

COVID-19: Understanding the Physician Self-Referral Law 1135 Waivers



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Agenda

Purpose and duration of the physician self-referral law waivers

"COVID-19 Purposes" for which the waivers can be utilized

Scope of the 18 blanket waivers – what is included and what is not

Practical tips regarding the use of the waivers

Process for obtaining arrangement-specific waivers

Background: 1135 Waivers

- **What is the legal basis for the 1135 Waivers?**
 - *Two Required Actions Have Occurred:*
 - President declared emergency under National Emergencies Act (March 13, 2020); and
 - HHS Secretary Azar declared public health emergency (January 31, 2020)
 - Authorizes CMS to issue waivers and modifications of program requirements (e.g., conditions of participation, licensure, physician self-referral sanctions)
- CMS Blanket Waivers Physician Self-Referral Law (eff. Mar. 1, 2020)
<https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf>
- CMS Spotlight Website: <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Spotlight>

Background:

Physician Self-Referral Waivers

- 18 “Blanket” Waivers
 - Do not suspend application of Stark law
 - Rather, waive sanctions for conduct covered by waivers
 - No need to request CMS review or approval
 - Nationwide
 - Maintain records when waivers are used
- Published March 30, 2020
- Retroactive Effective Date to March 1, 2020
- Effective Until...
 - Termination of the emergency period, or 60 days from the date the waiver/modification was first published, unless extended
 - Practice pointer: Have an exit strategy in place

What are the “COVID-19 Purposes”?

For waivers to apply, the remuneration and referral must be solely related to one of the broadly defined “COVID-19 Purposes”

Diagnosis and treatment of COVID-19, regardless of whether case is confirmed

Securing services of physicians and other health care practitioners to furnish health care services, even if services are unrelated to COVID-19

Ensuring ability of health care providers to address patient/community needs during COVID-19

Expanding capacity or shifting diagnosis/treatment to alternative settings to address patient/community needs during COVID-19

Addressing medical practice or business interruption during COVID-19 in order to maintain availability of medical care in community

The “Blanket” Waivers

- Above or Below FMV remuneration *from* an entity to physician (or immediate family member) for **personal services performed** (*CMS Waiver #1*)
- Below FMV **leases for equipment or office space** (*CMS Waivers # 2, 3, 5, 6*)
 - Applies whether *either* physician or entity is lessee
- Remuneration from an entity to a physician (or immediate family member) that is Below FMV **for items and services purchased by the entity** from the physician (or immediate family member) (*CMS Waiver # 4*)

The “Blanket” Waivers (continued)

- Payment of Below FMV remuneration by a physician to a DHS entity for **use of entity’s premises or for items or services purchased by the physician** from the entity (*CMS Waiver # 7*)
 - Timeshare arrangements
- Remuneration that exceeds limits under the **medical staff incidental benefits** and the **nonmonetary compensation** exceptions (*CMS Waivers # 8 & 9*)
 - Still cannot be cash or a cash equivalent
 - Tracking remuneration?

The “Blanket” Waivers (continued)

- **Loans** with interest Below FMV or on better terms than otherwise would be available (*CMS Waivers # 10-11*)
 - Applies to loans from entities to physicians, and vice versa (e.g., physician-owned hospitals)
 - What happens after waivers expire?

The “Blanket” Waivers (continued)

- Temporary expansion of bed capacity for **physician-owned hospitals** as permitted by state licensing requirements (*CMS Waiver #12*)
- **Conversion of a physician-owned ASC** to a hospital during the period of public emergency if certain requirements are met (*CMS Waiver #13*)
 - Medicare enrollment as a hospital
 - Compliance with any non-waived hospital conditions of participation
 - Consistent with the applicable state's Emergency Preparedness or Pandemic Plan

The “Blanket” Waivers (continued)

- Referrals to **home health agency** owned by physician (or immediate family member) (*CMS Waiver # 14*)
- Relaxation of "same building" and "centralized building" requirements under **group practice rules** and the **in-office ancillary services exception** (*CMS Waiver # 15*)
- Referrals by a physician in a group practice for DHS furnished by group to a patient at home, or in assisted or independent living facility (*CMS Waiver # 16*)
- Referrals of patients in **rural areas** to an entity owned by physician's immediate family member (*CMS Waiver # 17*)

The “Blanket” Waivers (continued)

- Waiver of the **writing and signature requirements** for compensation arrangements provided all other non-waived requirements of an exception are met (*CMS Waiver # 18*)

What Is Not Covered?

Physician
recruitment

Indirect
compensation

Set in
advance?

Practice Pointers

- One-year term requirement for compensation arrangements?
- Rent abatement
- Salary guarantees
- Hotel rooms, groceries and child care for physicians
- Any narrowing or termination of waivers by CMS will be prospective only
- Additional waivers possible, will be effective as of date included in those waivers

Checklist for Use of “Blanket” Waivers

- ❑ Must be “solely” related to a “COVID-19 Purpose”

- ❑ Maintain documentation of use of waivers
 - Must be made available to HHS/CMS upon request

- ❑ Application of waiver to financial relationships
 - Waiver applies only to requirements “waived” by CMS
 - Must comply with all “non-waived” elements of a Stark exception

- ❑ Proactively prepare for termination of waivers

Requesting Individual Waiver?

Providers can request a waiver for conduct not expressly covered by the “blanket” waivers

Requests are handled by CMS Central Office in Baltimore (1877CallCenter@cms.hhs.gov)

Must provide basis why waiver is needed for COVID-19 purposes and is not otherwise covered by existing blanket waivers

OIG Guidance

- ***OIG Policy Statement (April 3, 2020)*** OIG will exercise enforcement discretion to not impose administrative sanctions under federal AKS for remuneration covered by “blanket” Stark law waivers
 - Avoid need for parties to undertake separate review of AKS
 - Must comply with all “conditions and definitions” from Stark waiver document
 - Expressly applies to waivers covered by Section II.B(1)-(11) of CMS document (process for submitting questions related to waivers (12)-(17))
 - Applies to conduct on or after April 3, 2020
 - Terminates as of same date as Stark “blanket” waivers unless OIG reconsiders, modifies or terminates the policy earlier

<https://oig.hhs.gov/coronavirus/OIG-Policy-Statement-4.3.20.pdf>

Questions?



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