C.F.R. 491.8(b)(1) Waiver	CMS is 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.
3/1/20	CMS/HHS	IPPS Hospitals	Housing Acute Care Patients in the IRF or Inpatient Psychiatric Facility (IPF) Excluded Distinct Part Units Waiver	Blanket waiver to inpatient prospective payment system (IPPS) hospitals that, as a result of the emergency, need 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 inpatient. The IPPS hospital should bill for the care and annotate the patient's medical record to indicate the patient

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				is an acute care inpatient being housed in the excluded unit because of capacity issues related to the emergency.
3/1/20	CMS/HHS	Acute Care Hospitals with Excluded Inpatient Psychiatric Units	Care for Excluded Inpatient Psychiatric Unit Patients in the Acute Care Unit of a Hospital Waiver	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 such patients and annotate the medical record to indicate the patient is a psychiatric inpatient being cared for in an acute care bed because of capacity or other exigent circumstances related to the 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.
3/1/20	CMS/HHS	Acute Care Hospitals with Excluded Distinct Part Inpatient Rehabilitation Units	Care for Excluded Inpatient Rehabilitation Unit Patients in the Acute Care Unit of a Hospital Waiver	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 (IRF) prospective payment system for such patients and annotate the medical record to indicate the patient is a rehabilitation inpatient

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				being cared for in an acute care bed because of capacity or other exigent circumstances related to the 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.
3/1/20	CMS/HHS	IPPS and Other Acute Care Hospitals	Flexibility for Inpatient Rehabilitation Facilities Regarding the "60 Percent Rule" Waiver	IRFs may exclude patients from the hospital's or 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, CMS would also apply the exception to facilities not yet classified as IRFs, but that are attempting to obtain classification as an IRF.
3/1/20	CMS/HHS	IPPS Hospitals	Extension for Inpatient Prospective Payment System (IPPS) Wage Index Occupational Mix Survey Submission Waiver	CMS collects data every 3 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, are 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 is currently granting an extension for hospitals nationwide affected by COVID-19 until August 3, 2020. If hospitals encounter difficulty

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				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.
3/1/20	CMS/HHS	Long-Term Care Acute Hospitals (LTCHs)	Supporting Care for Patients in Long-Term Care Acute Hospitals (LTCH)s	CMS has determined it is appropriate to issue a blanket waiver to long-term care hospitals (LTCHs) to exclude patient stays 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 which allows these facilities to be paid as LTCHs.
3/1/20	CMS/HHS	Extended Neoplastic Disease Care Hospitals	Care for Patients in Extended Neoplastic Disease Care Hospitals Waiver	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 IPPS 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).
3/1/20	CMS/HHS	SNF	3-Day Prior Hospital Stay Waiver	Using the authority under Section 1812(f) of the Social Security 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

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				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).
3/1/20	CMS/HHS	SNF	Reporting Minimum Data Set Requirements under 42 CFR 483.20 Waiver	This waiver provides relief to SNFs on the timeframe requirements for Minimum Data Set assessments and transmission (Blanket waiver for all impacted facilities).
3/1/20	CMS/HHS	LTCFs	Staffing Data Submission Waiver	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.
3/1/20	CMS/HHS	SNFs & NFs	Waiver of Pre-Admission Screening and Annual Resident Review (PASARR)	CMS is waiving the following requirements related to PASARR for nursing home residents who may also have a mental illness or intellectual disability (42 CFR §483.106(b)(4)).
3/1/20	CMS/HHS	LTCFs, SNFs, NFs	Physical Environment Requirements under 42 CFR 483.90 Waiver	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 as 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 is available while protecting other vulnerable adults.

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				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.
3/1/20	CMS/HHS	LTCFs, SNFs, NFs	Resident Groups Waiver	CMS is waiving the requirements at §483.10(f)(5) which allow for residents to have the right to participate in-person in resident groups. This waiver would only permit the facility to restrict having 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.
3/1/20	CMS/HHS	SNFs & NFs	Training and Certification of Nurse Aids Waiver	CMS is waiving the requirements at §483.35(d) (with the exception of 42 CFR 483.35(d)(1)(i)), which requires that a SNF and NF may not employ anyone for longer than 4 months unless they met the training and certification requirements under §483.35(d).
3/1/20	CMS/HHS	LTCFs, SNFs, NFs	Physician Visits in Skilled Nursing	CMS is waiving the requirement in 42 CFR 483.30 for physicians and non-physician practitioners to perform in-

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			Facilities/Nursing Facilities Waiver	person visits for nursing home residents and allow visits to be conducted, as appropriate, via telehealth options.
3/1/20	CMS/HHS	LTCFs, SNFs, NFs	Resident Roommates and Grouping Waiver	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.
3/1/20	CMS/HHS	LTCFs, SNFs, and/or NFs	Resident Transfer and Discharge Waiver	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 facility (LTCF) to transfer or discharge residents to another LTCF 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;

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				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 that meets certain requirements.
3/1/20	CMS/HHS	LTCFs, SNFs, and/or NFs	Physician Services: Physician Delegation of Tasks in SNFs and Physician Visits Requirements under 42 C.F.R. 483.30(e)(4) and 42 C.F.R. 483.30(c)(3) Waiver	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 C.F.R. 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 C.F.R. 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. CMS is temporarily

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				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 C.F.R. 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. CMS is 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, CMS has only

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				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, CMS noted that it is 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.
3/1/20	CMS/HHS	Home Health Agencies	Waiver Allowing Extension of Autocancellation Dates of RAPs	To ensure the correct processing of home health emergency related claims, Medicare Administrative Contractors (MACs) are allowed to extend the autocancellation date of Requests for Anticipated Payment (RAPs).
3/1/20	CMS/HHS	Home Health Agencies	OASIS Transmission Reporting Waiver	Provides relief to Home Health Agencies on the timeframes related to OASIS Transmission. This waiver includes: • Extension of the 5-day completion requirement for the comprehensive assessment to 30 days. • Waives the 30-day OASIS submission requirement. Delayed submission is permitted during the PHE.
3/1/20	CMS/HHS	Home Health Agencies	Initial Assessments Waiver	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

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				remotely or by record review.
3/1/20	CMS/HHS	Home Health Agencies	Onsite Visits for HHA Aide Supervision Waiver	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.
3/1/20	CMS/HHS	Home Health Agencies	Allow Occupational Therapists (OTs) to Perform Initial and Comprehensive Assessment for All Patients Requirements under 42 C.F.R. 484.55(a)(2) and 484.55(b)(3) Waiver	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 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

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				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 to include OTs provides HHAs with additional flexibility that may decrease patient wait times for the initiation of home health services.
3/1/20	CMS/HHS	Hospice	Use of Volunteers Waiver	CMS is waiving the requirement 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 anticipated quarantine. (42 CFR §418.78(e)).
3/1/20	CMS/HHS	Hospice	Comprehensive Assessments Waiver	CMS is waiving certain requirements for Hospices (§418.54) related to update of the comprehensive assessments of patients. This waiver applies the timeframes for updates to the comprehensive assessment (§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.
3/1/20	CMS/HHS	Hospice	Non-Core Services Waiver	CMS is waiving the requirement for hospices to provide certain non-core hospice services during the national emergency, including the requirements at §418.72 for physical therapy, occupational therapy, and speech-language pathology.
3/1/20	CMS/HHS	Hospice	Onsite Visits for Hospice Aide Supervision Waiver	CMS is waiving the requirements at 42 CFR §418.76(h), which require a nurse to conduct an onsite supervisory

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				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.
3/1/20	CMS/HHS	Hospice	Hospice Aide Competency Testing Allow Use Of Pseudo Patients Requirements under 42 C.F.R. 418.76(c)(1) Waiver	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).
3/1/20	CMS/HHS	Hospice	12-Hour Annual In-Service Training Requirement for Hospice Aides Requirements under 42 C.F.R. 418.76(d) Waiver	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.
3/1/20	CMS/HHS	ESRD Facilities	Training Program and Periodic Audits Waiver	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

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				the water/dialysate equipment are waived to allow for flexibilities.
3/1/20	CMS/HHS	ESRD Facilities	Defer Equipment Maintenance & Fire Safety Inspections Waiver	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.
3/1/20	CMS/HHS	ESRD Facilities	Emergency Preparedness Waiver	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.
3/1/20	CMS/HHS	ESRD Facilities	Ability to Delay Some Patient Assessments Waiver	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,

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				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.
3/1/20	CMS/HHS	ESRD Facilities	Time Period for Initiation of Care Planning and Monthly Physician Visits Waiver	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.

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				• §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.
3/1/20	CMS/HHS	ESRD Facilities	Dialysis Home Visits to Assess Adaptation and Home Dialysis Machine Designation Waiver	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.
3/1/20	CMS/HHS	ESRD Facilities	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.

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3/1/20	CMS/HHS	ESRD Facilities	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 SPRDF related to COVID-19 does not require Federal survey prior to providing services.
3/1/20	CMS/HHS	ESRD Facilities	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.
3/1/20	CMS/HHS	ESRD Facilities	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

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				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.
3/1/20	CMS/HHS	ESRD Facilities	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.

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3/1/20	CMS/HHS	ESRD Facilities	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.
3/1/20	CMS/HHS	DMEPOS Suppliers	Emergency Durable Medical Equipment, Prosthetics, Orthotics, and Supplies for Medicare Beneficiaries	When DMEPOS is lost, destroyed, irreparably damaged, or otherwise rendered unusable, CMS is allowing DME 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

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			Impacted by the Emergency Waiver	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. For more information refer to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies for Medicare Beneficiaries Impacted by an Emergency or Disaster Fact Sheet.
3/1/20	CMS/HHS	Certain Medicare Practitioners	Practice Location Waiver	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

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				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.

3/1/20	CMS/HHS	Medicare Providers and Suppliers	Provider Enrollment Waiver	• 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.

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				• 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.
3/1/20	CMS/HHS	Medicare Providers and Suppliers	Medicare Appeals in Fee For Service (FFS), Medicare Advantage (MA) and Part D	• CMS is allowing Medicare Administrative Contractors (MACs) and Qualified Independent Contractors (QICs) in the FFS program pursuant to 42 CFR §405.942 and 42 CFR §405.962 (including for MA and Part D plans), as well as the MA and Part D Independent Review Entities (IREs) under 42 CFR §422.562, 42 CFR §423.562, 42 CFR §422.582 and 42 CFR §423.582, to allow extensions to file an appeal. • CMS is allowing MACs and QICs in the FFS program under 42 CFR §405.950 and 42 CFR §405.966 and the MA and Part D IREs to waive requests for timeliness requirements for additional information to adjudicate appeals. • CMS is allowing MACs and QICs in the FFS program under 42 CFR §405.910 and MA and Part

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				D plans, as well as the MA and Part D IREs, to process an appeal even with incomplete Appointment of Representation forms as outlined under 42 CFR §422.561 and 42 CFR §423.560. However, any communications will only be sent to the beneficiary. • CMS is allowing MACs and QICs in the FFS program under 42 CFR §405.950 and 42 CFR §405.966 (also including MA and Part D plans), as well as the MA and Part D IREs, to process requests for appeals that do not meet the required elements using information that is available as outlined within 42 CFR §422.561 and 42 CFR §423.560. • CMS is allowing MACs and QICs in the FFS program under 42 CFR §405.950 and 42 CFR §405.966 (also including MA and Part D plans), as well as the MA and Part D IREs under 42 CFR §422.562 and 42 CFR §423.562 to utilize all flexibilities available in the appeal process as if good cause requirements are satisfied.

MEDICARE FEE-FOR-SERVICE (FFS) RESPONSE TO THE PUBLIC HEALTH EMERGENCY FLEXIBILITIES AND POLICIES & PROCEDURES WITHOUT § 1135 WAIVERS

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3/1/20	CMS/HHS	Part B Drug Dispenser	Replacement Prescription Fills	Medicare payment may be permitted for replacement prescription fills (for a quantity up to the amount originally dispensed) of covered Part B drugs in circumstances where dispensed medication has been lost or otherwise rendered unusable or unavailable due to the emergency.

3/28/20	CMS/HHS	Medicare Fee-For-Service Providers and Suppliers	Emergency-Related Policies and Procedures That May Be Implemented Without § 1135 Waivers	Guidance regarding emergency-related policies and procedures that may be implemented without section 1135 Waivers.

TELEMEDICINE BLANKET WAIVERS & FLEXIBILITIES				
Effective Date	**Authority**	**To Whom it Applies**	**Requirement Waived**	**Summary**
3/6/20	CMS/HHS	A range of providers, such as doctors, nurse practitioners, clinical psychologists, and licensed clinical social workers	Waiver of Telehealth Geographic Limitation and Site Restriction	Medicare can pay for office, hospital, and other visits furnished via telehealth across the country and including in patient's places of residence. Additionally, the HHS Office of Inspector General (OIG) is providing flexibility for health care providers to reduce or waive cost-sharing for telehealth visits paid by federal health care programs.

TELEMEDICINE BLANKET WAIVERS & FLEXIBILITIES				
Effective Date	**Authority**	**To Whom it Applies**	**Requirement Waived**	**Summary**
3/6/20	CMS/HHS	Health care providers using telecommunications between provider and patient	Telehealth Pre-Existing Patient-Provider Relationship Enforcement Flexibility	HHS will not enforce through audit the requirement that a pre-existing patient relationship be in place to take advantage of the waiver. To the extent the waiver (section 1135(g)(3)) requires that the patient have a prior established relationship with a particular practitioner, HHS will not conduct audits to ensure that such a prior relationship existed for claims submitted during this public health emergency.
3/15/20	OCR/HHS	Covered Hospitals	Limited HIPAA Privacy Rule Waiver	No Administrative Sanctions or Penalties for Non-Compliance with HIPAA Privacy Rule
3/17/20	OCR/HHS	Covered Entities and Business Associates	Non-Public Facing Remote Communication with Patients Enforcement Flexibility	OCR is exercising its enforcement discretion to not impose penalties for noncompliance with the HIPAA Rules in connection with the good faith provision of telehealth using such non-public facing audio or video communication products during the COVID-19 nationwide public health emergency. This exercise of discretion applies to telehealth provided for any reason, regardless of whether the telehealth service is related to the diagnosis and treatment of health conditions related to COVID-19. (Such products include Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, or Skype; but DO NOT include Facebook Live, Twitch, TikTok, and similar video communication applications).
3/17/20	OIG/HHS	Physicians and Other Practitioners that meet certain conditions	No Administrative Sanctions for Reducing or Waiving any Cost-Sharing Obligations	OIG will not subject physicians and other practitioners to OIG administrative sanctions for arrangements that satisfy both of the following conditions: • A physician or other practitioner reduces or waives cost-sharing obligations (i.e., coinsurance and deductibles) that a beneficiary

TELEMEDICINE BLANKET WAIVERS & FLEXIBILITIES				
Effective Date	**Authority**	**To Whom it Applies**	**Requirement Waived**	**Summary**
				may owe for telehealth services furnished consistent with the then-applicable coverage and payment rules. • The telehealth services are furnished during the time period subject to the COVID-19 Declaration.
3/17/20	DEA/DOJ	DEA Qualifying Practitioners and Other Practitioners	DEA – Prescribing Controlled Substances without In-Person Medical Evaluation	DEA-registered practitioners may issue prescriptions for controlled substances to patients for whom they have not conducted an in-person medical evaluation, provided all of the following 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.
3/19/20	DEA/DOJ	DEA Qualifying Practitioners and Other Practitioners	Use of Telephone Evaluations to Initiate Buprenorphine Prescribing	DEA advises that, only for the duration of the public health emergency (unless DEA specifies an earlier date), OTPs should feel free to dispense, and DATA-waived practitioners should feel free to prescribe, buprenorphine to new patients with OUD for maintenance treatment or detoxification treatment following an evaluation via telephone voice calls, without first performing an in-person or telemedicine evaluation. This may only be done, however, if the evaluating practitioner determines that an adequate evaluation of the patient can be accomplished via the use of a telephone, and if in compliance with CSA and

TELEMEDICINE BLANKET WAIVERS & FLEXIBILITIES				
Effective Date	**Authority**	**To Whom it Applies**	**Requirement Waived**	**Summary**
				DEA requirements to only prescribe for a legitimate medical purpose.

STARK LAW BLANKET WAIVER (Issued March 30, 2020)

Effective Date	Authority	To Whom it Applies	Requirement Waived	Summary

3/1/20	CMS/HHS	Physicians, Physician Groups, and Others Subject to Stark Law	Blanket Waivers of Section 1877(g) of the Social Security Act Due to Declaration of COVID-19 Outbreak in the United States as a National Emergency	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.

CARES ACT (Passed March 27, 2020), FAMILIES FIRST CORONAVIRUS RESPONSE ACT PROVISIONS (Passed March 18, 2020), & CORONAVIRUS PREPAREDNESS AND RESPONSE SUPPLEMENTAL APPROPRIATIONS ACT (Passed March 6, 2020)				
Effective Date	**Authority**	**To Whom it Applies**	**Provision**	**Summary**
3/27/20	CARES Act	Medicare Part A Providers and Part B Suppliers	Expansion of the Accelerated and Advance Payments Program For Providers and Suppliers During COVID-19 Emergency	Under the CARES Act, CMS has expanded the current Accelerated and Advance Payment Program to a broader group of Medicare Part A providers and Part B suppliers. View the Fact Sheet here. Expands the existing option for hospitals to request and receive "accelerated" Medicare payments from 70% to 100%.
3/27/20	CARES Act	Hospitals	$100 Billion Emergency Fund	$100 billion emergency fund for hospitals and health systems for health care related expenses or lost revenues not otherwise reimbursed that are directly attributable to COVID-19.
3/27/20	CARES Act	Hospitals	DSH Cut Delay	Medicaid Disproportionate Share Hospital (DSH) cut delay, eliminating the $4 billion in Medicaid DSH cuts scheduled for FY 2020, and reducing the cut for FY 2021 to $4 billion from $8 billion.
3/27/20	CARES Act	Medicare Providers	DRG Add-On Payment	Medicare 20% DRG add-on payment for patients with COVID-19.
3/27/20	CARES Act	IRFs	IRF 3 Hour Rule Waiver	Waiver of the inpatient rehabilitation facility (IRF) 3-hour rule.
3/27/20	CARES Act	LTCHs	Site-Neutral 50% Rule Waiver	Waiver of the 50% rule and the site neutral payment policy for long-term care hospitals (LTCHs).
3/27/20	CARES Act	Home Health Agency	Improving Care Planning for Medicare Home Health Services	This provision amends the eligibility requirements for HHAs to allow for involvement of nurse practitioners, clinical nurse specialists and physician's assistants. As amended, an individual no longer has to be solely under the care of a physician. The Act allows an individual who is under the care of a nurse practitioner, clinical nurse specialist or physician assistant (non-physician practitioner) to qualify as well. The non-physician

CARES ACT (Passed March 27, 2020), FAMILIES FIRST CORONAVIRUS RESPONSE ACT PROVISIONS (Passed March 18, 2020), & CORONAVIRUS PREPAREDNESS AND RESPONSE SUPPLEMENTAL APPROPRIATIONS ACT (Passed March 6, 2020)				
Effective Date	**Authority**	**To Whom it Applies**	**Provision**	**Summary**
				practitioner must be practicing in accordance with state law and appropriately supervised. This will allow the non-physician practitioner to sign the Home Health Certification and Care Plan – Form 485 and interim orders directly.
3/27/20	CARES Act	Hospice	Use Of Telehealth To Conduct Face-To-Face Encounter Prior To Recertification Of Eligibility For Hospice Care During Emergency Period	The Act amends the hospice face-to-face requirement and adds the qualification that "during the emergency period described in section 1135(g)(1)(B), a hospice physician or nurse practitioner may conduct a face-to-face encounter required under this clause via telehealth, as determined appropriate by the Secretary." This does not simply add telehealth, but gives the Secretary freedom, during the current emergency to allow it.
3/27/20	CARES Act	Home Health Agency	Use of Telehealth in Home Health	The CARES Act directs HHS to "consider ways to encourage the use of telecommunications systems, including for remote patient monitoring."
3/27/20	CARES Act	Volunteer Health Care Professionals	Limitation on liability for volunteer health care professionals during COVID–19 emergency response	Granting limitation on liability to volunteer health care professionals in the provisions of health care services during the PHE with respect to COVID-19.
3/27/20	CARES Act	Health Care Workforce	Health Care Workforce	Provisions reauthorizing health care workforce development programs for geriatric and nursing programs.
3/27/20	CARES Act	Community Health Centers, National Health Service Corps Participants,	Extension for community health centers, the National Health Service Corps, and teaching	HHS may, notwithstanding Section 333 of the Public Health Services Act, assign members with voluntary agreements of the National Health Service Corps to provide health services at reasonable places and hours

CARES ACT (Passed March 27, 2020), FAMILIES FIRST CORONAVIRUS RESPONSE ACT PROVISIONS (Passed March 18, 2020), & CORONAVIRUS PREPAREDNESS AND RESPONSE SUPPLEMENTAL APPROPRIATIONS ACT (Passed March 6, 2020)				
Effective Date	**Authority**	**To Whom it Applies**	**Provision**	**Summary**
		and Teaching Health Centers that Operate GME Programs	health centers that operate GME programs	as HHS deems necessary to respond to PHE.
3/27/20	CARES Act	FQHCs and RHCs	Enhancing Telehealth Services for FQHCs and RHCs During PHE	HHS will pay for telehealth services that are furnished via a telecommunications system by FQHCs and RHCs to an eligible, enrolled telehealth individual.
3/27/20	CARES Act	Eligible Borrowers	Keeping Workers Paid and Employed Act	Availability of loan opportunities for organizations with less than 500 total employees. These loans are equally open to health care providers and may be up to $10 million. The loans can be used to pay salaries, health benefits, rent, retirement obligations, among other things.
3/27/20	CARES Act	Health Care Providers	Supporting America's Health Care System in the Fight Against the Coronavirus	Provisions addressing supply shortages, mitigating drug shortages, access to health care for COVID-19 patients, and support for health care providers.
3/18/20	FFCR Act	Employers & Employees	Emergency Family and Medical Leave Expansion Act and the Emergency Paid Sick Leave Act	The new law creates excused time off and paid leave for certain employees dealing with COVID-19.
3/6/20	CPRSA Act	Medicare Providers	Telehealth Services During Certain Emergency Periods Act of 2020	Intended to protect public health during the outbreak, and allow Medicare providers to extend telemedicine services to seniors regardless of where they live.

Interim Final Rule and Temporary Rule Changes (Effective March 30, 2020HHS Interim Final Rule (IFR) Effective March 30, 2020 and Applicability Date March 1, 2020, DOL Temporary Rule Effective April 2, 2020, and FEMA Temporary Final Rule Effective April 10, 2020)				
Effective Date	**Authority**	**To Whom it Applies**	**Provision**	**Summary**
3/31/20	HHS IFR "Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency ("PHE")"	Home Health Agency	Homebound Status	CMS provides two examples of where a patient may be considered confined to the home due to COVID-19: 1. An individual for whom leaving the home is contraindicated due to confirmed or suspected diagnosis of COVID-19; or 2. An individual for whom leaving the home is medically contraindicated because the patient has a condition that may make the patient more susceptible to contracting COVID-19. Although (2) would appear to include anyone who is self-quarantining, a patient who is self-quarantining for their own safety is not "confined to the home" "unless a physician certifies that it is medically contraindicated for the patient to leave the home."
3/31/20	HHS IFR	Home Health Agency	Use of Technology in Home Health	CMS acknowledges that telehealth may be used in home health but that telehealth visits are not billable. CMS indicates that as long as the LUPA thresholds are met, telehealth visits may be used as appropriate supplements to home health visits. The use of technology must be outlined in the patient's plan of care.
3/31/20	HHS IFR	Home Health Agency	Technology and Hospice	As with home health, the use of technology in a hospice plan of care: (i) must be noted on the plan of care; (ii) must meet the requirements of 42 C.F.R. § 418.56; (iii) must be tied to the patient-specific needs identified in the comprehensive assessment; and (iv) must be linked to the measurable outcomes.

Interim Final Rule and Temporary Rule Changes (Effective March 30, 2020HHS Interim Final Rule (IFR) Effective March 30, 2020 and Applicability Date March 1, 2020, DOL Temporary Rule Effective April 2, 2020, and FEMA Temporary Final Rule Effective April 10, 2020)				
Effective Date	**Authority**	**To Whom it Applies**	**Provision**	**Summary**
3/31/20	HHS IFR	Hospice	Telehealth and Hospice Face-to-Face	The Rule amends the hospice face-to-face regulations to allow the hospice physician or nurse practitioner to perform the hospice face-to-face encounter via telehealth. The Rule also gives an example of a pandemic related situation in which the hospice physician or NP may provide billable patient care during a face-to-face encounter.
3/31/20	HHS IFR	GME Programs, residents/fellows, teaching hospitals/physicians	Revisions to Moonlighting Regulations for Residents and Fellows	In the March 30 IFR, CMS removed a barrier for residents/fellows to be able to moonlight for inpatients in their home training facilities during a PHE. Without that change, such moonlighting was prohibited by CMS.
3/31/20	HHS IFR	GME Programs, residents/fellows, teaching hospitals/physicians	Counting of Resident Time During the PHE for the COVID-19 Pandemic	Currently, there is no provision in the regulations for a hospital to claim a resident for indirect medical education (IME) or Direct graduate medical education (DGME) if the resident is performing patient care activities within the scope of his or her approved program in his or her own home, or in a patient's home. For the duration of this emergency situation, we are permitting the hospital that is paying the resident's salary and fringe benefits for the time that the resident is at home or in the home of a patient that is already a patient of the physician or hospital, but performing patient care duties within the scope of the approved residency program (and meets appropriate physician supervision requirements as stated in section II.O. of this IFC) to claim that resident for IME and DGME purposes.

Interim Final Rule and Temporary Rule Changes (Effective March 30, 2020HHS Interim Final Rule (IFR) Effective March 30, 2020 and Applicability Date March 1, 2020, DOL Temporary Rule Effective April 2, 2020, and FEMA Temporary Final Rule Effective April 10, 2020)				
Effective Date	**Authority**	**To Whom it Applies**	**Provision**	**Summary**
3/31/20	HHS IFR	Hospitals	Inpatient Hospital Services Furnished Under Arrangements Outside the Hospital During the Public Health Emergency (PHE) for the COVID-19 Pandemic	"We continue to believe that our current policy prohibiting routine services from being provided under arrangement outside the hospital is consistent with the [Social Security Act] and appropriate for the reasons discussed in the FY 2012 IPPS/LTCH PPS rulemaking. However, we wish to give hospitals that provide services to Medicare beneficiaries flexibility to respond effectively to the serious public health threats posed by COVID-19. Recognizing the urgency of this situation, and understanding that our current policy may inhibit use of capacity in settings that might otherwise be effective in the efforts to mitigate the impact of the pandemic on Medicare beneficiaries and the American public, we are changing our under arrangements policy during the PHE for the COVID-19 pandemic so that hospitals are allowed broader flexibilities to furnish inpatient services, including routine services outside the hospital."
3/31/20	HHS IFR	Hospitals	Physician Supervision Flexibility for Outpatient Hospitals—Outpatient Hospital Therapeutic Services Assigned to the Non-Surgical Extended Duration Therapeutic Services (NSEDTS) Level of Supervision	CMS has assigned, "on an interim basis, all outpatient hospital therapeutic services that fall under § 410.27(a)(1)(iv)(E), a minimum level of general supervision to be consistent with the minimum default level of general supervision that applies for most outpatient hospital therapeutic services, and we are revising § 410.27(a)(1)(iv)(E) to reflect this change in the minimum level of supervision. General supervision, as defined in our regulation at § 410.32(b)(3)(i) means that the procedure is

Interim Final Rule and Temporary Rule Changes (Effective March 30, 2020HHS Interim Final Rule (IFR) Effective March 30, 2020 and Applicability Date March 1, 2020, DOL Temporary Rule Effective April 2, 2020, and FEMA Temporary Final Rule Effective April 10, 2020)				
Effective Date	**Authority**	**To Whom it Applies**	**Provision**	**Summary**
				furnished under the physician's overall direction and control, but that the physician's presence is not required during the performance of the procedure."
3/31/20	HHS IFR	Hospitals	Application of Certain National Coverage Determination and Local Coverage Determination Requirements During the PHE for the COVID-19 Pandemic	1. Face-to-Face and In-Person Requirements. CMS has finalized on an interim basis "that to the extent an NCD or LCD (including articles) would otherwise require a face-to-face or in-person encounter for evaluations, assessments, certifications or other implied face-to-face services, those requirements would not apply during the PHE for the COVID-19 pandemic. 2. Clinical Indications for Certain Respiratory, Home Anticoagulation Management and Infusion Pump Policies. CMS has finalized "on an interim basis that [CMS] will not enforce the clinical indications for coverage across respiratory, home anticoagulation management and infusion pump NCDs and LCDs (including articles) allowing for maximum flexibility for practitioners to care for their patients. This enforcement discretion will only apply during the PHE for the COVID-19 pandemic." 3. Requirements for Consultations or Services Furnished by or with the Supervision of a Particular Medical Practitioner or Specialist. To the extent NCDs and LCDs require a specific practitioner type or physician specialty to furnish a service, procedure or any portion thereof, we are

Interim Final Rule and Temporary Rule Changes (Effective March 30, 2020HHS Interim Final Rule (IFR) Effective March 30, 2020 and Applicability Date March 1, 2020, DOL Temporary Rule Effective April 2, 2020, and FEMA Temporary Final Rule Effective April 10, 2020)				
Effective Date	**Authority**	**To Whom it Applies**	**Provision**	**Summary**
				finalizing on an interim basis the chief medical officer or equivalent of the facility can authorize another physician specialty or other practitioner type to meet those requirements during the PHE for the COVID-19 pandemic. Additionally, to the extent NCDs and LCDs require a physician or physician specialty to supervise other practitioners, professionals or qualified personnel, the chief medical officer of the facility can authorize that such supervision requirements do not apply during the PHE for the COVID-19 pandemic.
4/2/20	DOL Temporary Rule	Employers and Employees	Temporary Rule: Paid Leave under the Families First Coronavirus Response Act	On April 1, 2020, the Department of Labor (DOL) announced new action regarding how American workers and employers will benefit from the protections and relief offered by the Emergency Paid Sick Leave Act and Emergency Family and Medical Leave Expansion Act, both part of the Families First Coronavirus Response Act (FFCRA). This rule is effective through December 31, 2020.
4/10/2020	FEMA Temporary Rule	Exporters of certain types of PPE	Temporary Final Rule: Prioritization and Allocation of Certain Scarce or Threatened Health and Medical Resources for Domestic Use	FEMA published a temporary final rule giving the Agency the authority to block the export of critical PPE during the COVID-19 pandemic, including masks, respirators (and their filters and cartridges), non-sterile gloves and surgical gloves. The rule is effective until August 8, 2020.

CMS MEMORANDA AND GUIDANCE				
Effective Date	**Authority**	**To Whom it Applies**	**Guidance Document Name**	**Summary**
3/4/20	CMS Memo Guidance	Health Care Facilities and Clinical Laboratories	Suspension of Survey Activities ("QSO Memo")	CMS is suspending non-emergency inspections across the country, allowing inspectors to turn their focus on the most serious health and safety threats like infectious diseases and abuse. This shift in approach will also allow inspectors to focus on addressing the spread of COVID-19. CMS is issuing this memorandum to State Survey Agencies to provide important guidelines for the inspection process in situations in which a COVID-19 is suspected.
3/4/20	CMS Guidance	Hospitals Psychiatric Hospitals, & CAHs	Guidance for Infection Control and Prevention of Coronavirus Disease (COVID-19) in Hospitals, Psychiatric Hospitals, and Critical Access Hospitals (CAHs): FAQs and Considerations for Patient Triage, Placement, Limits to Visitation and Availability of 1135 Waivers (Issued March 4, 2020 and Revised March 30, 2020)	CMS issued memoranda providing guidance for Infection Control and Prevention of COVID-19 for Hospitals, Psychiatric Hospitals, and CAHs which address concerns relating to screening staff and visitors, the severity of infection that would warrant hospitalization instead of self-isolation, the process for transferring patients between nursing homes and hospitals, and the circumstances under which providers should take precautionary measures for patients and residents diagnosed with or showing signs and symptoms of COVID-19.
3/9/20	CMS Guidance	Hospice	Guidance for Infection Control and Prevention Concerning COVID-19 by Hospice Agencies	This guidance addresses concerns related to the screening, treatment and transfer procedures health care workers must follow when interacting with patients to prevent the spread of COVID-19 in a hospice setting. Additionally, CMS supplemented and revised its March 4, 2020 Guidance for Infection Control and Prevention of COVID-19 in Nursing Homes in recognition of the

CMS MEMORANDA AND GUIDANCE				
Effective Date	**Authority**	**To Whom it Applies**	**Guidance Document Name**	**Summary**
				high-risk patient populations in these facilities. As revised, the guidance offers expanded FAQs regarding care and treatment of patients diagnosed with or showing signs and symptoms of COVID-19 to help control and prevent the spread of the virus.
3/9/20	CMS Guidance	Hospitals and CAHs	Emergency Medical Treatment and Labor Act (EMTALA) requirements and implications related to COVID-19 (Issued March 9, 2020 and Revised March 30, 2020)	The Memo offers guidance to hospitals EDs on patient screening, treatment and transfer requirements to prevent the spread of infectious disease and illness, including COVID-19. The memo directs Medicare-participating hospitals to follow both CDC guidance for infection control as well as EMTALA requirements and includes FAQs relating to EMTALA to ensure that hospitals fully understand their obligations in light of COVID-19.
3/10/20	CMS Guidance	Home Health Agencies	Guidance for Infection Control and Prevention of COVID-19 for Home Health Agencies	CMS issued Guidance for Infection Control and Prevention of COVID-19 for Home Health Agencies. The guidance provides actionable information for health care workers on screening, treatment and transfer procedures to follow when interacting with patients considering the COVID-19 pandemic.
3/10/20	CMS Guidance	Dialysis Facilities	Guidance for Infection Control and Prevention of COVID-19 for Dialysis Facilities (Issued March 10, 2020 and Revised March 30, 2020)	CMS issued Guidance for Infection Control and Prevention of COVID-19 for Dialysis Facilities. The guidance provides actionable information for health care workers on screening, treatment and transfer procedures to follow when interacting with patients considering the COVID-19 pandemic.
3/13/20	CMS Guidance	SNFs & NFs	Guidance for Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in Nursing	"CMS is responsible for ensuring the health and safety of nursing home residents by enforcing the standards required to help each resident attain or maintain their highest level of well-being. In light of the recent spread

CMS MEMORANDA AND GUIDANCE				
Effective Date	**Authority**	**To Whom it Applies**	**Guidance Document Name**	**Summary**
			Homes	of COVID-19, we are providing additional guidance to nursing homes to help control and prevent the spread of the virus."
3/18/20	CMS Guidance	Health Care Providers	Recommendations on Adult Elective Surgeries	Recommends delay of all elective surgeries, non-essential medical, surgical, and dental procedures during the COVID-19 outbreak. The recommendations seek to preserve personal protective equipment, beds and ventilators and free up the health care workforce to aid in the care of patients most in need.
3/22/20	CMS Guidance	Quality Payment Program Participants	QPP Policy Exceptions	CMS announced a series of extreme and uncontrollable circumstances policy exceptions and extensions relating to upcoming measure for reporting and data submission deadlines for clinicians, providers, and facilities participating in Medicare quality reporting programs, including the Quality Payment Program - Incentive Payment System (MIPS) and the Medicare Shared Savings Program Accountable Care Organizations (ACOs).
3/23/20	CMS Guidance	Medicare Providers and Suppliers	Fact Sheet re COVID-19 Coverage and Payment	CMS updated a previously published Fact Sheet (updated April 9) for Medicare Coverage and Payment Related to COVID-19 summarizing Medicare coverage and payment updates in response to COVID-19. Notable among these updates was a second Healthcare Common Procedure Coding System (HCPCS) code for certain COVID-19 laboratory tests.
3/26/20	CMS Guidance	Clinical Laboratories	Clinical Laboratory Improvement Amendments (CLIA) Laboratory Guidance During COVID-19 PHE	In an effort to ensure that America's clinical laboratories are prepared to respond to the COVID-19 pandemic, CMS issued a memo providing guidance during these uncertain times.

CMS MEMORANDA AND GUIDANCE				
Effective Date	**Authority**	**To Whom it Applies**	**Guidance Document Name**	**Summary**
3/23/20	CMS Guidance	Medicare Providers and Suppliers	Coverage and Payment Related to COVID-19 Medicare	Guidance related to coverage and payment provisions for diagnostic tests, vaccines, inpatient hospital care services, inpatient hospital quarantines, ambulatory services in a hospital or other location, telehealth services, requests for prescription refills, Medicare Advantage, Emergency Ambulance Transportation, Part D Coverage, and Prior Authorization.
3/28/20	CMS Guidance	Hospitals and CAHs	APP Fact Sheet	CMS published a fact sheet summarizing the expansion of the Accelerated and Advanced Payments program in accordance with the passage of the Coronavirus Aid, Relief and Economic Security Act ("CARES") Act. Most providers and suppliers will be able to request up to 100% of the Medicare payment amount for a three-month period. Inpatient acute care hospitals, children's hospitals, and certain cancer hospitals are able to request up to 100% of the Medicare payment amount for a six-month period. CAH can request up to 125% of their payment amount for a six-month period. Repayment of these accelerated/advance payments will begin 120 days after the date of the payment and hospitals will have one year from the date of the accelerated payment to repay the balance whereas all other providers and supplier will have 210 days. Additional considerations including eligibility criteria, processing times, and recoupment and reconciliation, are detailed in the Fact Sheet.

CMS MEMORANDA AND GUIDANCE				
Effective Date	**Authority**	**To Whom it Applies**	**Guidance Document Name**	**Summary**
3/29/20	CMS Letter	Hospitals	CMS Letter to All Hospitals	CMS sent a letter on behalf of Vice President Pence to all U.S. Hospitals requesting that they report additional COVID-19 testing data to HHS. The letter also requests daily reporting regarding bed capacity and supplies to the CDC National Healthcare Safety Network Covid-19 Patient Impact and Hospital Capacity Module. CMS has already been collecting data from other public and private laboratory companies but does not have data from hospital labs that conduct laboratory testing in their hospital. CMS believes this data will help them to keep a better pulse on the spread of COVID-19 and help support the Federal Emergency Management Agency and the CDC in their efforts to support states and localities responding to the pandemic.
3/1/20	CMS Guidance	Medicare FFS Providers and Supplies	Medicare Fee-for-Service (FFS) Response to the Public Health Emergency on the Coronavirus (COVID-19) (Issued April 3, 2020 and Revised April 10, 2020)	Information regarding blanket waivers as described in more detail above, as well as additional guidance and resources.
3/5/20	CMS Guidance	Medicaid Providers	Coverage and Benefits Related to COVID-19 Medicaid and CHIP	Medicaid and CHIP programs cover a broad range of benefits, which may vary by state. Some benefits are mandatory which means states are required to provide them while other benefits are optional for states to provide. More information about some benefits is described in this document.
3/17/20	CMS Guidance	ESRD Suppliers	ESRD Provider Telehealth and Telemedicine Tool Kit	Guidance document for ESRD suppliers and telehealth.

CMS MEMORANDA AND GUIDANCE				
Effective Date	**Authority**	**To Whom it Applies**	**Guidance Document Name**	**Summary**
3/30/20	CMS Guidance	Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IIDs) and Psychiatric Residential Treatment Facilities (PRTFs)	Guidance for Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IIDs) and Psychiatric Residential Treatment Facilities (PRTFs)	"CMS is responsible for ensuring the health and safety of ICF/IID and PRTF clients/residents by enforcing the standards required to help each client/resident attain or maintain their highest level of well-being. In light of the recent spread of COVID-19," CMS is providing additional guidance to ICF/IIDs and PRTFs to help control and prevent the spread of the virus SARS-CoV-2 and the disease it causes, COVID-19.
3/30/20	CMS Guidance	Outpatient Facilities (ASCs, CMHCs, CORFs, OPTs, and RHCs/FQHCs)	Guidance for Infection Control and Prevention of Coronavirus Disease (COVID-19) in Outpatient Settings: FAQs and Considerations	"CMS is responsible for ensuring the health and safety of patients receiving care, treatment and services in healthcare facilities from the spread of infectious disease, including being committed to taking critical steps to ensure America's healthcare facilities can respond to the threat of COVID-19. This memorandum responds to questions we have received and provides important guidance for outpatient settings other than hospital outpatient departments, specifically ASCs, CMHCs, CORFs, OPTs, and RHCs/FQHCs (herein referred to as healthcare facilities) in addressing the COVID-19 outbreak and minimizing transmission to other individuals."
4/7/20	CMS Letter	Health Care Providers	Dear Clinician Letter Outlining Various Programs and Summarizing Information	CMS issued a letter to clinicians outlining various programs and summarizing information, such as Medicare telehealth information and testing and claims reporting for COVID-19.
4/2/20	CMS Guidance	Long-Term Care Facilities (LTCFs)	COVID-19 Long-Term Care Facility Guidance	CMS and the Centers for Disease Control and Prevention (CDC) are issuing new recommendations to

CMS MEMORANDA AND GUIDANCE				
Effective Date	**Authority**	**To Whom it Applies**	**Guidance Document Name**	**Summary**
				State and local governments and long-term care facilities (also known as nursing homes) to help mitigate the spread of COVID-19.

OIG MEMORANDA AND GUIDANCE				
Effective Date	**Authority**	**To Whom it Applies**	**Requirement Waived**	**Summary**
4/3/20	Policy Statement	Individuals and Entities Subject to OIG Enforcement	OIG Policy Statement Regarding Application of Certain Administrative Enforcement Authorities Due to Declaration of Coronavirus Disease 2019 (COVID-19) Outbreak in the United States as a National Emergency	Ordinarily, some financial relationships that implicate the physician self-referral law also may implicate, and potentially violate, the Federal Anti-Kickback Statute. However, recognizing the unique circumstances of the COVID-19 outbreak, OIG will not impose administrative sanctions under sections 1128(b)(7) or 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute, with respect to remuneration that is covered by section II.B.(1)-(11) of the Blanket Waivers. For more information, see the FAQs–Application of OIG's Administrative Enforcement Authorities to Arrangements Directly Connected to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency.
3/30/20	Message	Individuals and Entities Subject to OIG Enforcement	Message from leadership on minimizing burdens on providers	"Health care organizations that need extensions of OIG deadlines, such as to produce data for an OIG review or to comply with a Corporate Integrity Agreement, are encouraged to ask their OIG contact. OIG will work with organizations on a reasonable solution." "For any conduct during this emergency that may be subject to OIG administrative enforcement, OIG will carefully consider the context and intent of the parties when assessing whether to proceed with any enforcement action."
4/6/20	OIG Report	Hospitals	Hospital Experiences Responding to the COVID-19 Pandemic: Results of a National	Hospitals reported that their most significant challenges centered on testing and caring for patients with known or suspected COVID-19 and keeping staff safe. Hospitals also reported substantial challenges maintaining or expanding their facilities' capacity to

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			Pulse Survey March 23–27, 2020	treat patients with COVID-19. Hospitals described specific challenges, mitigation strategies, and needs for assistance related to PPE, testing, staffing, supplies and durable equipment; maintaining or expanding facility capacity; and financial concerns.

DEA MEMORANDA AND GUIDANCE				
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3/20/20	Policy	DEA Qualifying Practitioners and Other Practitioners	Registrant Guidance on Controlled Substance Prescription Refills	Policy related to refills of controlled substances during the COVID-19 Response.
3/31/20	Policy	DEA Qualifying Practitioners and Other Practitioners	COVID-19 Prescribing Guidance	This chart only addresses prescribing controlled substances and does not address administering or direct dispensing of controlled substances, including by narcotic treatment programs (OTPs) or hospitals.
3/25/20	Policy	DEA Registrants	Exception to Separate Registration Requirements Across State Lines	DEA will grant an exception for practitioners in such states to those provisions of DEA regulations that normally require practitioners to register in each state where they dispense controlled substances. Practitioners must otherwise comply with applicable state law. Practitioners must be registered with DEA in at least one state and have permission under state law to practice using controlled substances in the state where the dispensing occurs.
3/27/20	Policy	Practitioner Registrants and Pharmacists	Exception to Regulations Emergency Oral CII Prescription	DEA has announced 2 temporary exceptions to the criteria to enable greater flexibility in oral prescribing of Schedule II controlled substances.
Ongoing – Last Visited 4/7/20	Guidance	DEA Registrants	Remote Identity Proofing EPCS at hospital/clinics	DEA regulations generally authorize the use of remote identity proofing when issuing authentication credentials for use in the electronic prescribing of controlled substances (EPCS), even in the absence of a public health emergency. If a hospital/clinic wishes to conduct remote identity proofing, DEA suggests using a device that allows for real-time, two-way, audio-visual interactive communication.
3/23/20	Policy	DEA Registrant Bulk Manufacturers	65% Bulk Manufacture Exception to Regulations	DEA will grant an exception to those provisions of 21 CFR 1303.24(b) that normally require the inventory for individual manufacturers to remain at 65 percent or

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				less. Under this exception, all DEA registered bulk manufacturers are allowed to exceed the 65 percent ceiling in order to supply dosage form manufacturers with the active pharmaceutical ingredient(s); this may be necessary to manufacture specific products to avoid existing or potential shortages. This exception does not authorize any manufacturer to exceed his previously established annual manufacturing quota.
3/31/20	Policy	DEA Qualifying Practitioners and Other Practitioners	Questions and Answers for Prescribing Practitioners (EPCS)	General FAQ guidance for prescribing practitioners regarding EPCS and including EPCS during COVID-19 pandemic.
8/16/18	Guidance	DEA Qualifying Practitioners and Other Practitioners	Use of Mobile Devices in the Issuance of EPCS	Statement regarding the use of mobile devices for issuing EPCS due to confusion surrounding this issue.
4/7/20	Policy	DEA Qualifying Practitioners and Other Practitioners	Use of Unregistered Off-Site Location in MAT	DEA will exercise its authorities to permit OTPs to regularly use off-site locations located in the same state in which the OTP is registered with DEA to deliver take-home doses of methadone to their patients without separately registering those locations, subject to certain limitations.
3/16/20	Guidance	Narcotic Treatment Programs	Exemption Allowing Alternate Delivery Methods for OTPs	Allowing alternative delivery methods using the NTP's established chain of custody protocol for take-home medications.
Ongoing	Guidance	DEA Registrants	Methadone Shortages	Q&A regarding potential methadone shortages during COVID-19 pandemic.
Ongoing	Guidance	DEA Registrants	Questions and Answers for Registration of Emergency Temporary Sites and Picking Up Controlled Substances	Q&As re how a distributor can set up an alternate location from which to deliver controlled substances, can obtain expedited approval to deliver to an alternate address for their customers in the event that a pharmacy or health care facility is shut down for quarantine or

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			Orders from Distributors	cleaning, and can pick up controlled substances orders from a distributor.
Ongoing	Guidance	DEA Registrants	Records and Reports in Response to COVID-19	Summary of requirements and exceptions for inventory reporting for pharmacies and shipment receiving.
3/20/2020	Policy	DEA Registrants	Exception to Regulations to Email or Fax DEA Form 222s	All DEA registrants who order controlled substances are permitted to fax or scan/email a DEA Form 222 to their respective suppliers. Likewise, when a supplier receives a faxed or scanned/emailed DEA Form 222 pursuant to this exception, the supplier shall treat the faxed or scanned/emailed form as the original for purposes of 21 CFR 1305.13.
4/10/2020	Notice and Final Order	Pharmaceutical Manufacturers	Adjustments to Aggregate Production Quotas for Certain Schedule II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine and Pseudoephedrine for 2020, in Response to the Coronavirus Disease 2019 Public Health Emergency	"DEA is adjusting the established 2020 aggregate production quotas and assessment of annual needs for selected schedule II controlled substances and list I chemicals, to be manufactured in the United States to provide for the estimated needs of the United States. These adjustments are necessary to ensure that the United States has an adequate and uninterrupted supply of these substances as the country moves through this public health emergency. Although the existing 2020 quota level is sufficient to meet current needs, DEA is acting proactively to ensure that—should the public health emergency become more acute—there is sufficient quota for these important drugs."

FDA MEMORANDA AND GUIDANCE				
Effective Date	**Authority**	**To Whom it Applies**	**Requirement Waived**	**Summary**
3/16/20	Guidance	Clinical Laboratories, Commercial Manufacturers, and FDA Staff	Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency	"The Food and Drug Administration (FDA or Agency) is issuing this guidance to provide a policy to help accelerate the availability of novel coronavirus (COVID-19) diagnostic tests developed by laboratories and commercial manufacturers during the public health emergency."
Ongoing	FAQ	Clinical Laboratories	FAQs on Diagnostic Testing for SARS-CoV-2	This page provides answers to FAQs relating to the development and performance of diagnostic tests for SARS-CoV-2.
April 2020	Temporary Policy Guidance	Drug Compounders	Temporary Policy Regarding Non-Standard PPE Practices for Sterile Compounding by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency	"FDA is issuing this guidance to communicate its temporary policy related to PPE [PPE includes face masks, gloves, gowns, shoe covers, hair/head covers, and other garb worn during the compounding of drug products that are intended to be sterile, to help protect the product from contamination] use during human drug compounding at State-licensed pharmacies or Federal facilities that are not registered with FDA as outsourcing facilities (referred to collectively in this guidance as compounders). This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the U.S. Department of Health and Human Services (HHS), including any renewals made by the HHS Secretary in accordance with section 319(A)(2) of the Public Health Service Act (42 U.S.C. 247d(a)(2))."
March 2020 (Updated 4/2/20)	Guidance	Clinical Trial Industry, Investigators, and IRBs	FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic	"FDA is issuing this guidance to provide general considerations to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practice (GCP), and minimizing risks to trial integrity during the COVID-19 pandemic. The

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				appendix to this guidance further explains those general considerations by providing answers to questions about conducting clinical trials that the Agency has received during the COVID-19 pandemic."

OTHER AGENCY MEMORANDA AND GUIDANCE				
Effective Date	**Authority**	**To Whom it Applies**	**Requirement Waived**	**Summary**
3/23/20	HRSA Guidance	340B Program Participants and Stakeholders	COVID-19 Resources	All COVID-19 information related to the 340B Program will appear on this page, and HRSA will update resources as they become available.
Ongoing	SAMHSA Guidance	Medicated-Assisted Treatment (MAT) Providers	COVID-19 Guidance for Opioid Treatment Programs	Guidance website for more information on SAMHSA initiatives.
4/13/20	FCC Guidance	Health Care Providers	FCC Applications for COVID-19 Telehealth Program	FCC issued a Public Notice stating that it would begin accepting applications for its COVID-19 Telehealth Program at 12:00p.m. ET Monday, April 13. This follows the FCC's Public Notice from Wednesday providing additional guidance on the types of equipment and services it would consider eligible under the Program.
3/13/20	HHS OCR Guidance	HIPAA Covered Entities and Business Associates	Notification of Enforcement Discretion for Community-Based Testing Sites During the COVID-19 Nationwide Public Health Emergency	"As a matter of enforcement discretion, the HHS Office for Civil Rights (OCR) will not impose penalties for noncompliance with the regulatory requirements under the HIPAA Rules against covered health care providers or their business associates in connection with the good faith participation in the operation of a COVID-19 Community-Based Testing Site (CBTS) during the COVID-19 nationwide public health emergency."
Ongoing	CDC Guidance	Health Care Professionals	CDC Resources for Health Care Facilities an Professionals	Summary of resources available for health care professionals and facilities responding to COVID-19. See also CDC's What's New page for regular updates of available resources.
4/8/20	HHS OASH Guidance	Licensed Pharmacists	Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act	HHS Office of the Assistant Secretary for Health issues this guidance authorizing licensed pharmacists to order and administer COVID-19 tests, including serology tests, that the FDA has authorized.

IRS MEMORANDA AND GUIDANCE				
Effective Date	**Authority**	**To Whom it Applies**	**Requirement Waived**	**Summary**
3/31/20	IRS Guidance	Employers & Employees	IR 2020-62 – Employee Retention Credit	The IRS offered initial guidance on the Employee Retention Credit, which was established by the CARES Act as another way to encourage businesses to keep employees on their payroll.
4/1/20	IRS Guidance	Employers & Employees	Notice 2020-22: Relief from Penalty for Failure to Deposit Employment Taxes	The IRS formally announced it is waiving penalties for failure to make a deposit of employment taxes (including income tax withholding, Federal Insurance Contributions Act taxes, and taxes pursuant to the Railroad Retirement Tax Act). The waiver will apply to the extent that the amounts not deposited are equal to or less than the amount of refundable tax credits to which the employer is entitled and claiming under FFCRA and the CARES Act. The new IRS guidance and FAQs can be found here.
Ongoing	IRS Guidance	Taxpayers, businesses, and others	Coronavirus Tax Relief	The IRS has established a special section focused on steps to help taxpayers, businesses and others affected by the coronavirus. This page will be updated as new information is available.

DOL MEMORANDA AND GUIDANCE				
Effective Date	**Authority**	**To Whom it Applies**	**Requirement Waived**	**Summary**
4/1/20	DOL Guidance	Employers and Employees	Guidance re Temporary Rule: Paid Leave under the Families First Coronavirus Response Act	Additional Resources, Q&A, Facts Sheets, and Field Assistance Bulletin
3/17/20	DOL OFCCP Guidance	All Contracting Agencies Of The Federal Government	Contracts for Coronavirus Relief Efforts	OFCCP Memo: National Interest Waiver Exemption for Coronavirus Related Federal Contracts
3/19/20	EEOC Guidance	Employer & Employees	What You Should Know About the ADA, the Rehabilitation Act and the Coronavirus	The EEOC has provided guidance (a publication entitled Pandemic Preparedness in the Workplace and the Americans With Disabilities Act [PDF version]), consistent with these workplace protections and rules, that can help employers implement strategies to navigate the impact of COVID-19 in the workplace. This pandemic publication, which was written during the prior H1N1 outbreak, is still relevant today and identifies established ADA and Rehabilitation Act principles to answer questions frequently asked about the workplace during a pandemic. It has been updated as of March 19, 2020 to address examples and information regarding COVID-19; **the new information appears in bold**.
March 2020	DOL OSHA Guidance	Employers & Employees	Guidance on Preparing Workplaces for COVID-19	The Occupational Safety and Health Administration (OSHA) developed this COVID-19 planning guidance based on traditional infection prevention and industrial hygiene practices. It focuses on the need for employers to implement engineering, administrative, and work practice controls and PPE, as well as considerations for doing so.

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Effective Date	**Authority**	**To Whom it Applies**	**Requirement Waived**	**Summary**
4/3/2020	DOL OSHA Memorandum Guidance	Employers & Employees	Enforcement Guidance for Respiratory Protection and the N95 Shortage Due to the COVID-19 Pandemic	OSHA has issued interim guidance for enforcing its Respiratory Protection standard and certain other health standards (29 CFR Part 1910) with regard to supply shortages of disposable N95 filtering facepiece respirators. Specifically, it outlines enforcement discretion to permit the extended use and reuse of respirators, as well as the use of respirators that are beyond their manufacturer's recommended shelf life (sometimes referred to as "expired").
4/10/2020	DOL OSHA Memorandum Guidance	Employers & Employees	Enforcement Guidance for Recording Cases of COVID-19	OSHA has issued interim guidance for enforcing its recordkeeping requirements (29 CFR Part 1904) as it relates to recording cases of COVID-19.

THE JOINT COMMISSION GUIDANCE				
Effective Date	**Authority**	**To Whom it Applies**	**Requirement Waived**	**Summary**
March 2020	The Joint Commission	Provider accredited by or seeking accreditation from TJC	Resources from TJC	• Frequently Asked Questions regarding Personal Protective Equipment – FAQ on Mask Considerations and FAQ on Conserving Facemasks and Respirators During a Critical Shortage • The Joint Commission also issued an FAQ on Emergency Management – Duration for Continuing Disaster Privileges • Notice of Suspension of The Joint Commission Surveys (March 16, 2020)