

# COVID-19: NAVIGATING THE PATH TO RECOVERY - PLANNING FOR LIFE AFTER 1135 WAIVERS & OTHER REGULATORY FLEXIBILITY ENDS (PART 2: THE STARK WAIVERS)

Date: 1 June 2020

## **U.S. Health Care and FDA Alert**

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On March 30, 2020, the Secretary (Secretary) of the Department of Health and Human Services (HHS) issued blanket waivers of Section 1877(g) of the Social Security Act (commonly known as the Stark Law) as part of HHS's broader efforts to provide short-term relief from certain regulatory requirements during by the COVID-19 pandemic (the Stark Waivers).<sup>1</sup> Acknowledging that certain regulatory requirements under the Stark Law may be particularly burdensome for providers during the COVID-19 pandemic, HHS has temporarily waived certain Stark Law requirements related to compensation and ownership arrangements between a physician and an entity that provides designated health services (DHS entity) if such arrangement meets a "COVID-19 Purpose," as defined in the Stark Waivers. "COVID-19 Purposes" include a provider's ability to provide treatment for COVID-19, expand the capacity of providers to address community needs due to COVID-19, shift care to appropriate alternative settings due to COVID-19-related concerns, and address business interruption due to COVID-19 in order to maintain availability of medical care. The Stark Waivers are time-limited, and providers will need to be prepared to appropriately transition their physician arrangements to fit within an applicable Stark Law exception without reliance on such waivers once the Stark Waivers are no longer available.

## **ABOUT THE STARK WAIVERS**

The Stark Waivers were issued by the Secretary under the authority of Section 1135 of the Social Security Act (Section 1135). The intent behind modifications and waivers under Section 1135 is to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in federal health care programs during an emergency, as well as to ensure that health care providers furnishing such items are appropriately reimbursed and exempt from certain requirements that may otherwise prevent such reimbursement (in the absence of any fraud or abuse).

In response to the COVID-19 pandemic, the Secretary authorized waivers of 18 specific requirements that would otherwise be required for compliance with an exception to the Stark Law. The Stark Waivers are structured to provide temporary flexibility for providers who may have difficulties meeting certain requirements of the exceptions during a time of emergency. For more information on the specifics of the Stark Waivers, see our Triage podcast episode on the COVID-19 Stark Waivers. Additional discussion related to the termination of all COVID-related Section 1135 waivers can be found in our recent alert.

## APRIL 2020 EXPLANATORY GUIDANCE

On April 21, 2020, the Centers for Medicare & Medicaid Services (CMS) released additional explanatory guidance related to the Stark Waivers (Explanatory Guidance) with regard to the following arrangements.<sup>2</sup> The Explanatory Guidance provides some helpful commentary regarding use of the Stark Waivers both during and after the termination of the waiver period.

### Compliance with Non-Waived Requirements of an Applicable Exception

As noted above, the Stark Waivers waive certain requirements of Stark Law exceptions for physician compensation arrangements and ownership and investment arrangements related to a COVID-19 Purpose. CMS clarifies in its Explanatory Guidance that arrangements must continue to satisfy all other non-waived requirements of the applicable exception. To illustrate, under the Personal Services Arrangement Exception at 42 C.F.R. § 411.357(d), while the requirement for a signed writing is waived under the Stark Waivers, the parties must continue to meet the other requirements, including, for example, that the services provided do not involve the counseling or promotion of a business arrangement or other activity that violates any federal or state law. Failure to maintain non-waived requirements may result in liability under the Stark Law whether during or after termination of the Stark Waivers.

### Restructuring of Existing Recruitment Arrangements With Income Guarantees

In response to provider questions, CMS clarifies that the Stark Waivers do not affect requirements under the Physician Recruitment Exception at 42 C.F.R. § 411.357(e), based on the understanding that once relocated, additional compensation would not further the intended purpose of inducing the physician to relocate to the new community. However, CMS offers that other specific waivers may be utilized to assist a recently relocated physician whose medical practice has been interrupted due to COVID-19. For example, CMS suggests that such physicians may utilize waivers related to the provision of office space at below fair market value or additional physician loans with interest rates below fair market value. Given the complexity of physician recruitment arrangements, we would recommend reviewing with legal counsel any utilization of the waivers with physicians who also have recruitment arrangements.

### Amendment of Compensation Arrangements

Under a number of the Stark Law exceptions, the terms of the arrangement must be set forth for at least one year, which has raised questions as to arrangements that will need to be amended pursuant to the Stark Waivers. As noted above, CMS clarifies in its Explanatory Guidance that so long as all non-waived requirements are met, the arrangement may be amended during the emergency period. Once the emergency period is over, the compensation terms may again be modified to return to the original terms of the arrangement or to effectuate additional necessary modifications, so long as all other requirements of an applicable exception are satisfied, the amended remuneration is determined before the amendment is implemented, the formula for the amended remuneration does not take into account volume or value of referrals or business generated, and the arrangement will remain in place for at least one year following the amendment. CMS also suggests that, depending on the individual facts and circumstances, a modification of an existing compensation arrangement could alternatively be considered a separate compensation arrangement between the same parties for the duration of the emergency period only.

### Applicability of Stark Waivers to Indirect Compensation Arrangements

As initially released, it was unclear whether the Stark Waivers were intended to cover indirect compensation arrangements. The Explanatory Guidance clarifies that the Stark Waivers do not apply to indirect compensation arrangements and that interested parties would need to seek individual waiver of sanctions related to indirect arrangements. However, CMS does note that waiver may not be necessary as a practical matter, given that all physicians with non-titular ownership or investment interests stand in the shoes of their physician organizations and any other physicians are permitted to stand in the shoes of their organization, and, as such, the remuneration directly provided between a DHS entity and a physician organization is deemed between the DHS entity and the physician “standing in the shoes” of the organization. In this regard, the individual physicians standing in the shoes of their organization may utilize the Stark Waivers.

### **Repayment Options for Loans between a DHS Entity and a Physician (or the Immediate Family Member of a Physician)**

The Stark Waivers included specific waivers addressing physician loans with interest rates below fair market value or on terms that are unavailable from a lender that is not in a position to refer. In the Explanatory Guidance, CMS addresses whether such a loan may be repaid through in-kind items or services and notes that neither of the applicable exceptions for this scenario (the Isolated Transaction Exception at 42 C.F.R. § 411.357(f) or the Fair Market Value Exception at 42 C.F.R. § 411.357(l)) require cash payment to satisfy debt to a lender, so in-kind remuneration such as provision of office space, items, or services to the lender may qualify as acceptable repayment. The aggregate value of in-kind payments must be consistent with the balance of the loan that is reduced through such in-kind payments, and the compensation arrangement must be commercially reasonable. In this regard, CMS further notes that maintenance of a medical practice in a particular community may constitute in-kind repayment of a loan, depending on the facts and circumstances of the situation.

### **Repayment of Loans, Rent Abatement, or Other Amounts Due Following the End of the Emergency Period**

Several of the specific waivers in the Stark Waivers allow repayment of loan debts, office or equipment rent, or payment for services to be provided below fair market value during the effective period of the Stark Waivers. This led many providers to question whether repayment of certain debts or other remuneration provided during the waiver period could be extended after the waiver period. CMS confirms in its Explanatory Guidance that appropriate loan repayment terms that were agreed by the parties prior to termination of the Stark Waivers may continue beyond such termination. However, with regard to continuing arrangements, CMS clarifies that any disbursement of loan proceeds or additional remuneration for office space, equipment, items, or services furnished by or to an entity or physician after the termination of the Stark Waivers must satisfy all requirements of an applicable exception. In this regard, arrangements utilizing a waiver that allows for remuneration outside of fair market value must be restructured to fit within fair market value upon expiration or termination of the Stark Waivers.

Practically speaking, providers may be left wondering how to reconcile the somewhat conflicting guidance above under which repayment of loan debts provided during the waiver period can be extended past the waiver period, but that all disbursements of loan proceeds or other remuneration must occur during the waiver period. We believe that it is reasonable to presume that CMS intended to allow for extended repayment of low-interest loans after the waiver period, but that all disbursement of the loaned remuneration would have needed to occur during

the waiver period. It is also clear that any disbursement of remuneration for personally performed services that meets the requirements for being waived under the Stark Law will need to occur during the waiver period.

## DURATION OF THE STARK WAIVERS

As noted above, the Stark Waivers were initially published on March 30, 2020, and providers seeking to utilize the Stark Waivers were given the flexibility to retroactively utilize the Stark Waivers beginning March 1, 2020.

However, the end date of the protections under the Stark Waivers is somewhat less clear. The Stark Waivers state that the waivers will “terminate as set forth in Section 1135(e),” and separately, that providers may not use the Stark Waivers after the expiration of the Secretary’s authority to grant waivers for the COVID-19 outbreak.<sup>3</sup> According to Section 1135, a waiver issued under this provision will terminate upon (a) termination of the applicable declaration of emergency or disaster, (b) termination of the applicable declaration of a public health emergency (PHE), or (c) 60 days from the date the waiver was first published, which in this case, is May 29, 2020.<sup>4</sup>

With regard to the first prong, the President declared a national emergency due to COVID-19 on March 13, 2020.<sup>5</sup> A national emergency will automatically expire after one year, unless the President renews the proclamation, or can be terminated in less than one year if the President issues a proclamation or if Congress enacts a joint resolution terminating the emergency.<sup>6</sup> As to the second prong, prior to the presidential declaration, the Secretary declared a PHE on January 31, 2020.<sup>7</sup> The Secretary’s PHE declaration is effective for the duration of the PHE or 90 days (whichever is earlier), and it may be extended by the Secretary for additional 90-day periods.<sup>8</sup> Secretary Azar has already renewed the COVID-19 PHE once and the Secretary’s current PHE declaration extends through July 25, 2020.<sup>9</sup> Notably, Section 1135 also provides some flexibility for continuation of waivers by allowing the Secretary to extend the length of the waiver by subsequent 60-day periods.<sup>10</sup>

While the timing of the termination of the Stark Waivers is not entirely clear, the Stark Waivers also state that any revisions that narrow or terminate the waivers “will be effective on a prospective basis only,” potentially supporting an interpretation that the Stark Waivers would not terminate until prospective notice is provided by HHS. While providers may have hoped to receive clarity as to the formal extension of the Stark Waivers, affected entities and physicians will need to be prepared for what to do after May 29, 2020, if the Stark Waivers are not formally extended. Based on the language of the Stark Waivers and Section 1135, we believe it is reasonable for providers to rely on the Stark Waivers for the duration of the declaration of the PHE, which as noted above, currently extends through July 25, 2020, assuming the president’s emergency declaration also remains in effect.

In any event, we would expect that the termination of Stark Waivers would be subject to a prospective notice, as specifically addressed in the publication. In light of the numerous logistical considerations required to revert waived arrangements back into Stark-compliant ones, providers would be well-advised to begin to think about the steps necessary to bring the waived arrangements back into compliance once the Stark Waivers terminate, taking into account additional guidance given in the Explanatory Guidance document.

## PLANNING FOR THE END OF THE STARK WAIVERS

Given the continuing effects of the COVID-19 outbreak across the country, it is not unreasonable to expect that the Secretary may extend the Stark Waivers until the pandemic is no longer a PHE so long as the president’s emergency declaration also remains in effect. While the Stark Waivers will not be available forever, it is not clear

how much notice providers will receive that they are ending or how much latitude there will be to wind down operations that have been conducted in reliance on these waivers. While we cannot predict when the emergency declarations on which the Stark Waivers are premised will end, providers can begin taking steps now to plan for a post-Stark Waivers transition with regard to physician financial arrangements.

As an initial matter, providers should inventory the waivers that they are relying upon for all financial relationships with physicians, including professional service arrangements, rental of office space and equipment, physician loans, and any other waived arrangement.

Providers should also assess the practical action items that will be required to unwind or transition the arrangement to an applicable Stark Law exception, including all executed documentation of such arrangement. For example, this could include:

- Reverting compensation or rental rates in physician agreements that have temporarily been amended to return the applicable rate to fair market value;
- Ensuring that any in-kind remuneration is consistent with fair market value or otherwise within a Stark Law exception;
- For any loan arrangements that rely on the Stark Waivers, ensuring that all terms for repayment agreed to by the parties during the waiver period continue to be observed after it ends, provided that any disbursement of loan proceeds or additional remuneration for office space, equipment, items, or services must meet an applicable Stark Law exception after the waiver period is over; and
- For any arrangements that are time-limited to apply only during the duration of the Stark Waivers, providers could set mechanisms that will automatically terminate such financial arrangements upon termination of the Stark Waivers.

Finally, it is important to note that while CMS did not require notification of reliance on the Stark Waivers, the guidance clearly indicates that providers should keep any documentation related to physician arrangements utilizing a waiver in a manner consistent with their standard record-keeping practices. The Stark Waivers do not prescribe any particular requirements for documentation or submission of information in order to rely on the waivers; however, they do state that providers must make records relating to use of the Stark Waivers available to the Secretary upon request, potentially indicating that audits are possible. Providers should carefully document both use of the waiver and approach for returning to compliance with an applicable Stark Law exception when the waiver period has ended.

K&L Gates LLP has created a HUB webpage to address the legal implications of the COVID-19 outbreak on businesses generally and health care providers, in particular. K&L Gates' health care and FDA practice can provide guidance to providers and suppliers on these and other matters related to the COVID-19 pandemic. Contact the authors of this article or your K&L Gates lawyer for assistance or to receive updates during the COVID-19 emergency.

## FOOTNOTES

<sup>1</sup> Secretary of Health and Human Services, Blanket Waivers of Section 1877(g) of the Social Security Act Due to



Declaration of COVID-19 Outbreak in the United States as a National Emergency, [available here](#) (last accessed May 26, 2020) [hereinafter Stark Waivers].

<sup>2</sup> Ctrs. for Medicare & Medicaid Servs., Explanatory Guidance, March 30, 2020, Blanket Waivers of Section 1877(g) of the Social Security Act, Apr. 21, 2020, [available here](#).

<sup>3</sup> Stark Waivers at 2.

<sup>4</sup> Section 1135(e)(1), Social Security Act.

<sup>5</sup> Proclamation No. 9994, 85 Fed. Reg. 15,337 (Mar. 13, 2020), [available here](#).

<sup>6</sup> 50 U.S.C. § 1622.

<sup>7</sup> Alex M. Azar, DETERMINATION THAT A PUBLIC HEALTH EMERGENCY EXISTS (2020), [available here](#).

<sup>8</sup> U.S. Dep't of Health & Human Servs., PUBLIC HEALTH EMERGENCY DECLARATION (2019), [available here](#).

<sup>9</sup> Alex M. Azar, RENEWAL OF DETERMINATION THAT A PUBLIC HEALTH EMERGENCY EXISTS (effective Apr. 26, 2020), [available here](#).

<sup>10</sup> Section 1135(e)(2), Social Security Act.

<sup>11</sup> Stark Waivers at 1.

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