

PUBLICATION

CMS Issues Physician Self-Referral Law Blanket Waivers Under Section 1135

March 31, 2020

Updated April 23, 2020: Please see the following developments that have occurred since the original publishing of this article.

In an effort to provide additional guidance and clarity regarding the blanket waivers regarding the physician self-referral law during the COVID-19 public health emergency, CMS issued Explanatory Guidance on April 21, 2020. Additionally, the OIG issued a Policy Statement on April 3, 2020, notifying interested parties that it will exercise its enforcement discretion not to impose sanctions under the federal Anti-Kickback Statute for remuneration covered under certain of the Blanket Waivers.

Original Alert (March 31, 2020): On March 30, 2020, the Centers for Medicare & Medicaid Services (CMS) issued physician self-referral law "blanket waivers" under Section 1135 of the Social Security Act (Section 1135). The waivers are effective nationwide as of March 1, 2020. They provide broad relief from sanctions under the physician self-referral law for activities related to addressing COVID-19 purposes during the public health emergency as declared by the President and HHS Secretary Alex Azar.

What Do the Waivers Cover?

The Secretary exercised his authority under Section 1135 to issue wide-ranging waivers intended to ensure that sufficient health care items and services are available to meet the needs of individuals in the area included in the public health emergency.

Although called "blanket waivers," they do not suspend application of the physician self-referral law during the emergency time period. Rather, they waive sanctions for a variety of circumstances that would otherwise violate the self-referral law. The arrangements included in the eighteen individual waivers address financial arrangements between physicians and designated health services (DHS) entities. At this time, the waivers allow:

- Remuneration to a physician above or below fair market value (FMV) for personal services performed;
- Rental charges to either physicians or entities below FMV for office space or equipment;
- Remuneration to a physician that is below FMV for items and services purchased by an entity
- Remuneration from entities to physicians that exceeds limits under the medical staff incidental benefits and the nonmonetary compensation exceptions (*note*: the waiver does not remove the requirements that the remuneration is neither cash or a cash equivalent, nor solicited by the physician or physician practice);
- Loans from entities to physicians, or from a physician to an entity, with interest that is below FMV or on better terms than otherwise would be available;
- Temporary expansion of bed capacity for physician-owned hospitals **as permitted by state licensing requirements**;
- Conversion of a physician-owned ASC to a hospital during the period of public emergency if certain requirements are met, including Medicare enrollment as a hospital during the period of emergency, compliance with any hospital conditions of participation not otherwise waived by CMS during the

emergency, and compliance consistent with the applicable state's Emergency Preparedness or Pandemic Plan;

- Relaxation of "same building" and "centralized building" requirements under group practice rules and the in-office ancillary services exception;
- Referrals to home health agencies in which the physician or the physician's immediate family member has an ownership or investment interest;
- Referrals for patients in rural areas to an entity with which the physician's immediate family member has a financial relationship; and
- Waiver of the writing and signature requirements for compensation arrangements provided that all other non-waived requirements of an exception are met.

The waiver document also provides a non-exclusive list of examples to which the waivers would apply.

Parties utilizing the waivers need not need provide notice to CMS, nor is CMS approval required. The parties must maintain records relating to the use of the blanket waivers, which must be made available to the Secretary upon request. It is advisable to implement a process to document use of these waivers in a timely manner, including how the waiver was used to meet one of the "COVID-19 Purposes" discussed below.

Purposes

To be within the scope of the waiver, the remuneration and referral must be solely related to one of the broadly defined "COVID-19 Purposes" set forth in the waiver document:

- 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 COVID-19
- Securing the services of physicians and other health care practitioners and professionals to furnish medically necessary patient care services, **including services unrelated to the diagnosis and treatment of COVID-19**
- Ensuring the ability of health care providers to address patient and community needs due to the COVID-19 outbreak
- Expanding the capacity of health care providers or shifting care to appropriate alternative settings to address patient and community needs 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

Effective Date

The waivers are effective retroactively as of March 1, 2020. It is very important to note that these waivers will come to an end. The blanket waivers are effective only while the Secretary has authority to grant waivers for the COVID-19 public health emergency. Once the waivers end under Section 1135(e), arrangements that were permitted under a blanket waiver that do not otherwise satisfy the elements of an exception to the physician self-referral law must be unwound. It is unclear how much time providers will be given, if any, to unwind the arrangements. Thus, hospitals and physicians entering into waived arrangements should consider proactively how to handle the unwind process expeditiously when the waivers end.

The current waivers may be revised or terminated during the period of the emergency, but CMS affirmatively states that any such revisions or terminations will be prospective from the date issued. To the extent that CMS issues any additional blanket waivers, the effective date of such waivers would be identified in those waivers at the time issued.

Interaction with Anti-Kickback Statute (AKS)

Although these waivers provide broad relief to requirements under the physician self-referral law, the OIG has stated that it does not have the authority to issue similar waivers. Due to the intent element of the AKS, the analysis under AKS is different than the physician self-referral law. In a [message](#) to the industry on March 30, 2020, the OIG acknowledged that COVID-19 presents extraordinary challenges and "[f]or any conduct during this emergency that may be subject to OIG administrative enforcement, OIG will carefully consider the context and intent of the parties when assessing whether to proceed with any enforcement action." Because there are no waivers under the AKS, it would be prudent to document that a decision to use the CMS waivers for a particular arrangement is not based on the volume or value of referrals or other business generated by a particular physician.

Final Thoughts

The physician self-referral waivers issued by the Secretary and CMS address many of the issues faced by hospitals, physicians, and other health care providers trying to address the unique and challenging circumstances of COVID-19 across the country. While the waivers provide a great deal of needed flexibility, analysis of the impact of the waivers will develop over time as new challenges are confronted. Some areas that may require additional consideration in the coming weeks include: can recruitment agreements be changed if needed due to the emergency; whether waivers are needed for indirect financial arrangements; and how will hospitals and other entities ensure that they are able to unwind these arrangements effectively when the waiver authority ends.

We expect that providers may receive requests from multiple physicians for assistance and it will be critical to ensure that any decisions are made based on the consistent application of reasonable criteria that are unrelated to the volume or value of referrals.

For questions related to this alert or specific to a financial arrangement, please contact [Craig Holden](#), [Sandy Teplitzky](#) or any member of [Baker Donelson's Health Law Group](#). Also, for more information visit the [Coronavirus \(COVID-19\): What You Need to Know information page](#) on our website.