

Publications

Health Care Alert: Have You Relied on the Stark Law Blanket Waivers? Now is the Time to Act.

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Health Care

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On March 30, 2020, the Secretary of the Department of Health and Human Services (the Secretary) issued 18 blanket waivers of sanctions under the physician self-referral law (Stark) due to the COVID-19 national emergency. Sanctions are waived for referrals and claims that would violate Stark due to the failure of the applicable financial relationship or referral to satisfy the specified requirements of a Stark exception. These waivers came at a time where health care providers faced impossible challenges – shortages of essential practitioners, practices struggling to remain afloat, the need to secure new, temporary service locations. Relying on these waivers, providers may have quickly implemented new arrangements or amended existing arrangements, but have they done enough to ensure their arrangements are blanketed in waiver protection? Here are some considerations to keep in mind:

Does the Arrangement Satisfy All Conditions of the Blanket Waivers?

Each blanket waiver is limited to the circumstances described in the individual waiver, and parties must satisfy all conditions of the blanket waiver in order to rely on the waiver. Our previous *Health Care Alert* with an overview of the 18 separate waivers is available [here](#) and the full details of the blanket waivers are available [here](#).

Although parties should closely evaluate their arrangements and applicable blanket waiver to ensure complete compliance with waiver terms, there are certain prerequisites that apply before parties can rely on any waiver. Initially, blanket waivers apply only to financial relationships and referrals of items and services that relate directly to COVID-19 purposes. This has been broadly defined not only to include arrangements for the potential diagnosis or medically necessary treatment of COVID-19 patients, but also to secure services of practitioners to furnish medically necessary services in response to the COVID-19 outbreak even if such services are not related to the diagnosis and treatment of COVID-19. Additionally, arrangements are for COVID-19 purposes if they are designed to ensure the availability of

health care providers to address patient and community needs or to shift care to alternative settings due to the COVID-19 outbreak. Even with this broad definition, parties may want to reevaluate their arrangements to ensure they are related to COVID-19 purposes.

Does the Arrangement Satisfy all Non-Waived Requirements of a Stark Exception?

Financial relationships or referrals must satisfy all non-waived requirements of an applicable exception in order to avoid the referral or billing prohibitions of Stark. The failure of a financial relationship or specific referral to satisfy one or more of the non-waived requirements of an applicable exception would trigger Stark's referral and billing prohibitions. Parties may be well-served to review any "waived" arrangement and evaluate its compliance with the remaining requirements of an applicable Stark exception.

Have you Amended the Remuneration Terms of an Existing Compensation Arrangement?

Parties may have utilized the blanket waivers to amend the remuneration terms of an existing compensation arrangement. Following the expiration of the emergency period, the remuneration terms of the compensation arrangement may again need to be modified to return to the original terms of the arrangement or to effectuate additional necessary modifications. Parties must bear in mind that each time the remuneration terms are amended, all requirements of an applicable exception must be satisfied, the amended remuneration must be determined before the amendment is implemented, the formula for the amended remuneration cannot take into account the volume or value referrals or other business generated by the referring physician, and the overall arrangement must remain in place for at least one year following the amendment.

Do you Have Sufficient Documentation?

Parties relying on the blanket waivers are not required to seek approval or complete any specific documentation. That said, records relating to the use of the waivers must be made available to the Secretary upon request. We strongly recommend parties maintain documentation of their use of the waivers specifying when the arrangement or use of the waiver began, how the arrangement relates to a COVID-19 purpose, which of the 18 blanket waivers the parties are relying upon, and how the arrangement satisfies both the terms of the applicable waiver and the remaining elements of a Stark exception. We also recommend that the parties implement some tracking mechanism to flag these arrangements at the end of the emergency period when the waivers will no longer apply.

If you have any questions about the application of any of the Stark blanket waivers or arrangements entered into pursuant to a waiver, please contact your Vorys attorney.

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VORYS COVID-19 TASK FORCE

Vorys attorneys and professionals are counseling our clients in the myriad issues related to the coronavirus (COVID-19) outbreak. We have also established a comprehensive Coronavirus Task Force, which includes attorneys with deep experience in the niche disciplines that we have been and expect to continue receiving questions regarding coronavirus. Learn more and see the latest updates from the task force at [vorys.com/coronavirus](https://www.vorys.com/coronavirus).