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CLIENT ALERT

New and Pre-Existing Federal Waivers and Flexibilities Available to Health Care Providers During a National Emergency

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In response to the 2019 novel coronavirus ("COVID-19") pandemic, one of Congress's first actions was the passage of emergency supplemental appropriations on March 5, 2020. Then, on March 18, 2020, a subsequent relief bill, H.R. 6201 (the Families First Coronavirus Response Act),[1] was passed by the Senate and signed into law by President Trump. Congress is now actively debating new comprehensive stimulus legislation to respond to COVID-19.

In addition, on March 13, 2020, when the President declared a national emergency under the Stafford Act,[2] the Secretary of Health and Human Services ("HHS") was authorized to take particular actions, such as temporarily waiving or modifying certain Medicare, Medicaid, and Children's Health Insurance Program ("CHIP") requirements—otherwise known as an "1135 Waiver." HHS waivers are an exercise of long-standing federal health care emergency authorities that provide some immediate flexibility to providers treating Medicare and Medicaid patients, and potentially offer more flexibility if providers engage in follow-up communications with Centers for Medicare & Medicaid Services ("CMS") Regional Offices.

This Client Alert sets out a summary of the blanket waivers that have already been adopted (and which still require a provider to contact the CMS Regional Office to ask that such waivers apply to its facility/operations), describes provider-specific waivers, and explains other flexibilities that have been afforded to CMS, CMS Regional Offices, and Medicare Administrative Contractors ("MACs") that *do not* require an 1135 Waiver.

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[1] For more information about H.R. 6201, see the Epstein Becker Green *Health Care & Life Sciences Client Alert* available at https://www.ebglaw.com/news/families-first-coronavirus-response-act-guidance-for-health-care-providers-and-plans-regarding-covid-19/, and the *Act Now* Advisory available at https://www.ebglaw.com/news/families-first-coronavirus-response-act-employers-new-paid-family-and-sick-leave-obligations-take-effect-by-april-2/.

[2] The White House, Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), *available at:* https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.

Scope of Waivers Determined by Stakeholder Input to HHS

In determining the scope of an 1135 Waiver, the HHS Assistant Secretary for Preparedness and Response coordinates with CMS and other HHS agencies to determine what kind of providers need what relief in which geographic areas in order to respond to the emergency. Relevant input is also considered from governor's offices, health care trade groups and professional societies, individual providers, and CMS Regional Offices.

Generally, when waivers or modifications are declared, *providers must still affirmatively contact their CMS Regional Office to request that a waiver be applied to them*. On occasion, CMS issues waivers or modifications on a "blanket" basis if it is determined that all similarly situated providers in an area are in need. At the same time, CMS warns that "[w]hile blanket authority for these modifications may be allowed, the provider should still notify the State Survey Agency and CMS Regional Office if operating under these modifications to ensure proper payment."[3]

National Blanket Waivers

Upon the Secretary's formal exercise of his 1135 Waiver authority,[4] HHS announced the following nationwide "blanket" waivers.

- **Physicians, Practitioners, and Part B Suppliers.** Licensed providers may render services to Medicare and Medicaid patients outside their state of enrollment. This waiver, however, only enables these providers to submit claims to and receive reimbursement from CMS for these services. State law governs whether a non-federal provider is authorized to provide services in the state without state licensure.

  To increase the supply of enrolled providers, CMS will establish a hotline to expedite enrollment of non-participating physicians, Part B suppliers, and non-physician practitioners to receive temporary Medicare billing privileges. CMS will waive the application fee, certain criminal background check requirements, and the site visit requirements. CMS will expedite any pending or new provider enrollment applications and postpone all revalidation actions.

  CMS may also waive certain sanctions relating to limitations on physician referrals under conditions CMS deems appropriate. Further guidance on this matter has not yet been issued.

- **Hospitals.** CMS's blanket waivers primarily focus on addressing capacity issues that acute care hospitals ("ACHs") may face when treating COVID-19 patients.

[3] CMS, 1135 Waiver at a Glance, *available at:* https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Downloads/1135-Waivers-At-A-Glance.pdf.
[4] HHS, Waiver or Modification of Requirements under Section 1135 of the Social Security Act (Mar. 13, 2020), *available at:* https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx.

Through the waivers, the following are permitted when ACHs face capacity issues:

- ACHs may house inpatients in excluded units if the beds are appropriate for acute care inpatients. To submit claims, an ACH must annotate the capacity issues related to the disaster or emergency in the patient's medical record.

- ACHs may care for psychiatric inpatients in an acute care bed rather than in the ACHs' excluded distinct part inpatient psychiatric unit. To use the waiver, ACHs must perform an assessment to ensure the acute care bed, the unit location, the staff, and the environment are conducive to the safe care of psychiatric patients, particularly for patients at risk of harm to self or others. To submit psychiatric inpatient bills under the Inpatient Psychiatric Facility Prospective Payment System, the ACH must include an annotation in the patient's medical record indicating the capacity or other exigent circumstances.

- ACHs may relocate rehabilitation inpatients from excluded distinct part rehabilitation units to acute care beds and units. To use the waiver, the acute care beds must be appropriate for rehabilitation patients and the patients must continue to receive intensive rehabilitation services. The ACH should continue to bill for inpatient rehabilitation services and must include an annotation in the patient's medical records indicating the capacity or other exigent circumstances.

For Critical Access Hospitals ("CAHs"), the 25-bed limit and the 96-hour length-of-stay limit is waived.

Typically, HHS requires that long-term care hospitals ("LTCH") have an average Medicare inpatient length of stay of greater than 25 days to be classified as an LTCH. Under the waiver, patient stays that do not meet the 25-day average length of stay requirement because the patient was admitted or discharged to meet the demands of the emergency will not count against the hospital's average length of stay calculation.

HHS has waived for hospitals certain Health Insurance Portability and Accountability Act Privacy Rule-related sanctions and penalties associated with requirements to obtain a patient's signature to speak with a family member or friends, or to honor a patient's request to opt out of the facility directory; the requirement to distribute a notice of privacy practices; and the patient's right to request privacy restrictions and confidential communications. This waiver is available effective March 15, 2020, but it applies only (1) if a hospital has implemented a disaster protocol or state emergency plan, and (2) for up to 72 hours following implementation of the protocol.

- **Skilled Nursing Facilities ("SNFs").** SNFs may provide temporary nursing coverage and SNF services without the three-day prior hospitalization stay

requirement if an individual requires a transfer as a result of the COVID-19 emergency. CMS will waive certain Resident Assessment Requirements. CMS has also authorized that SNF coverage may be renewed for certain beneficiaries who have exhausted SNF benefits without having to wait for a new benefit period.

- **Inpatient Rehabilitation Facilities ("IRFs").** Facilities classified as IRFs (or that are seeking to obtain IRF classification) may exclude patients from the hospital's or unit's inpatient population to calculate the applicable thresholds associated with IRF payments. This only applies if the IRF admits the patient solely in response to the emergency and properly annotates the circumstances in the patient's medical record.

- **Home Health Agencies ("HHAs").** Relief will be provided on the timeframes related to OASIS Transmissions. The MACs that process Medicare claims may extend the auto-cancellation date of Requests for Anticipated Payment.

- **Telehealth.** Medicare can pay for office, hospital, and other visits furnished via telehealth across the country and including in patient's places of residence effective March 6, 2020. A range of providers, such as doctors, nurse practitioners, clinical psychologists, and licensed clinical social workers, will be able to offer telehealth to their patients with reduced or waived cost-sharing. Prior to this waiver, Medicare could only pay for telehealth on a limited basis—i.e., when the person receiving the service is in a designated rural area and when he or she leaves his or her home and goes to a clinic, hospital, or certain other types of medical facilities for the service.[5]

  Also in connection with telehealth services, the HHS Office of the Inspector General has stated that physicians and other practitioners will not be subject to administrative sanctions for reducing or waiving any cost-sharing obligations that federal health care program beneficiaries may owe for telehealth services furnished consistent with the applicable coverage and payment rules.[6]

- **Durable Medical Equipment ("DME") Suppliers.** DME MACs may waive replacement requirements, including the face-to-face requirement, a new physician's order, and new medical necessity documentation, for DME Prosthetics, Orthotics, and Supplies ("DMEPOS") that are lost, destroyed, irreparably damaged, or otherwise rendered unusable as a result of the emergency. The supplier's claim must include a narrative description that explains the reason for the replacement. The supplier must maintain

[5] For more detail, see the Epstein Becker Green blog post available at https://www.healthlawadvisor.com/2020/03/19/ocr-waives-penalties-for-telehealth-communications-during-covid-19-national-emergency/.

[6] HHS, OIG Policy Statement Regarding Physicians and Other Practitioners That Reduce or Waive Amounts Owed by Federal Health Care Program Beneficiaries for Telehealth Services During the 2019 Novel Coronavirus (COVID-19) Outbreak (Mar. 17, 2020), *available at:* https://protect-us.mimecast.com/s/dU53Cv2Dq1CAxW86tXCJwh?domain=click.connect.hhs.gov.

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

- **Appeals Process for Fee for Service, Medicare Advantage ("MA"), and Part D Plans.** The blanket waivers include an extension to file an appeal and waive the timeliness requirements for requests for additional information to adjudicate appeals. The appeal may be processed even with incomplete Appointment of Representation forms through communications with the beneficiary. CMS will also process requests for appeal that do not meet the required elements based on the information available. CMS will use all flexibilities in the appeals process if good cause requirements are met.

Provider-Specific Waivers

In addition to the nationwide blanket waivers, section 1135 of the Social Security Act gives the Secretary authority to waive or modify other program requirements "to the extent necessary" to meet the needs of beneficiaries. These potentially include waiving or modifying the following:

- Conditions of participation or other certification requirements
- Program participation and similar requirements
- Preapproval requirements
- Emergency Medical Treatment and Labor Act ("EMTALA") sanctions for directing or relocating individuals to another location for a medical screening if performed under an appropriate state emergency plan or transferring an individual not yet stabilized if the transfer is necessary under the circumstances of COVID-19
- Stark self-referral sanctions
- Required performance deadlines and timetables
- Limitations on payment for care furnished to MA enrollees by non-network providers

Until the time that such waivers are declared "blanket waivers," providers must contact their CMS Regional Office to specifically request them. CMS approves specific waivers and modifications only to the extent that the provider in question has been affected by the disaster or emergency and the requested relief is related to the emergency's impact. In fact, CMS states that "[o]ne of the best indicators for the need and geographic scope of an 1135 Waiver is healthcare provider and provider association contacts with CMS Regional Offices."[7]

Requests, including information on the provider and justification for requesting the waiver, can be made by sending an email to the CMS Regional Office in the service area. CMS depends on such provider outreach to inform the agency of the impact of the emergency and potential relief. Providers are encouraged to coordinate their requests

[7] CMS, 1135 Waiver at a Glance, *available at:* https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Downloads/1135-Waivers-At-A-Glance.pdf.

and input with state health departments, state provider associations, or professional societies, etc.

Flexibilities Available from CMS Regional Offices and MACs Without an 1135 Waiver

In general, absent a specific 1135 Waiver stating otherwise, standard Medicare billing rules will continue to apply, and services must be reasonable and necessary in order to receive payment for them, even in an emergency/disaster situation. For example, Medicare will not make duplicate payments on overlapping dates of service or for the same month when multiple providers are furnishing care for a patient. Therefore, even in an emergency/disaster situation, it is imperative to use appropriate billing modifiers to designate when transfers have occurred and when services are being provided due to the emergency/disaster situation (e.g., the "DR" condition code for facility claims and the "CR" modifier for professional service claims). Further, providers may not seek reimbursement for no-cost items.

At the same time, there are additional areas of flexibility that exist under the normal business rules and under the CMS Administrator's authority for Medicare fee-for-service providers. Where such flexibilities exist, temporary adjustments can be made to allow health care providers and suppliers to function during an emergency/disaster situation. Examples of such areas where flexibilities exist without the need for an 1135 Waiver are outlined below. Adopting these flexibilities requires contacting either the local CMS Regional Office or MAC, as indicated below.

- **Hospital Services.** Under current EMTALA laws and regulations, ACHs are permitted to move individuals out of their dedicated emergency departments to another part of the hospital (e.g., a "fast-track clinic") in order to provide the required medical screening examination and then, if an emergency medical condition exists, to provide stabilizing treatment or arrange for an appropriate transfer. An ACH may bill for emergency visit services furnished in an outpatient area of the hospital that is being used as an extension to see overflow patients from the emergency department, as long as the separately identifiable area meets the definition of a "Type A" or "Type B" emergency department and all other applicable requirements. An ACH may also establish a mobile facility or an "alternative care site" at a remote location to provide inpatient services under the hospital's existing provider agreement, as long as that location satisfies the requirements to be provider-based to the hospital's main campus, including being compliant with hospital Conditions of Participation ("CoPs") and remaining within 35 miles of the main provider.

  An ACH may apply to the CMS Regional Office for Capital Prospective Payment System Extraordinary Circumstances Exception payments if the ACH incurs unanticipated capital expenditures in excess of $5 million (net of proceeds from other funding sources, including insurance, litigation, and government funding (e.g., FEMA aid)) due to extraordinary circumstances beyond the ACH's control. The written request must be made within 180 days after the occurrence of the

extraordinary circumstance causing the unanticipated capital expenditures for a determination by CMS.

- **Ambulance Transports.** Medicare payment for ambulance transports can be made only when the transport is to a covered destination. However, Medicare payment for an ambulance transport to an "alternative care site" may be available if the site is determined to be part of an institutional provider (hospital, CAH, or SNF) that is an approved destination for an ambulance transport. Further, should a facility that would normally be the nearest appropriate facility be unavailable during an emergency/disaster, Medicare may pay for transportation to another facility so long as that facility meets all Medicare requirements and is still the nearest facility that is available and equipped to provide the needed care for the illness or injury involved. If there are exceptional circumstances that require transport outside the locality, Medicare can pay for this transport, but only if the destination is still the nearest appropriate facility.

- **Laboratory Specimens.** In situations in which laboratory specimens are destroyed or compromised by a disruptive event, MACs may consider payment for another drawing fee, specimen transport, or test if the results have not been communicated to the patient's physician.

- **Part B Drug Supplies.** MACs have discretion to pay for a greater-than-30-day supply of drugs, taking into account the nature of the particular drug, the patient's diagnosis, the extent and likely duration of disruptions to the drug supply chain during an emergency, and other relevant factors that would be applicable when determining whether an extended supply of the drug is reasonable and necessary. Further, in the event of an emergency, MACs may consider allowing payment for a medically necessary, greater-than-30-day supply of Medicare-covered, immunosuppressive drugs on a case-by-case basis. MACs may also allow payment for replacement prescription fills (for a quantity up to the amount originally dispensed) when reasonable and necessary in circumstances where the dispensed medication is lost or otherwise rendered unusable due to the emergency.

- **Dialysis Treatment.** When an end-stage renal disease ("ESRD") patient cannot obtain his or her regularly scheduled dialysis treatment at a certified ESRD facility and has a medical need to receive an unscheduled or emergency dialysis session in an outpatient hospital setting, the service is payable under the outpatient prospective payment system. As a result of an emergency/disaster, the unscheduled or emergency dialysis treatment may be necessary for a longer period of time than under otherwise normal circumstances. Hospital outpatient departments may continue to provide this service on an emergent or unscheduled basis, absent any functional, nearby, certified dialysis facility to perform the service.

- **Home Health Services.** Under the Medicare statute, beneficiaries must be confined to the home in order to be eligible to receive home health services.

However, under the temporary, extraordinary circumstance of a declared emergency or disaster, the beneficiary's "place of residence" can include services provided at temporary locations, such as a family member's home, a shelter, a community facility, a church, or a hotel. A hospital, SNF, or nursing facility would not be considered a temporary residence.

Further, a Medicare-approved HHA that is able to provide home health services beyond its current geographic service area may do so on a temporary basis during an emergency period, provided that the HHA is in full compliance with state and local law, that the HHA can ensure that staff is competent and able to provide appropriate patient care, and that the purpose of the expansion is to provide care to the patients affected by the emergency.

- **Hospice Services.** A MAC can determine if circumstances encountered by a hospice qualify the hospice for an exception to the timely filing requirement for the hospice Notice of Election ("NOE"). The hospice must document the circumstances to support a request for an exception, which would waive the payment consequences of filing the NOE more than five calendar days after the effective date of election.

  Further, a Medicare beneficiary may transfer from one hospice agency to another hospice for any reason once per election period. If the beneficiary has already utilized this one-time right to transfer but needs to move again because of a public health emergency, a hospice agency may make arrangements with another hospice for the delivery of services in "extraordinary circumstances." Further, if a beneficiary uses the services of an alternate hospice agency for a short period of time under arrangement with the patient's "home" hospice due to extraordinary circumstances, neither the departure from nor return to the original hospice agency would be considered a voluntary transfer.

- **Claims Submission and Payment Requirements.** MACs have discretion to waive various requirements related to the claims submission process, including the timely claim filing window (e.g., one calendar year from the date of service), mandatory electronic claims filing, cost report submission deadlines, and cost report desk review and audit activities. For good cause, MACs may accept late claims denial appeal requests from providers, suppliers, or beneficiaries. In addition, in order to ensure appropriate cash flow, MACs may issue accelerated or advance payments to providers that are still rendering services or that are taking steps to be able to render services again, and CMS may allow additional time to repay the accelerated or advance payment, if needed. MACs may delay issuing tentative and final settlements to providers impacted by the emergency. Providers under an Extended Repayment Schedule may be able to defer monthly payments for a period of time, and CMS or the Secretary may waive interest on debts arising from a Medicare overpayment.

Medicaid Relief Available Upon State Request

To further increase flexibility within Medicaid, CMS may grant a range of flexibilities to better address COVID-19, if requested by states. These flexibilities include waiving prior authorization requirements, simplifying provider enrollment processes, allowing care to be provided in alternative settings in the event a facility is evacuated to an unlicensed facility, suspending certain SNF screening requirements, and extending deadlines for appeals and state fair hearing requests.

On March 17, 2020, Florida became the first state to have requested and been granted Medicaid flexibilities to respond to COVID-19.[8] To increase provider participation, CMS waived the Florida Medicaid requirement that limits the instances of care that unenrolled providers may furnish and the number of Medicaid participants that can receive care from unenrolled providers within a 180-day period under the condition that the provider is enrolled in Medicare or another state's Medicaid program. Florida will be able to waive certain screening and enrollment requirements to allow providers not already enrolled in Medicare or another state's Medicaid program to gain temporary provisional enrollment in Florida if certain minimum data and information collection requirements are met. The waiver specifies that Florida must allow a retroactive effective date for provisional temporary enrollments that is no earlier than March 1, 2020, and must follow certain processes once the emergency designation is lifted. The waiver also permits Florida to perform expedited enrollment of out-of-state facilities to accommodate participants displaced by the emergency.

CMS will also allow Florida to waive a modification of preauthorization requirements for beneficiaries whose permanent residence falls within the geographic area of the public health emergency. CMS will also waive the Level 1 and Level 2 Preadmission Screening and Annual Resident Review ("PASRR") Assessments typically required by nursing facilities for 30 days and will allow all new admissions to be treated like exempted hospital discharges. CMS specifies certain parameters of the waiver, including that the Resident Review should be conducted as resources become available, and that after 30 days, new admissions with mental illness or intellectual disability should receive a Resident Review as soon as resources become available.

Under Florida's waiver, CMS will also allow care to be provided in alternative settings in the event a facility, such as a nursing facility or hospital nursing facility, is evacuated to an unlicensed facility. The facility is responsible for determining how to reimburse the unlicensed alternative facility. After 30 days, the unlicensed facility would be required to seek licensure or the evacuating facility would need to relocate individuals. The waiver also permits Florida to extend deadlines for appeals and state fair hearing requests.

More Flexibilities to Follow

New flexibilities are expected to follow on a daily or weekly basis from HHS. In addition, Congress may grant still further relief to providers. Clients should track HHS

[8] CMS Letter to Florida Agency for Health Care Administration (Mar. 16. 2020), *available at:* https://www.medicaid.gov/state-resource-center/downloads/fl-section-1135-appvl.pdf.

developments[9] related to the current emergency and follow Epstein Becker Green publications for further updates. Epstein Becker Green has also organized all of its Client Alerts and issuances on COVID-19 in its Coronavirus Resource Center.[10]

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This Client Alert was authored by **Helaine I. Fingold, Philo D. Hall, Lesley R. Yeung,** *and* **Alexis Boaz.** *For additional information about the issues discussed in this Client Alert or if you would like to discuss these current and prospective waivers in more detail, please contact one of the authors or the Epstein Becker Green attorney who regularly handles your legal matters.*

[9] CMS, Current Emergencies, *available at:* https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page.
[10] This Coronavirus Resource Center is available at https://www.ebglaw.com/coronavirus-resource-center/.