Healthcare Legal Alert: CMS Medicare Waiver Updates

The Centers for Medicare & Medicaid Services (CMS) continues to waive various federal regulations in the face of the current public health emergency. On March 30, 2020, CMS issued extensive waivers of certain federal requirements to ensure health systems have the capacity to absorb and manage potential surges of COVID-19 patients.

The waivers are retroactive to March 1, 2020 and relax an array of federal rules, including conditions of participation, certification requirements, preapproval requirements and various federal statutes including the physician self-referral ("Stark") law and EMTALA. This bulletin summarizes the most recent waivers as well as updates to previously announced waivers. It also explains some of the requirements that may be of greatest interest to healthcare providers, and highlights those that coincide with New York requirements that have already been relaxed through Governor Cuomo's Executive Orders. As "blanket waivers", these waivers do not require a request or notification to be sent to CMS in order for providers to take advantage; however, healthcare providers will need to meet documentation requirements and make such documentation available to the Secretary of HHS upon request. Please note, however, that for purposes of the State licensure waiver described below, there is a notification requirement, for billing purposes.

Stark Blanket Waivers

On March 30, 2020, the Secretary of HHS waived certain provisions of the Stark law to help providers address the unique challenges of the COVID-19 outbreak. The waiver means it will no longer be a violation of Medicare regulations for a provider (such as a hospital) to submit claims and receive payment for designated health care services (including all hospital inpatient and outpatient services) provided to Medicare beneficiaries referred to the provider by physicians who themselves, or whose immediate family members, have certain kinds of financial relationships with the provider which, absent the waiver, would prohibit the submission of or payment for such claims. While these waivers are certainly welcome and demonstrate the commitment of the regulators to remove impediments to addressing COVID-19 related challenges, as with all things Stark, the devil is in the details. Providers and the physicians who refer patients to them must exercise great caution when structuring new financial arrangements, as the waiver requirements are detailed and should not be misconstrued as a complete suspension of the Stark prohibitions.

The Waivers: Eighteen specific waivers are further detailed in the Blanket Waiver document located at the link below. The majority suspend fair market value requirements that are part of existing exceptions, one eliminates the writing and signature requirements found in the existing compensation arrangement exception, others waive the monetary caps applicable to the incidental medical staff benefits and non-monetary compensations exceptions, and still others relate to the physician practice exception and the location of services.

While these blanket waivers do not require advance approval of or notification to CMS before providers and physicians may rely on them, CMS has encouraged parties to document the use of a waiver and the

details of the transaction, **including the reasons why the parties entered into the arrangement**, because only financial arrangements and associated referrals that are related to the COVID-19 outbreak and national emergency are eligible to be protected by the waivers. Such purposes are limited to:

1. Diagnosis or medically necessary treatment of COVID-19 for any patient or individual, whether or not the patient or individual is diagnosed with a confirmed case of COVID19;
2. Securing the services of physicians and other health care practitioners and professionals to furnish medically necessary patient care services, including services not related to the diagnosis and treatment of COVID-19, in response to the COVID-19 outbreak in the United States;
3. Ensuring the ability of health care providers to address patient and community needs due to the COVID-19 outbreak in the United States;
4. Expanding the capacity of health care providers to address patient and community needs due to the COVID-19 outbreak in the United States;
5. Shifting the diagnosis and care of patients to appropriate alternative settings due to the COVID-19 outbreak in the United States; or
6. Addressing medical practice or business interruption due to the COVID-19 outbreak in the United States in order to maintain the availability of medical care and related services for patients and the community

ONLY FINANCIAL RELATIONSHIPS ENTERED INTO FOR THESE PURPOSES WILL BE PROTECTED BY THE WAIVER.

In addition, the announcement is clear that the anti-kickback laws are not waived. Thus, if the reason the parties enter into the financial arrangement is to induce or reward referrals of Medicare beneficiaries, the parties are still subject to sanctions and penalties for violating the anti-kickback laws.

The Examples: Most helpful in CMS's waiver announcement are the examples given of how waivers can be utilized in real-life situations. They include:

- A hospital increases the previously contracted rate for professional services for COVID-19 patients rendered in particularly hazardous or challenging environments.
- A hospital provides free medical office space on its campus to physicians so they can provide timely and convenient services to patients who came to the hospital but do not require inpatient care.
- A hospital sells PPE to a physician or permits them to use space or a tent at below fair market value or at no charge.
- A hospital provides meals, a change of clothes or even onsite childcare, which are valued at more than $36 per item, to medical staff members working extended hours at the hospital caring for patients during the COVID-19 outbreak.
- A hospital provides hotel rooms and meals to a physician who must isolate.
- A hospital provides free telehealth equipment to a physician practice so they can provide care to their patients while practicing social distancing or while in isolation or quarantine.

Timing and Unwind: The waivers are only effective while the Secretary's public health emergency declaration is in effect. Therefore, any waived arrangement will have to be unwound when the

declaration ends. This provides a level of uncertainty when putting such relationships in place, but it is clear that the parties need to understand that these are temporary measures.

Best Practices: Providers and physicians are advised to follow these best practices if they wish to establish new financial relationships in reliance on the new blanket waiver:

1. For each waived financial relationship, document:
    1. the purpose of the arrangement;
    2. the unwind process for the arrangement; and
    3. because these waivers do not impact the Anti-Kickback Statute, that no payments or benefits are conferred or offered based on the value or volume of referrals by the physicians.
2. The documentation should be retained by the hospital for at least six years.
3. The documentation can be a memo to the file by the hospital. If not done before the arrangement starts, do it as soon thereafter as possible.
4. Consult legal counsel prior to entering into the arrangement, if possible.

Extensive details about the structure of waived financial relationships can be found at the waiver document at this link.

https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf

Increasing Capacity – Temporary Expansion Locations

CMS is allowing hospitals to provide services in locations beyond their existing walls in order to quickly expand capacity and develop sites dedicated to COVID-19 treatment. The waivers will allow hospitals to transfer patients to outside facilities such as ambulatory surgery centers, inpatient rehabilitation hospitals, hotels and dormitories while still receiving payments under Medicare. CMS has waived the following requirements in order to allow hospitals to expand capacity:

- Physical Environment. CMS is waiving requirements under 42 CFR §482.41 and §485.623 to permit non-hospital buildings and space to be used for patient care and quarantine sites provided the location is approved by the state and is consistent with the state's emergency preparedness or pandemic plan.
- Temporary Expansion Locations. CMS is waiving requirements under 42 CFR §482.41 and §485.623, and the provider-based department requirements at §413.65, to allow hospitals to establish and operate as part of the hospital at any location meeting those conditions of participation for hospitals that have not been waived by CMS. Hospitals may 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.
- Housing Acute Care Patients in Excluded Distinct Part Units. CMS is waiving requirements to allow acute care hospitals to house acute care inpatients in excluded distinct part units, such as excluded distinct part unit IRFs or IPFs, where the beds are appropriate for acute care inpatients. Hospital may bill for such services under the IPPS, but must indicate in the patient's record that the acute care inpatient is being housed in the excluded unit because of capacity issues. Hospital may also relocate inpatients from the excluded distinct part units to an acute care unit, as necessary, to meet

patient needs during the emergency. The hospital should continue to bill the Medicare payment system (for IRF or IPF, as applicable) and should document in the patient's record to indicate the patient is being cared for in an acute care bed because of capacity or other exigent circumstances related to the COVID-19 emergency. The hospital must also document that care in the acute unit meets the patient's needs. For psychiatric patients, this includes an assessment to ensure those patients at risk of harm to self and others are safely cared for.

Recordkeeping Requirements

CMS is waiving certain recordkeeping requirements to allow hospitals to focus on increased care demands and patient care.

- Medical Records. CMS is waiving requirements under 42 CFR §482.24(a) through (c) related to staffing of the medical records department, requirements for the form and content of the medical record, and record retention requirements. In addition, CMS is waiving §482.24(c)(4)(viii) to allow flexibility in completing medical records within 30 days following discharge from a hospital. Waiver of recordkeeping requirements related to COVID-19 have also been included in Governor Cuomo's Executive Orders.
- Verbal Orders. CMS is waiving the requirements of 42 CFR §482.23, §482.24 and §485.635(d)(3) to provide additional flexibility related to verbal orders. Authentication may now occur later than 48 hours. CMS has waived the following requirements for verbal orders: 482.23(c)(3)(i) (verbal orders for the use of drugs and biologicals (except immunizations), may only be used infrequently); §482.24(c)(2) (verbal orders must be dated, timed and authenticated promptly by the ordering practitioner or by another practitioner responsible for the care of the patient); §482.24(c)(3) (waiver of requirements for hospital to use pre-printed and electronic standing orders, order sets and protocols for patient orders); and §485.635(d)(3) (CAHs may use verbal orders for medication administration; a practitioner responsible for the care of the patient must authenticate the order in writing as soon as possible after the fact).
- CMS is waiving 42 CFR §489.102, which requires hospitals and CAHs to provide information about their advance directive policies to patients.
- CMS is waiving the requirements at 42 CFR §482.23(b)(4), which require the nursing staff to develop and keep current a nursing care plan for each patient.

Supervision

- Medical Residents. CMS has relaxed the requirements for medical residents providing services under the direction of a teaching physician. Teaching physicians can now provide supervision virtually using audio/video communications technology.
- Respiratory Care Services. CMS is waiving the requirements at 42 CFR §482.57(b)(1) that require hospitals to designate in writing the personnel qualified to perform specific respiratory care procedures and the amount of supervision required for personnel to carry out specific procedures.
- Physician Services. CMS is waiving requirements under 42 CFR §482.12(c)(1)–(2) and §482.12(c)(4) that require Medicare patients to be under the care of a physician.
- Anesthesia Services. CMS is waiving requirements under 42 CFR §482.52(a)(5), §485.639(c)(2), and §416.42(b)(2) for CRNA supervision by a physician. CRNA supervision will be at the discretion of the

hospital.

Limiting Discharge Planning

For patient discharge planning, CMS has relaxed the requirement that hospitals, psychiatric hospitals and critical access hospitals use and share data on post-acute care providers, such as home health agencies (HHAs), skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs) and long term care hospitals (LTCHs). Generally, discharge planning must include data on quality measures and data of resource use measures relevant to the specific patient to assist the patient in selecting a post-acute care provider. However, during the COVID-19 pandemic, a hospital may not be able to rely on such quality measures and data. Nonetheless, hospitals must still work with families to ensure that the patient discharge is to a post-acute care provider able to meet the patient's care needs.

In addition, CMS has waived the obligation for inclusion of detailed information generally required in the discharge plan under 42 CFR §482(c), including: (1) providing a list of HHAs, SNFs, IRFs, or LTCHs that are available to the patient; (2) informing patients of their freedom to choose among participating Medicare providers and suppliers of post-discharge services; and (3) identifying in the discharge plan any HHA or SNF to which the patient is referred in which the hospital has a disclosable financial interest, as specified by the Secretary, and any HHA or SNF that has a disclosable financial interest in a hospital under Medicare.

Waiver of State Licensure Requirements

CMS also updated its previous waiver of the requirement that practitioners (physicians and non-physicians) be licensed in the state where they are providing services in order for those services to be reimbursable by Medicare or Medicaid (this waiver is not applicable to services reimbursable by the Child Health Plus program). The update provides that this requirement is waived for services provided by out-of-state practitioners in states covered by a declared state of emergency when the following four conditions are satisfied:

1. the practitioner is currently enrolled in the Medicare program;
2. the practitioner possesses a valid license to practice in the state which relates to his or her Medicare enrollment;
3. the practitioner is furnishing services – whether in person or via telehealth – in a state where he/she is not licensed in order to contribute to relief efforts in his or her professional capacity; and
4. the practitioner is not affirmatively excluded from practice in the state in which he is not licensed or in any other state.

Notably, CMS clarified in this update that practitioners wishing to avail themselves of this waiver (i.e., practitioners who wish to provide Medicare or Medicaid services in states where they are not currently licensed) must request that they be covered by this waiver by contacting the Medicare Provider Enrollment Hotline for the Medicare Administrative Contractor (MAC) in their geographic area. The Part B MAC for New York is National Government Services. Its provider enrollment hotline number is 1-888-802-3898 and it is available 9:00 a.m. – 5:00 p.m. Monday through Friday.

Practitioners are advised, however, that CMS-issued waivers do not waive state or local licensure requirements. Therefore, in order for a practitioner to avail him or herself of this waiver, the state in

which he/she is not licensed must also have waived its licensure requirements, either individually or categorically, for the type of practice the practitioner is licensed to perform in his or her home state.

Streamlined Provider Enrollment Processes

Neither CMS nor New York State Medicaid have changed their requirements that only enrolled providers are eligible to bill Medicare or Medicaid for services provided to enrollees of those two programs. However, both agencies have expedited their enrollment processes and made other changes to expand the ability of practitioners and facilities to provide and bill for covered services.

CMS has had all MACs establish toll-free enrollment hotlines for practitioners as well as Part A certified providers and suppliers that may be establishing isolation facilities. Upon completing this streamlined process, practitioners will be granted temporary Medicare billing privileges. The streamlined process includes the following:

1. Waiver of application fee;
2. Waiver of criminal background checks associated with fingerprint-based criminal background checks;
3. Waiver of site visits;
4. Postponement of all revalidation actions;
5. Permission for licensed providers to render services outside of their state of enrollment;
6. Expedition of any pending or new applications from providers;
7. Permission for physicians and other practitioners to render telehealth services from their homes without reporting their home addresses on their Medicare enrollment while continuing to bill from their currently enrolled location; and
8. Permission for opted-out physicians and non-physician practitioners to terminate their opt-out status early and enroll in Medicare to provide care to more patients.

The Part A/B MAC for New York is National Government Services. Its provider enrollment hotline number is 1-888-802-3898 and it is available 9:00 a.m. – 5:00 p.m. Monday through Friday.

Similarly, New York State Medicaid is offering Provisional Temporary Enrollment for the duration of the public health emergency and has implemented multiple streamlined options for enrollment. This new provisional enrollment applies to providers in the following Categories of Service (COS):

- Nurse LPN – 0521
- Nurse RN – 0522
- Nurse Practitioner – 0469
- Physician – 0460
- Physician Assistant (Registered) – 0462

To enroll using the Online Web Form:

1. Via web browser, access the form at: www.emedny.org/COVID19/

2. Complete the form following instructions.
3. When complete, click “Submit” to send the form for processing.

To enroll via email:

1. A hard copy form can be found at: www.emedny.org/COVID19/
2. Complete the form.
3. Email completed form to: emednycovid19PE@csra.com

To enroll an individual provider or if you need support, contact the eMedNY Call Center at 800-343-9000. If enrolling by phone, have the following information available:

- Email address
- Category of Service (COS)
- Identifying Information
- Contact Information
- Home address, work address, and service address.

Those enrolling a large number of providers are also asked to call the eMedNY Call Center. Once approved, the enrollee will receive an enrollment letter including a Medicaid Provider ID number (MMIS) and will then be able to submit claims. Additional enrollment directions can be found here: https://www.emedny.org/COVID19/instructions.pdf

Please contact one of our Firm’ s health law attorneys identified below if you would like more information. This communication is for informational purposes and is not intended as legal advice.