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COVID-19 Stark Law Waiver

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On March 30—but retroactive to March 1—the Secretary of HHS issued a partial waiver of elements of the Stark Law. The waiver is subject to revision and termination, but presumptively will remain in effect for the duration of the COVID-19 public health emergency.

The waiver is not absolute. Much of the Stark Law remains in effect. But the waiver provides broad and welcome relief in particular to hospitals and physician groups seeking to address the simultaneous public health and fiscal crises brought upon them by COVID-19.

The waiver is available here. Our summary of key points follows.

For what period is the blanket waiver effective?

The waiver is effective retroactive to March 1, 2020. By statute, it will terminate upon conclusion of the federal public health emergency, but HHS may terminate (or narrow) it at an earlier date. Any termination or narrowing, however, would be prospective only.

What termination would mean for an arrangement that was entered into during the waiver period but by contract persists beyond it is a question of potential concern. Parties entering into arrangements that depend upon the waiver's ongoing effectiveness therefore should consider termination rights that would be triggered upon the waiver's expiration.

Does the waiver apply to all financial relationships?

No. It protects only direct financial relationships between an entity that furnishes designated health services and either (i) a physician (or immediate family member thereof) or (ii) a physician organization in whose shoes a physician stands. It does not protect indirect compensation arrangements.

Must a financial relationship relate to COVID-19 in order to be eligible for the waiver?

Yes. An arrangement "must be solely related to COVID-19 Purposes." But the agency has not established that as a particularly high hurdle. CMS will consider an arrangement to be "solely related to COVID-19 Purposes," and therefore eligible for the waiver, if it is related to any of six purposes, one of which is "[e]nsuring the ability of health care providers to address patient and community needs due to the COVID-19 outbreak in the United States." That is a generous standard. The other five permitted purposes are:

- Diagnosing and treating COVID-19, regardless of whether the case is confirmed.
- Securing the services of physicians and other health care professionals to furnish medically necessary patient care, including services not related to COVID-19.

- Expanding the capacity of health care providers to address patient and community needs in response to the COVID-19 outbreak.
- Shifting diagnosis and care of patients to appropriate alternative settings due to the COVID-19 outbreak.
- Addressing medical practice or business interruption due to the COVID-19 outbreak in order to maintain the availability of medical care and related services for patients and the community.

Does the waiver waive the Stark Law entirely?

No. It waives only some elements of some Stark Law exceptions. Somewhat frustratingly for lawyers used to working with the Stark Law exceptions, the waiver for the most part doesn't speak in terms of exceptions. Instead, it speaks in terms of transaction types, and, for those types, waives requirements without in some cases identifying the exception in play. But boiled down, the waiver waives:

- **The writing and signature requirements of compensation exceptions**. Eligible parties therefore can reduce their agreements to writing in due course. But the waiver does not waive the requirements that compensation must be set in advance. So, practically speaking, parties will need to show that they have agreed on financial terms before their arrangement begins.
- **The fair market value requirement of the personal services exception and fair market value exception**. There are a few points of significance here.
    - While the waiver does not identify them by name, the exceptions in play must be the personal services exception and the fair market value (FMV) exception.
    - But the waiver doesn't apply to all transactions under those exceptions. By its text, the waiver waives the FMV requirement for services "personally performed by the physician" and for "items or services purchased by the entity from the physician." So, what, for example, of services furnished by a group's non-physician staff? Applying an overlay of the stand-in-the-shoes rules (which seems fair, in light of both preexisting Stark rules and the waiver's application to physician organizations), the best answer seems to be that general services agreements with physician groups are protected. But the industry would have benefited from more clarity on the point.
    - Inconsistently, for "services personally performed by the physician," the waiver applies whether compensation is above or below FMV. But, for "items or services purchased by the entity from the physician" (or, vice versa, for items or services purchased by a physician from an entity), the waiver applies only if compensation is below FMV. The easy implication is that parties can pay what they wish for physician services, but are capped at FMV if buying something else, like supplies. The harder question is what if the hospital purchases administrative services that one may not normally consider to be "personally performed"? In light of this unevenness and ambiguity, parties would do well to build arrangements involving high compensation around "personally performed" services.
- **The fair market value requirement of the office lease exception and equipment lease exception**. But very significantly here, the waiver applies only if rent paid is below FMV for the space or equipment. It does not protect rent that is above FMV.

- **The dollar cap for the medical staff incidental benefits exception**. In examples, the waiver suggests that this might allow a hospital to provide child care during shifts.
- **The dollar cap for the nonmonetary compensation exception**. As an example, the waiver cites provision of a hotel room to meet physicians' isolation needs.
- **The fair market value requirement of the isolated transactions exception, as applicable to loans** between physicians and entities. Here, the waiver applies only if interest is below FMV. That makes sense as to interest payments on loans necessitated by the crisis. But one does wonder why as a policy matter the agency believes that it's ok for a hospital to help a physician group by providing a below-market interest rate, but not by paying above-market rent. Query whether parties may find loans a more attractive mechanism to provide financial assistance than leases or service agreements (for services that are not unambiguously "personally performed") in light of this.
- **The expansion cap for the whole-hospital exception**. Of course, absent a more permanent change to the Stark rules, a physician-owned hospital making use of this exception (to add operating rooms, procedure rooms, or beds) would need to be able to ratchet-down once the emergency period passes.
- **The prohibition on conversion of ASCs in the whole-hospital exception**. The waiver permits physician-owned ASCs to convert into hospitals, if they convert and enroll with Medicare during the period of the public health emergency (the waiver is unavailable to ASCs that might have converted before March 1, 2020) and meet the conditions of participation and any regulatory requirements not otherwise waived. As with the expansion cap described above, absent a more permanent change to the Stark rules, an eligible ASC that does convert would seem to be required to convert back to ASC status upon the waiver's expiration.
- **The rural area limitation in the exception for home health agencies**. The waiver permits physicians to refer to home health agencies in which they have ownership interest, regardless of whether the home health agency qualifies as a rural provider. This waiver is for home health agencies only. It does not reach to other provider types that may meet the rural provider exception requirements.
- **The same building requirement of the in-office ancillary services exception**. The waiver does not suspend other requirements of the in-office ancillary services exception, including the limitations on who may perform services (the referring physician, another physician in the group practice, or an individual supervised by the physician).
- **The principal place of practice requirement of the in-office ancillary services exception.** The waiver permits physicians to order in-office ancillary services that are furnished in a patient's home (including an assisted living facility or independent living facility), rather than in the physician's office.
- **The no-other-alternatives requirement of the intra-family rural referrals exception**. The waiver permits physicians in rural areas to refer to entities with which an immediate family member of the physician has a financial relationship. The waiver does not so explicitly state, but, based on the contours of the existing exception, the waiver appears to waive the requirement that the physician first attempt to find an alternative provider of services.

Are there documentation requirements?

No. But the waiver recommends maintaining contemporaneous documentation, and reserves the right to request records. And, as noted above, the waiver does not waive set-in-advance requirements, and so parties should document that they have set compensation in advance.

Does the waiver provide any surprising examples of waiver-eligible transactions?

The examples are interesting as illustrations of the breadth of the waiver. They include:

- A hospital pays physicians above their previously contracted rate, "for furnishing professional services . . . in particularly hazardous or challenging environments."
- A hospital provides free use of medical office space on its campus to allow physicians to provide convenient care to patients who come to the hospital but do not require inpatient care.
- An entity provides free telehealth equipment to a physician practice to facilitate telehealth for patients practicing social distancing.
- A hospital "lends money to a physician practice that provides exclusive anesthesia services at the hospital, to offset lost income resulting from the cancellation of elective surgeries or covers a physician's 15% contribution for electronic health records (EHR) items and services in order to continue the physician's access to patient records and ongoing EHR technology support services." Note that this example is somewhat unclear. Does the waiver anticipate that the hospital is just footing the bill for the physician's 15% share of EHR technology, or that the hospital is loaning the physician money to cover the cost? The waiver itself says nothing about the EHR exception itself, yielding some ambiguity here.

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If you have any questions regarding the scope of these waivers, please contact any of your contacts at Ropes & Gray.