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CLIENT ALERT

CMS Issues Additional Blanket Waivers to Help Medicare Providers and Suppliers Meet Beneficiaries' Health Care Needs During COVID-19 Emergency

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On March 13, 2020, when President Trump declared a national emergency under the Stafford Act, the Secretary of Health and Human Services utilized his authority to take particular actions, such as temporarily waiving or modifying certain Medicare, Medicaid, and Children's Health Insurance Program requirements—otherwise known as the Secretary's "1135 Waiver" authority. As set forth in our previous Client Alert entitled "New and Pre-Existing Federal Waivers and Flexibilities Available to Health Care Providers During a National Emergency," certain blanket waivers were adopted that required a provider to contact the applicable Regional Office of the Centers for Medicare & Medicaid Services ("CMS") in order to request that such waivers apply to its facility/operations.

On March 30, 2020, CMS announced another broad set of blanket waivers that affect a large range of provider and facility types that serve Medicare beneficiaries as well as Medicare Advantage ("MA") and Part D Prescription Drug Plans. This second round of blanket waivers is intended to ensure that sufficient health care items and services are available to meet the needs of Medicare beneficiaries in the emergency areas. Some of the waivers described in the recent release were previously announced, while others are new. In contrast to the earlier waivers, the Secretary's most recent waivers do not require providers to submit a waiver request to the applicable Regional Office.

More CMS Waivers and Flexibilities

On March 30, 2020, CMS released a set of blanket waivers applicable to the Stark Law, which are described in our previously issued Client Alert entitled "COVID-19: DHHS Secretary Issues 1135 Blanket Waivers Applicable to Stark Law During Public Health Emergency."

In addition, CMS released an interim final rule (scheduled to be published in the *Federal Register* on April 6, 2020) that also provides "individuals and entities that provide services to Medicare beneficiaries needed flexibilities to respond effectively to the serious public health threats posed by the spread of the 2019 Novel Coronavirus (COVID-19)." Epstein Becker Green is preparing a separate Client Alert on this interim final rule, which will be issued in the coming days.

This most recent set of waivers are divided into different categories of entities:

- Hospitals, Psychiatric Hospitals, and Critical Access Hospitals ("CAHs"), Including Cancer Centers, Inpatient Rehabilitation Facilities ("IRFs"), and Long-Term Care Hospitals ("LTCHs")
- Physicians and Other Practitioners
- Long-Term Care Facilities (Skilled Nursing Facilities ("SNFs") and Nursing Facilities)
- Home Health Agencies ("HHAs")
- Hospice
- End-Stage Renal Dialysis ("ESRD") Facilities
- Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS")
- Medicare Appeals in Fee for Service ("FFS"), MA, and Part D

HOSPITALS, PSYCHIATRIC HOSPITALS, AND CAHs, INCLUDING CANCER CENTERS, IRFs, AND LTCHs

Recognizing that the enormous influx of COVID-19 patients will make it difficult for hospitals to observe many of the usual conditions for payments from these government programs, CMS has issued broad-based waivers of a wide variety of hospital requirements effective for the duration of the emergency. CMS expects that waivers will be implemented only so long as they are not inconsistent with a state's emergency preparedness or pandemic plan. These waivers include:

Screening Location/Physical Environment/Temporary Expansion. CMS is allowing hospitals, psychiatric hospitals, and CAHs to screen patients at a location offsite of the hospital's campus. These facilities are also being allowed to use non-hospital buildings/space for patient care and quarantine sites, *provided that the space is approved by the state*. Provider-based department requirements are also waived to allow the establishment and operation of any location otherwise meeting hospital conditions of participation applicable during the public health emergency.

Addressing Capacity Issues in Hospitals and Distinct Part Units. Hospitals may house inpatients in excluded distinct part units, such as psychiatric and rehabilitation units, where the distinct part unit's beds are appropriate for acute care inpatients. CMS also is allowing hospitals to relocate inpatients from excluded distinct part psychiatric and rehabilitation units to an acute care bed, if the hospital's acute care beds are appropriate for the impacted patients and the staff and environment are conducive to safe care based on the patient's needs. In all cases, the hospital should continue to bill under the original prospective payment system ("PPS") and annotate the patient's medical record

accordingly to reflect that the patient's relocation was due to capacity or other exigent circumstances related to the COVID-19 emergency.

Flexibilities for Certain Excluded Hospitals. CMS is allowing IRFs, and facilities that are attempting to obtain classification as an IRF, to exclude certain patients 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 COVID-19 emergency and the patient's medical record properly identifies the patient as such. CMS is allowing 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. In addition, 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 inpatient PPS.

Verbal Orders. CMS is allowing for additional flexibility in the use and authentication of verbal orders by waiving requirements related to the frequency of verbal orders for the use of drugs and biologicals (except immunizations); the prompt dating, timing, and authentication of verbal orders; limits on hospital use of standing orders, order sets, and protocols for patient orders; and signed written order requirements for medication administration.

Soft Wrist Restraints. CMS is waiving the requirement that hospitals report the use of soft wrist restraints to prevent patients from pulling tubes/IVs, no later than close of business the next business day.

Patient Rights. CMS is waiving certain paperwork requirements related to timeframes for providing medical record copies, having written policies and procedures on visitation of patients who are in COVID-19 isolation and quarantine processes, and limitations on seclusion, but *only* for hospitals that are considered to be impacted by the widespread outbreak of COVID-19 (i.e., located in a state with 51 or more confirmed cases).

Use of Face Masks/Sterile Compounding. CMS is waiving certain hospital sterile compounding requirements to allow for face masks to be removed and reused in the sterile compounding area during the same work shift. CMS will not review the hospital's use and storage of face masks during the emergency.

Discharge Planning. In order to expedite the discharge planning process, CMS is waiving certain requirements such as providing lists of post-acute care service providers that are available to the patient, informing the patient of his or her freedom to choose post-discharge service providers, and identifying any entities in which the hospital has a disclosable financial interest. A patient must nonetheless be discharged to an appropriate setting with the necessary medical information and goals of care.

Medical Staff Privileges. For physicians whose privileges will soon expire, CMS is allowing these physicians to continue practicing at the hospital. CMS is also allowing new physicians to begin to practice in the hospital before full medical staff/governing body review and approval.

Medical Records. CMS is waiving requirements regarding the organization and staffing of the medical records department, the form and content of the medical record, and record retention requirements. CMS also is allowing flexibility in the completion of medical records within 30 days following discharge.

Advance Directives. CMS is waiving various requirements related to providing information about advance directive policies to patients.

Telemedicine. CMS is waiving certain telemedicine provisions for hospitals and CAHs to facilitate telemedicine services being provided at distant hospital locations.

Physician Services Extender. CMS is waiving the requirement that Medicare patients be under the care of a physician, in order to allow for hospitals to use other licensed providers to the greatest extent possible. Similarly, for hospitals, CAHs, and ambulatory surgery centers, CMS is waiving the requirement that a certified registered nurse anesthesiologist must be supervised by a physician.

Utilization Review. CMS is waiving the utilization review condition of participation, which requires hospitals to have a utilization review plan and conduct reviews of services in order to evaluate the medical necessity of the admission, duration of stay, and services provided to Medicare and Medicaid beneficiaries.

Written Policies and Procedures for Appraisal of Emergencies/Emergency Preparedness Policies and Procedures. At new *surge facilities or surge sites* that have been set up to help hospitals manage surge capacity, CMS is waiving the requirements for hospitals to establish written policies and procedures related to the evaluation of emergencies and emergency preparedness policies and procedures at these new sites.

Quality Assessment and Performance Improvement ("QAPI") Program. While CMS is waiving certain requirements related to hospital and CAH QAPI programs, these facilities must still maintain a QAPI program.

Nursing & Respiratory Care Services/Care Plans. CMS is waiving the requirement that nursing staff develop and maintain a nursing care plan for each patient. CMS also is waiving the requirement that hospitals have policies regarding the presence of a registered nurse in outpatient settings, and the requirement that hospitals designate in writing the personnel qualified to perform and supervise specific respiratory care procedures.

CAH-Specific Requirements. CMS is waiving the following CAH-specific requirements:

- Bed number (limited to 25 beds) and length of stay (limited to 96 hours).

- Location in a rural area, as well as off-campus and co-location requirements, to allow flexibility in establishing temporary off-site locations.

- Minimum personnel qualifications for clinical nurse specialists, nurse practitioners, and physician assistants. These practitioners will still have to meet state licensure requirements and scope-of-practice rules.

- That staff of the CAH be licensed, certified, or registered in accordance with applicable federal, state, and local laws and regulations. CMS instead is deferring to state law. The CAH and its staff must still be in compliance with applicable federal, state, and local laws and regulations, and must provide patient care in compliance with state and local laws and regulations.

Inpatient PPS Survey. Hospitals affected by COVID-19 have been granted an extension until August 3, 2020 (from July 1), to submit their 2019 Occupational Mix Surveys for the Wage Index beginning fiscal year 2022. Additional extensions may be requested via the Medicare Administrative Contractors ("MACs").

PHYSICIANS AND OTHER PRACTITIONERS

Practitioner Locations. CMS is temporarily waiving requirements that out-of-state practitioners be licensed in the state where they are providing services when they are licensed in another state. CMS has established the following four conditions that must be met in order for physicians and non-physician practitioners to use this waiver. The physician must (1) be enrolled as a physician or non-physician practitioner in the Medicare program, (2) possess a valid license to practice in the state that relates to his or her Medicare enrollment, (3) be furnishing services—whether in person or via telehealth—in a state in which the emergency is occurring in order to contribute to relief efforts, and (4) not be affirmatively excluded from practice in the state or any other state that is part of the 1135 emergency area. Further, in order for a physician or non-physician practitioner to use this waiver, the state in which the physician or non-physician practitioner would like to provide services must also 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.

Provider Enrollment. CMS has established a toll-free hotline for physicians and non-physician practitioners, as well as for Medicare Part A certified providers and suppliers establishing isolation facilities, to enroll in Medicare and receive temporary Medicare billing privileges. CMS also is waiving certain Medicare enrollment screening requirements, including applicable application fees, criminal background checks, and site visits. CMS is expediting pending or new enrollment applications, and postponing all revalidation actions.

CMS is expanding the provider enrollment flexibilities to include allowing opted-out physicians and non-physician practitioners to terminate their opt-out status early and enroll in Medicare. Further, CMS is allowing licensed providers to render (1) services outside of their state of enrollment, and (2) telehealth services from their home without reporting their home address on their Medicare enrollment while continuing to bill from their currently enrolled location.

Emergency Medical Treatment and Labor Act ("EMTALA")

Under Section 1135 of the Social Security Act, CMS has restricted authority on what aspects of EMTALA can be waived. Specifically, what can be waived are only those requirements to enable (1) the transfer of an individual who has not been stabilized in accordance with EMTALA requirements if the transfer arises out of the circumstances of the emergency, and/or (2) the direction or relocation of an individual to receive medical screening in an alternative location.

Previously, on March 9, 2020, CMS issued a reminder to hospitals regarding their ongoing EMTALA obligations during the public health emergency. In sum, CMS notes that if an individual comes to an emergency department of a hospital by ambulance or walk-in, CMS is expecting the hospital to provide an appropriate medical screening exam. If the hospital concludes that the patient who has come to its emergency department may be a COVID-19 case, the hospital should isolate the patient consistent with accepted standards of practice. CMS is expecting hospitals to initiate stabilizing treatment while also maintaining isolation. Further, CMS wants hospitals to know that a hospital's EMTALA obligations are no different during the COVID-19 pandemic. CMS requires hospitals that have the capability and capacity to offer stabilizing treatment to patients to accept appropriate transfers from other hospitals that do not have the necessary capabilities or capacities. *See* Memorandum from Director of the Quality Safety and Oversight Group to State Survey Agency Directors, CMS, EMTALA Requirements and Implications Related to Coronavirus Disease 2019 (COVID-19) (Mar. 9, 2020).

Under the most recent broad waiver announcement, CMS is allowing hospitals to screen patients at offsite locations from the hospital's campus, recognizing hospitals' need for flexibility

LONG-TERM CARE FACILITIES (SNFs AND NURSING FACILITIES)

CMS is waiving the requirement for a three-day prior hospitalization for coverage of an SNF stay, and CMS is authorizing renewed SNF coverage for certain beneficiaries who recently exhausted their SNF benefits without first having to start a new benefit period. CMS also is waiving the timeframe requirements for Minimum Data Set assessments and transmission.

CMS is expanding the flexibilities available to long-term care facilities to include:

- allowing for a non-SNF building to be temporarily certified and available for use by an SNF in the event there are needs for isolation processes for COVID-19-positive residents, so long as the state has approved the location as one that sufficiently addresses safety and comfort for patients and staff;

- waiving conditions of participation and certification requirements related to opening a nursing facility if the state determines there is a need to quickly stand up a temporary COVID-19 isolation and treatment location;

- allowing for rooms that are not normally used as residents' rooms (e.g., activity rooms, meeting/conference rooms, and dining rooms) to accommodate beds and residents to help with surge capacity, so long as residents can be kept safe and this is not inconsistent with a state's emergency preparedness or pandemic plan;

- allowing physicians and non-physician practitioners to perform in-person visits for nursing home residents, as appropriate, via telehealth options;

- allowing facilities to restrict in-person meetings given the recommendations of social distancing and limiting gatherings of more than 10 people;

- allowing facilities to group or cohort 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;

- waiving certain nurse aide training and certification requirements to assist in potential staffing shortages; however, facilities must not use a nurse aide for more than four months, on a full-time basis, unless that individual is able to demonstrate competency to provide nursing and nursing-related services;

- waiving requirements for submitting staffing data through the Payroll-Based Journal system; and

- suspending pre-admission screening and annual resident review assessments for new residents for 30 days.

CMS is allowing facilities to transfer or discharge residents to another facility solely for cohorting purposes when the receiving facility (1) is dedicated to the care of residents with symptoms of a respiratory infection or confirmed diagnosis of COVID-19, (2) is dedicated to the care of residents without symptoms of a respiratory infection or confirmed to not have COVID-19 to prevent them from acquiring COVID-19, or (3) agrees to accept residents without symptoms of a respiratory infection to observe them for any signs or symptoms of a respiratory infection over 14 days.

HHAs

CMS is waiving several conditions of participation for HHAs to facilitate operations under the current emergency and to support infection control for patients. These waivers will enable HHAs to remotely perform Medicare-covered initial assessments and to determine patients' homebound status or to complete these through record review. CMS also is waiving the requirement for on-site nurse (or other professional) visits to supervise and evaluate the care provided by HHA aides, while at the same time encouraging HHAs to use virtual supervision during this period.

HOSPICE

During this national emergency, CMS is waiving the requirement that hospices use volunteers and, similar to the HHA waiver, that a nurse conduct an on-site visit every two weeks in order to supervise hospice aides. In addition, even though hospices are not exempted from completing comprehensive assessments, CMS has extended the timeframes (from 15 to 21 days) under which hospices must complete and update these comprehensive assessments. Further, CMS is waiving the requirement that hospices provide certain non-core services during the national emergency, including physical therapy, occupational therapy, and speech-language pathology services.

ESRD FACILITIES

For the period of the public health emergency, CMS is waiving a number of requirements normally applicable to ESRD facilities, including the following:

- the requirement to conduct on-time preventive maintenance of dialysis machines and ancillary dialysis equipment as well as the requirement to conduct on-time fire inspections;

- the requirement for facility staff to maintain and demonstrate maintenance of CPR certification during the COVID-19 emergency due to the limited availability of CPR classes;

- requirements regarding the frequency of patient assessments (e.g., that all dialysis patients receive a monthly in-person visit from a member of the interdisciplinary team if the patient is considered stable), although such assessments must continue to be completed;

- the requirement for periodic monitoring of the patient's home adaptation, including visits to the patient's home by personnel from the facility; and

- the requirement to provide dialysis services directly on a facility's main premises. ESRD facilities will be allowed to provide services to its patients in nursing homes or SNFs, rather than having those patients transported to the ESRD facility. ESRD facility staff must 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.

As part of the blanket waivers, CMS has authorized the establishment of **Special Purpose Renal Dialysis Facilities** to address access to care issues due to the COVID-19 emergency and the need to mitigate transmission among this vulnerable population, with no need for a federal survey prior to providing services. In addition, CMS is modifying the requirement that newly employed dialysis **Patient Care Technicians ("PCTs")** be appropriately certified within 18 months of hire and allowing PCTs to continue working

even if they have not achieved certification within 18 months or have not met on-time renewals.

DMEPOS

CMS is allowing the DME MACs to waive requirements for replacement DMEPOS, such that the face-to-face requirement need not be met and a new physician's order and new medical necessity documentation would not be required. Suppliers must still include a narrative description on the claim explaining why the equipment must be replaced, and they must maintain documentation indicating that the DMEPOS was lost, destroyed, irreparably damaged, or otherwise rendered unusable or unavailable as a result of the emergency.

MEDICARE APPEALS IN FFS, MA, AND PART D

The MACs and Qualified Independent Contractors in the Medicare FFS program, MA, and Part D plans, and the MA and Part D Independent Review Entities may allow extensions to file an appeal, and may waive timeliness requirements for additional information to adjudicate appeals. In addition, these entities may process appeals, even with incomplete Appointment of Representation forms, and process requests for appeals that do not meet the required elements using information that is available. These entities should utilize all flexibilities available in the appeals process as if good cause requirements are satisfied.

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CMS continues to issue waivers, guidance, and other information to support providers, suppliers, and facilities in providing needed services during the COVID-19 public health emergency. Stakeholders should continue to monitor the CMS website for the release of relevant information, including CMS's provider-specific fact sheets describing applicable waivers and flexibilities.[1]

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This Client Alert was authored by **Helaine I. Fingold, Arthur J. Fried, Lesley R. Yeung, and Daniel L. Fahey.** *For additional information about the issues discussed in this Client Alert or if you have any questions or concerns, please contact one of the authors or the Epstein Becker Green attorney who regularly handles your legal matters.*

[1] CMS, Waivers and Flexibilities, https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers (Accessed March 31, 2020).

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