



Health Law Alert: HHS Grants Midwest States Waiver Requests; CMS Issues Guidance on Stark Law Waivers

April 1, 2020

On March 27, 2020, the U.S. Department of Health and Human Services (HHS) approved the waiver request submitted by the Minnesota Department of Human Services (DHS) earlier this month (the "Minnesota Waiver"). In addition to the Minnesota Waiver, on March 25, 2020, HHS approved the waiver request submitted by the Missouri HealthNet Division, Missouri Department of Social Services (DSS) (the "Missouri Waiver"); on March 24, 2020, HHS approved the waiver request submitted by the Kansas Department of Health and Environment, Division of Health Care Finance (KDHE) (the "Kansas Waiver"); and on March 23, 2020, HHS approved the waiver request submitted by the Illinois Department of Healthcare and Family Services (IDHFS) (the "Illinois Waiver") (collectively the "Waivers").

Meanwhile, on March 30, 2020, CMS issued guidance on implementation of the "blanket" Stark Law waivers intended to assist providers in addressing the patient care challenges and financial problems they are facing due to the epidemic ("Stark Law Waivers"). Under the Stark Law Waivers, CMS will reimburse providers for designated health services that would otherwise violate the Law so long as the Waivers' conditions are satisfied. Providers can use the Stark Law Waivers immediately. It is not necessary to request approval. Providers should maintain records documenting their compliance with the conditions of the relevant Stark Law Waivers

Background on Waivers

These Waivers follow on the heels of the nationwide waiver issued by HHS Secretary Azar on March 13, 2020. HHS has authority under Section 1135 of the Social Security Act to waive or modify certain Medicare, Medicaid, Children's Health Insurance Program (CHIP) and HIPAA Requirements. The national waiver modified a variety of regulatory requirements under these programs. The national waiver was effective retroactively to March 1, 2020.

State Waivers

HHS granted the Waivers shortly after receiving requests from the various state agencies noted above. All of the Waivers build on the national waiver and modify a variety of specific regulatory requirements from each of those states. A summary of some of the key changes and notation as to which state the changes apply to



is below:

Allowing Certain Providers to Render Services in Alternate Settings (Minnesota, Missouri, Illinois, & Kansas) - the Minnesota, Missouri, Illinois, and Kansas Waivers allow nursing facilities, intermediate care facilities for individuals with intellectual and developmental disabilities, psychiatric residential treatment facilities and hospital nursing facilities to be fully reimbursed for services provided in an unlicensed location as a result of relocating residents. The relocation must be due to an emergency evacuation or because of relocations as a result of facility efforts to treat COVID-19 patients. The facility that places residents in unlicensed facilities is responsible for determining how to reimburse the unlicensed facility.

Provider Enrollment & Program Integrity (Minnesota, Missouri, Illinois, & Kansas) - Relaxation of numerous provider enrollment requirements under CHIP and Medicaid, including:

- Allowing DHS, DSS, IDHFS or KDHE to reimburse out-of-state providers (not enrolled in the state's Medicaid program) for multiple services provided to multiple Medicaid enrollees over a 180-day period. This is an expansion of the current rules, which permit only limited reimbursement for out-of-state providers not enrolled with DHS, DSS, IDHFS or KDHE.
- Permitting providers enrolled in Medicare or Medicaid programs in other states to be temporarily enrolled in the requesting state's Medicaid program and thus eligible to provide services to Medicaid beneficiaries. Separate enrollment with Minnesota, Missouri, Illinois or Kansas Medicaid would not be needed.
- For providers not enrolled in Medicare or another state's Medicaid program, DHS, DSS, IDHFS or KDHE can waive a variety of enrollment standards, including the obligation to: charge an application fee, perform criminal background checks, conduct site visits and meet licensure requirements.
- There will also be a pause in the Medicaid enrollment revalidation process.

Suspension in Prior Authorization Requirements for Fee-for-Service Care (Minnesota, Missouri, Illinois, & Kansas) - DHS, DSS, IDHFS and KDHE are allowed to waive requirements for providers to obtain prior authorization to determine medical necessity for services paid under Medicaid fee-for-service reimbursement.

Extend pre-existing authorizations for which a beneficiary has previously received prior authorization (Missouri, Illinois, & Kansas) - DSS, IDHFS or KDHE may continue to provide services approved on or after March 1, 2020 without requiring a new or renewed prior authorization, including extensions for beneficiaries with a permanent residence in the geographic area of the public health emergency.

Suspend Pre-Admission Screening and Annual Resident Review (PASRR) Level I and Level II Assessments for 30 Days (Missouri, Illinois, & Kansas) - All new admissions can be treated like exempted hospital discharges for 30 days, and mental illness (MI) and intellectual disability (ID) admissions



should receive a Resident Review as soon as resources are available. Level I and Level II preadmission screens are not required for patients transferred between nursing facilities (NF).

Modification of Fair Hearing Plan Timeline (Minnesota, Missouri, Illinois, & Kansas) -Enrollees in fee-for-service Medicaid are granted an extension of time (up to 120 days) to file a fair hearing request. Medicaid managed care programs also saw changes under the Minnesota, Missouri, Illinois and Kansas Waivers, with beneficiaries of these programs eligible for an accelerated internal health plan appeals process and therefore quicker fair hearings from DHS, DSS, IDHFS or KDHE.

There are other changes as well, including flexibility for DHS to submit Amendments to the State Medicaid Plan related to the COVID-19 response. Missouri also received a waiver of the public notice requirements with respect to SPAs that provide or increase access to items and services related to COVID-19. In its approval letter to DHS, DSS, IDHFS and KDHE, HHS noted that for specific items requested in their respective submissions (and not specifically approved in the Waivers), HHS will "continue to work with your team to review and make determinations regarding approval as quickly as possible." It appears, therefore, that additional modifications to the respective state Medicaid and CHIP programs will be forthcoming.

The Waivers are effective retroactively to March 1, 2020 and will last throughout the ongoing COVID-19 public health emergency.

National Waiver

The Waivers build on Secretary Azar's nationwide waiver. The nationwide or "blanket" waiver modified a variety of regulatory requirements:

- Waiver of certain conditions of participation, certification requirements, program participation and pre-approval requirements.
- Waiver of individual state licensing requirements, so as physicians or other health care professionals have the ability to provide services in a State in which they are unlicensed, provided he or she holds an equivalent license from another State (and are not affirmatively barred from practice).
- Lifting of sanctions for violations of the Emergency Medical Treatment and Labor Act (EMTALA) for the direction or relocation of an individual to another location to receive medical screening, or for the transfer of an individual who has not been stabilized, if the transfer is necessitated by the COVID-19 pandemic.
- Lifting of sanctions for violations of the Stark Law. As described below, CMS issued guidance on this via the Stark Law Waivers.
- Waiver of limitations on the ability to make direct payments to providers for services to Medicare Advantage enrollees.
- Lifting of sanctions and penalties arising from noncompliance with certain provisions of HIPAA. Read more here.



- Modification of certain deadlines and for the performance of certain activities required to receive reimbursement.

Secretary Azar also clarified that these waivers are conditioned on the fact that there has not been any determination of fraud or abuse. The nationwide waivers, including the Stark Law Waiver discussed below, will last throughout the duration of the ongoing COVID public health emergency, unless terminated at an earlier date.

Stark Law Waivers

The Stark Law Waivers protect the exchange of certain types of remuneration between an entity and a physician (or immediate family member) and referrals from the physician to the entity so long as the remuneration and referrals are "solely related to COVID-19 purposes." CMS provides a list of COVID-19 Purposes, which include:

- Addressing medical practice or business interruption due to the outbreak so as to maintain the availability of medical care and related services for patients and the community.
- Securing services of physicians and other practitioners to provide patient care services (including services not related to COVID-19).
- Ensuring the ability and expanding the capacity of providers to address patient and community needs due to the outbreak.
- Shifting diagnosis and care of patients to alternative settings.
- Diagnosis or treatment of COVID-19 (does not require the patient to have a confirmed diagnosis).

CMS is waiving all Stark Law sanctions for referrals and claims related to the exchange of specific types of remuneration between physicians and the entities to which they refer designated health services. Examples include the following:

- Payments from an entity to a physician that are above or below fair market value of services provided. For example, a hospital could pay physicians at rates that exceed the parties' contracted payment rates so that the physicians can treat COVID-19 patients. Similarly, a hospital could send personnel to a practice (without charge) to assist in care coordination between the hospital and practice or buy/sell supplies with the practice at below market rates.
- Rent for equipment or space that is above or below fair market value. This could include hospitals providing equipment or space at no charge to a group practice for purposes of treating patients, affording the physicians the ability to use free space on the hospital's campus to see patients who show up at the hospital but do not require inpatient care or giving a physician group free telehealth equipment for use in treating patients who are trying to engage in social distancing.
- Loans between DHS entities and physicians that are on favorable terms, including below market interest rates. For instance, a hospital could loan money to a physician practice that has an exclusive arrangement for hospital-based services like anesthesia to offset lost income resulting from the



hospital's cancellation of elective procedures.

- Referrals by physician owners to group practices they own that fail to meet certain elements of relevant Stark Law exceptions that protect ownership interests, such as failing to meet the same building or centralized building tests under the in-office ancillary services exception or failing to meet the rural provider exception in some circumstances.
- Remuneration from hospitals to physicians that exceed limits established under various Stark Law exceptions, such as for nonmonetary compensation or medical staff incidental benefits.
- Compensation arrangements between entities and physicians that fail to meet the "writing" and "signature" requirements of various exceptions.

The Stark Law Waivers include several other types of relationships that are also protected. The Stark Law Waivers are effective retroactively to March 1, 2020. They apply to all parts of the Country.

Other States Waivers

Including Minnesota, Missouri, Illinois, and Kansas, there are now 34 states with 1135 waivers, including Colorado, California, Wyoming, Delaware, Pennsylvania, Connecticut, Maryland, Hawaii, Idaho, Massachusetts, New York, Iowa, Indiana, Rhode Island, Kentucky, Oregon, North Dakota, South Dakota, Oklahoma, Alabama, New Hampshire, New Mexico, New Jersey, Arizona, Virginia, North Carolina, Mississippi, Louisiana, Washington and Florida.

If you have questions about the Minnesota, Missouri, Illinois or Kansas Waivers, Section 1135 Waivers or CMS' Stark Law Waivers, please contact Jesse Berg, Denise Bloch, Julia Reiland or any member of the Lathrop GPM Health Law Team.