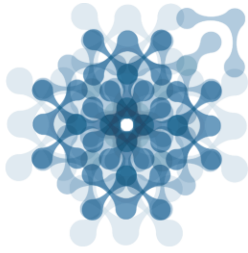

KUTAKROCK

COVID-19
SPECIAL PUBLICATION

Healthcare

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COVID-19: State and Federal Measures to Improve the Allocation of Healthcare Resources

On January 31, 2020, as a result of the numerous confirmed cases throughout the United States of the virus SARS-CoV-2, which can cause 2019 Novel Coronavirus Disease or COVID-19 (hereinafter, COVID-19), the Secretary of Health and Human Services (the "Secretary") used his authority under Section 319 of the Public Health Service Act to declare a nationwide public health emergency (the "PHE"), retroactive to January 27, 2020.[1] Following this declaration, on March 13, 2020, President Trump, under Sections 201 and 301 of the National Emergencies Act, declared that the COVID-19 outbreak in the United States constitutes a national emergency, retroactive to March 1, 2020.[2]

A significant challenge related to COVID-19 is the stress that it places on healthcare resources, which can become scarce or overwhelmed following a sudden influx of cases. One prong of the federal and state response to the COVID-19 pandemic has been a series of measures to facilitate the efficient allocation of healthcare resources during this uniquely stressful time. Such measures have been included in the waivers issued pursuant to section 1135 of the Social Security Act ("1135 Waivers"), the Coronavirus Aid, Relief, and Economic Security ("CARES") Act,[3] State Executive Orders and legislation, and, on March 26, 2020, the Interim Final Rule with Comment Period (the "IFC") announced by the Centers for Medicare and Medicaid Services ("CMS").[4]

Even though the initial wave of COVID-19 cases has already hit (and potentially crested) in many areas, healthcare providers and facilities are likely to face continuing resource allocation challenges as they navigate re-opening non-emergency operations and resume day-to-day services for non-COVID-19 patients, all while continuing to manage actual and potential COVID-19 cases. CMS recently issued guidance, for example, that counsels healthcare facilities on how to maximize resources and utilize resource allocation measures put in place during the PHE.[5] Resource allocation measures promulgated during the initial wave of COVID-19 cases may also provide relief to healthcare providers in the event of a second wave of COVID-19 cases later in the year.

Broadly, the COVID-19 resource allocation measures to-date fall into the following categories:

a. Relaxing supervision or licensure requirements;

b. Expanding the scope or use of non-physician providers and other clinical extenders;

c. Expanding permissible settings for care;

d. Relaxing or removing data reporting or program requirements; and

e. Expanding the use of telehealth and telemedicine.

This Client Alert provides a brief overview of each resource allocation measures category, along with examples of recent federal and/or state actions within that category.

Importantly, the duration of specific resource allocation measures described herein vary depending upon the source of the measure. Most changes facilitated by the CARES Act and the IFC will remain in place for the duration of the public

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[1] The Secretary's declaration of a public health emergency can be found here.
[2] The President's declaration of a national emergency can be found here.
[3] The CARES Act can be found here.
[4] The CMS Interim Final Rule with Comment Period can be found here. The IFC regulations are applicable beginning on March 1, 2020.
[5] *See* Opening Up America Again; Centers for Medicare & Medicaid Services (CMS) Recommendations for Re-opening Facilities to Provide Non-emergent Non-COVID-19 Healthcare: Phase I (Apr. 19, 2020) [hereinafter, CMS Recommendations], https://www.cms.gov/files/document/covid-flexibility-reopen-essential-non-covid-services.pdf.

health emergency declared by the Secretary. The 1135 Waivers will typically expire no later than the end of the emergency period, or sixty (60) days from the date the waiver or modification was first published. The Secretary, however, may extend the waiver by notice for additional periods of up to sixty (60) days, up to the end of the emergency period.[6] The effective period of state measures varies by state and individual measure; where possible, we have indicated such periods in the relevant citations.

RELAXING SUPERVISION OR LICENSURE REQUIREMENTS

Many medical procedures can be safely performed by non-physician providers under the supervision of a physician, rather than by a physician directly. Degrees of supervision can vary, ranging from the physician's actual attendance in the room during the procedure to simply being performed under the physician's overall (and potentially off-site) direction.[7] In order to receive reimbursement for supervised procedures, payors will typically designate specific levels of supervision that are required. These restrictions, which ensure appropriate physician oversight during normal periods, can create bottlenecks during periods of emergency. Reducing supervision requirements can improve resource allocation by permitting physicians to supervise a greater volume of procedures or by allowing physicians to supervise procedures in novel ways (such as via telecommunication).

- Revision of Direct Supervision Definition. Given the circumstances of the PHE, including the increased demand for health care professionals and the widespread use of telecommunications technology, CMS believes that individual practitioners are in the best position to make supervision decisions based on their clinical judgement in particular circumstances. Consequently, CMS is revising the definition of direct supervision[8] to allow, for the duration of the PHE, direct supervision to be provided using real-time interactive audio and video technology to reduce exposure risks for beneficiary or provider.[9]

- Supervision for NSEDTS Reduced to Minimum Level. Supervision for non-surgical extended duration therapeutic services ("NSEDTS"),[10] such as certain prolonged intravenous infusions requiring the use of a portable or implantable pump, have a significant monitoring component that can extend for a sizable period of time. The minimum default supervision level of NSEDTS is direct supervision during the initiation of the service, which may be followed by general supervision.[11] Given the circumstances of the PHE, CMS is providing hospitals with more flexibility and changing the minimum default level of supervision to general supervision for NSEDTS during the initiation of the service, which requires the physician's overall direction but not presence.[12]

- States Relaxing Supervision Requirements. In certain states, Governors have issued Executive Orders suspending provisions relating to certain healthcare professionals' supervisory responsibility within a designated facility at which they are employed or contracted, to the extent necessary to support the response to COVID-19. These Orders have included permitting physician assistants, advanced practice, licensed and registered nurses to render care without physician supervision that is ordinarily required and providing a degree of immunity from liability for certain personal injuries resulting from such care without supervision.[13]

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[6] *See* Waiver of Modification of Requirements Under Section 1135 of the Social Security Act, https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx.

[7] *See* 42 CFR §§ 410.26, 410.32.

[8] "Direct supervision" in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed. 42 CFR § 410.32(b)(3)(ii).

[9] *See* Section II.E. of Centers for Medicare and Medicaid Services ("CMS") Interim Final Rule (the "IFC") issued in response to COVID-19 pandemic, Direct Supervision by Interactive Telecommunications Technology, p. 55.

[10] CMS can designate certain therapeutic services meeting specific criteria as NSEDT services. These are outpatient therapeutic services that can last a significant period of time, have a substantial monitoring component that is typically performed by auxiliary personnel, have a low risk or requiring the supervisory practitioner's immediate availability to furnish assistance and direction after the initiation of the service, and that are not primarily surgical in nature. 42 CFR § 410.27(a)(1)(iv).

[11] "General supervision" means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician. 42 CFR § 410.32(b)(3)(i).

[12] *See* Section II.T. of the IFC, Physician Supervision Flexibility for Outpatient Hospitals – Outpatient Hospital Therapeutic Services Assigned to the Non-Surgical Extended Therapeutic Services (NSEDTS) Level of Supervision, p.126.

[13] *See, e.g.,* New Jersey Executive Order No. 112 (waiving certain requirements, including requiring eligible APRNs to enter into a joint protocol with a physician who is present or readily available through electronic communication and waiving certain statutory provisions that would otherwise

- Relaxing Provider Licensure Requirements. Some states are relaxing licensure requirements to increase the healthcare work force in the state during the PHE, such as allowing practitioners licensed and in current good standing in other states to practice without civil or criminal penalty related to such lack of in-state licensure.[14] Some states are also authorizing the licensure of healthcare providers who have retired from active practice.[15]

EXPANDING THE SCOPE OR USE OF NON-PHYSICIAN PROVIDERS AND OTHER CLINICAL EXTENDERS

Health care providers are generally limited in the scope of their practices by their education, experience, and/or licensure. These restrictions can arise from both state law sources (such as medical practice acts or nursing practice acts) but also from payor limitations on which practitioners can order or furnish certain services (such as only physicians being permitted to order home health services). By temporarily relaxing scope of practice boundaries or delegating such determinations to local administrators who are more familiar with staff experience and abilities, provider resources can be temporarily expanded even if the number of providers stays the same.

- Prescription of Home Health Services. To relieve pressure on physicians and other healthcare providers, nurse practitioners, physician assistants and other professionals are now authorized by the CARES Act to prescribe home health services for Medicare beneficiaries. This represents an effort to reduce delays and increase beneficiary access to care in the patient's home.[16]

- Visiting Nursing Services. Visiting nurse services are covered if a rural health clinic ("RHC") or a federally qualified health center ("FQHC") is located in an area in which the Secretary has determined that there is a shortage of Home Health Agencies ("HHAs").[17] During the PHE, CMS recognized the need for visiting nursing services furnished by RHCs or FQHCs may increase. Therefore, for the duration of the PHE, CMS determined that any area typically served by an RHC and any area that is included in an FQHC's service area plan is determined to have a shortage of HHAs.[18]

- National Coverage Determinations ("NCDs") and Local Coverage Determinations ("LCDs"). To the extent NCDs and LCDs require a specific practitioner type or physician specialty to furnish a service, procedure or any portion thereof, CMS is permitting the chief medical officer or equivalent of the facility to authorize another physician specialty or other practitioner type to meet those requirements during the PHE.[19] 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.[20]

- Pharmacists Ordering COVID-19 tests. On April 8, 2020, the Secretary issued a statement authorizing pharmacists to order and administer COVID-19 tests to their patients in an effort to provide easier access to testing to individuals.[21]

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require a PA obtain physician supervision for certain services, such as giving injections, administering medications and requesting diagnostic studies); Michigan Executive Order No. 2020-30 (effective through the end of the declared emergency and waiving certain requirements including that certain medical services performed by a PA be provided under supervision from a licensed physician, without regard to a written practice agreement).

[14] *See, e.g.,* New York Executive Order No. 202.5 (effective through May 15, 2020, as extended by E.O. No. 202.18), New Jersey Executive Order No. 112 (effective for the duration of New Jersey's State of Emergency or Public Health Emergency, whichever is longer), and Massachusetts Order Expanding Access to Physicians Services (March 17, 2020).

[15] *See, e.g.,* New Jersey Executive Order No. 112 (authorizing the licensure of physicians retired within the past 5 years), and Massachusetts Order Expanding Access to Physician Services (March 17, 2020) (authorizing the immediate license reactivation of physicians who have retired in the past year, until order is until rescinded or when State of Emergency is terminated, whichever is first).

[16] *See* section 3708 of the CARES Act.

[17] *See* 42 CFR §§ 405.2416(a)(1), 405.2417.

[18] *See* Section II.L.2(b) of the IFC, Revision of Home Health Agency Shortage Requirements for Furnishing Visiting Nursing Services, p.90.

[19] *See* Section II.U.3 of the IFC, Requirements for Consultations or Services Furnished by or with the Supervision of a Particular Medical Practitioner of Specialist, p. 129.

[20] *Id.*

[21] *See* HHS Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act available here. As a "covered person" under the Public Readiness and Emergency Preparedness (PREP) Act, Pharmacists receive immunity with respect to all claims for loss caused by, arising out of, relating to, or resulting from, the administration or use of FDA-authorized COVID-19 tests during the time a Declaration under the

- Expansion of Providers' Scope of Practice. Some states are expanding the scope of practice of certain healthcare providers, such as allowing the non-nursing staff to perform tasks otherwise limited to licensed nurses and allowing EMS personnel to provide community paramedicine and telemedicine to facilitate treatment of patients.[22]

- Use of Volunteers. There have been both federal and state actions to allow the use of volunteers and to limit the liability of such volunteers. Specifically, some states are permitting general hospitals affected by the COVID-19 emergency to maintain adequate staffing using qualified volunteers or personnel affiliated with other general hospitals. Additionally, healthcare facilities in some states are authorized to use students in programs to become licensed healthcare professionals to volunteer at the healthcare facilities for educational credit.[23] The CARES Act also limits the liability of physicians and other healthcare professionals who provide volunteer medical services, within the scope of the professional's license, registration or certification, related to the COVID-19 emergency during the PHE, with certain exceptions including acts or omissions of gross negligence, criminal misconduct and providing care while intoxicated.[24] Such protection afforded by the CARES Act are in addition to the more long-standing protections provided by the federal Volunteer Protection Act of 1997.[25]

EXPANDING PERMISSIBLE SETTINGS FOR CARE

For various reasons, including patient safety, the permissible settings for medical care and the permissible transitions between them are often carefully prescribed by licensing authorities and payors. For example, Medicare hospital conditions of participation include various requirements for a hospital's physical environment.[26] Likewise, state licensing statutes and regulations contain similar, though often even more extensive, requirements for hospitals and other facilities.[27] Such requirements, however, can hamper the ability of health care facilities to accommodate temporary surges of acutely ill patients, such as during the COVID-19 pandemic, or to otherwise respond to evolving emergency situations.

- Acute Care Hospitals Flexibility to Transfer. Acute care hospitals are being given more flexibility to transfer patients out of their facilities and into alternative care settings in order to provide acute care hospitals with greater ability to prioritize resources needed to treat COVID-19 cases. Specifically, during the PHE, the Secretary is waiving the Inpatient Rehabilitation Facility 3-hour rule,[28] the Long Term Care Hospital ("LTCH") 50-percent rule,[29] and the LTCH site-neutral IPPS payment rate for a discharge if the admission occurs during the emergency period and is in response to the public health emergency.[30]

- Inpatient Hospital Services Furnished Under Arrangements. Currently the policy for hospital services furnished under arrangements does not permit routine services to be provided outside the hospital. CMS is changing the current under arrangements policy during the PHE so that hospitals are allowed broader flexibilities to furnish inpatient services, including routine services, outside the hospital.[31]

PREP Act is in effect. *See* Notice of Declaration under the Public Readiness and Emergency Preparedness Act for medical countermeasures against COVID-19, https://www.phe.gov/Preparedness/legal/prepact/Pages/COVID19.aspx.

[22] *See, e.g.,* New York Executive Order No. 202 (effective through May 7, 2020, as extended by E.O. No. 202.14).

[23] *See, e.g.,* New York Executive Order No. 202.10 (effective through May 15, 2020, as extended with E.O. No. 202.18) and Michigan Executive Order No. 2020-30.

[24] *See* CARES Act, section 3215 limiting the liability of volunteer health care providers providing medical services during the PHE.

[25] *See* the Volunteer Protection Act of 1997, Pub. L. No. 105-19 (1997) (codified at 42 USC § 14501 et seq.) (establishing a minimum level of protection for volunteers performing services for nonprofit organizations or government entities).

[26] *See* 42 CFR § 482.21.

[27] *See* Ark. Code Ann §§ 20-9-212, 20-9-214. *See also* Code Ark. R. 007.05.17-1 et seq.

[28] *See* Section II.K. of the IFC, Removal of the IRF Post-Admission Physician Evaluation Requirement for the PHE for the COVID-19 Pandemic and Clarification Regarding the "3-Hour" Rule (p. 80) temporarily lifting certain requirements under 42 CFR § 412.622(a). The Inpatient Rehabilitation Facility ("IRF") 3-hour rule requires a Medicare beneficiary to participate in at least three (3) hours of intensive rehabilitation at least five (5) days per week to be admitted to an Inpatient Rehabilitation Facility.

[29] The LTCH 50-percent rule relates to the payment adjustment for LTCHs that do not have a discharge payment percentage for that period that is at least fifty (50) percent.

[30] *See* section 3711 of the CARES Act.

[31] *See* Section II.CC.1 of the IFC, Inpatient Hospital Services Furnished Under Arrangements Outside the Hospital During the Public Health Emergency (PHE) for the COVID-19 Pandemic, p. 167.

- Ambulance Destinations. In the context of the PHE, CMS recognizes that providers and suppliers furnishing ground ambulance services and other health care professionals are faced with new challenges regarding potential exposure risks for Medicare beneficiaries and for members of the community at large. During the PHE, CMS is expanding the list of destinations[32] for which Medicare covers ambulance transportation to include all destinations, from any point of origin, that are equipped to treat the condition of the patient consistent with Emergency Medical Services ("EMS") protocols established by state and/or local laws where the services will be furnished.[33]

- Pre-Triage Tents. Some states are encouraging hospitals to construct pre-triage tents outside their buildings in order to handle surge capacity, to screen and treat patients without risking the spread of COVID-19 virus and other airborne pathogens, rapidly evaluate, identify, and treat those with suspected COVID-19, screen and discharge minor cases to prevent congestion at hospitals, and to limit the risk to the health care providers evaluating patients.[34]

- "Hospital Without Walls". CMS recently issued the "Hospital Without Walls" initiative, which provide hospitals the flexibility to utilize non-traditional sites to provide hospital services, such as room and board, nursing, and other hospital services. For more information on this initiative, please see our Client Alert available here.

- EMTALA Waiver. The Secretary recently invoked his waiver authority and waived sanctions under EMTALA for certain medical screening exams and stabilization requirements. For more information on the EMTALA waiver, please see our Client Alert available here.

RELAXING OR REMOVING DATA REPORTING OR PROGRAM REQUIREMENTS

CMS uses quality measures as tools to help measure or quantify various aspects of healthcare to create a more effective, safe, efficient, patient-centered, equitable and timely system. In March 2020, CMS announced relief for clinicians, providers, and facilities participating in Medicare quality reporting programs, including granting exceptions and extensions for clinicians and providers with respect to upcoming measure reporting and data submission for those programs.[35] In an effort to further reduce regulatory burdens on healthcare providers, several more steps have been taken to relax or remove certain reporting requirements, and certain program requirements have been lifted where such requirements may be difficult to meet because of disruptions in staffing due to the COVID-19 emergency.

- Inpatient Rehabilitation Facility ("IRF") Post-Admission Physician Evaluation Requirement. IRF care is only considered by Medicare to be reasonable and necessary if the patient meets all of the IRF coverage requirements.[36] In an effort to provide rehabilitation physicians with as much flexibility as possible, CMS is removing the post-admission physician evaluation requirement[37] for all IRFs during the PHE. CMS believes that removal of this requirement will greatly reduce the amount of time rehabilitation physicians in IRFs spend on completing paperwork requirements and will free up their time to focus on caring for patients.[38]

- Level Selection for Office/Outpatient E/M Visits When Furnished Via Medicare Telehealth. CMS is revising its policy to specify that the office/outpatient E/M level selection for such services when furnished via telehealth can be based on medical decision making ("MDM") or time, with time defined as all of the time associated with the E/M on the day of the encounter. Additionally, CMS is removing any requirements regarding documentation of history and/or physical exam in the medical record.[39]

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[32] For a list of current permissible destinations see 42 CFR § 410.40(f).
[33] *See* Section II.AA of the IFC, Origin and Destination Requirements Under the Ambulance Fee Schedule (p. 160) temporarily amending 42 CFR § 410.40(f). *See also* New York Executive Order No. 202 (effective through May 7, 2020, as extended by E.O. No. 202.14).
[34] *See, e.g.,* New Jersey AR 146 (pending).
[35] For more information on changes in reporting requirements, see the CMS Press Release announcing exceptions from reporting requirements and extensions found here.
[36] 42 CFR § 412.622(a)(3), (4), and (5).
[37] 42 CFR § 412.6222(a)(4)(ii).
[38] *See* Section II.K. of the IFC, Removal of the IRF Post-Admission Physician Evaluation Requirement for the PHE for the COVID-19 Pandemic and Clarification Regarding the "3-Hour" Rule (p. 80) temporarily lifting certain requirements under 42 CFR § 412.622(a).
[39] *See* Section II.W. of the IFC, Level Selection for Office/Outpatient E/M Visits When Furnished Via Medicare Telehealth (p. 135) amending the CY 202 PFS Final Rule (84 FR 62847 and 62848).

- Receiving and Discharging Patients. In an effort to further relieve the regulatory burden on healthcare professionals, some states are authorizing general hospitals and nursing homes to rapidly discharge, transfer or receive patients and to permit facilities receiving patients to complete patient review instruments as soon as practicable.[40]

- Reporting Requirements for Quality Reporting Programs. CMS has implemented extreme and uncontrollable circumstances policy exceptions from reporting requirements and provided extensions for clinicians and providers participating in Medical quality reporting programs. For more information on these exceptions, please see our Client Alert available here.

EXPANDING THE USE OF TELEHEALTH AND TELEMEDICINE

Prior to the CARES Act and 1135 Waiver, Medicare could only pay clinicians for telehealth services under certain circumstances. Such circumstances required the beneficiary to live in a rural area and travel to a local medical facility to get telehealth services from a doctor in a remote location. The CARES Act and 1135 Waiver expanded telehealth flexibility to reduce the risk of COVID-19 transmission, and now the IFC has further expanded telehealth flexibility.

- Telehealth Waiver. CMS issued a telehealth waiver that significantly expands the telehealth benefits available to Medicare beneficiaries during the PHE. For more information on the telehealth waiver, please see our Client Alert available here.

- Telehealth Under CARES Act. The CARES Act further expanded telehealth services aimed at increasing patient access to providers while minimizing potential exposure associated with COVID-19. For more information on the expansion of telehealth under the CARES Act, please see our Client Alert available here.

- IFC Expansion of Telehealth Services. Under the IFC, CMS is adding several services to the Medicare telehealth list[41] during the PHE, including but not limited to:

  - Emergency department visits for evaluation and management of a patient;[42]
  - Initial and subsequent observation, and observation discharge day management;[43]
  - Initial hospital care for evaluation and management of a patient;[44]
  - Critical care services for the evaluation and management of the critically ill or critically injured patient;[45]
  - Home visits for the evaluation and management of a new or established patient;[46] and
  - Initial and continuing intensive care services.[47]

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Kutak Rock attorneys are actively engaged in monitoring the legislative and regulatory changes undertaken in response to the COVID-19 pandemic. Other client alerts and special publications relating to COVID-19 can be accessed on Kutak Rock's COVID-19 Legal Resource Portal. If you are interested in learning more about the allocation of healthcare resources during the COVID-19 emergency period, please contact a member of our national Healthcare practice group.

[40] *See, e.g.,* New York Executive Order No. 202 (effective through May 7, 2020, as extended by E.O. No. 202.14).
[41] *See* Section II. 2. of the IFC, Adding Services to the List of Medicare Telehealth Services (p. 15). A complete list of telehealth services, including the additions described herein, can be found at https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.
[42] For Levels 1-5, CPT code 99281-99285.
[43] For CPT codes 99217-99220; 99224 -99226; 99234-99236.
[44] For CPT codes 99221-99223; 99238-99239.
[45] For CPT codes 99291-99292.
[46] For CPT codes 99341-99345; 99347-99350.
[47] For CPT codes 99477-99480.

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