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Challenges of maintaining compliant provider arrangements during and after a public health emergency

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The COVID-19 pandemic has required many healthcare providers to enter quickly into new or modified arrangements for the delivery of essential healthcare goods and services. Some of these arrangements may conflict with the Stark Law (Section 1877 of the Social Security Act) and its regulations and may expose providers to administrative sanctions by the Office of Inspector General (OIG) pursuant to the federal Anti-Kickback Statute (AKS). In response to the unique circumstances of the pandemic, the secretary of the Department of Health & Human Services (HHS) and the OIG published temporary waivers^[1] and a policy statement^[2] to provide compliance assistance during the COVID-19 pandemic. The blanket waivers and OIG policy statement will be in effect temporarily, until the end of the federal public health emergency declared in response to the COVID-19 pandemic (the emergency period).^[3] This article provides general guidance on the relationship between the blanket waivers granted by HHS, the policy statement published by the OIG, and the return to full compliance upon the conclusion of the emergency period.

Compliance during the pandemic

Arrangements entered during the emergency period that do not meet an exception to the Stark Law but satisfy all of the conditions of one of the blanket waivers to the Stark Law issued by the HHS secretary will not be subject to sanctions for such noncompliance. Compliance officers should ensure their organizations know that the waivers are available and understand the requirements that must be satisfied if the organization elects to take advantage of a blanket waiver. The organization, through counsel and its compliance officer, would be well advised to ensure that the temporary arrangement will expire and that a mechanism is in place to resume full compliance upon expiration.

Satisfy the blanket waiver requirements

If a provider intends to enter into a temporary arrangement that does not comply with the Stark Law during the emergency period, the compliance officer should determine whether a specific blanket waiver is applicable and ensure conformance of the arrangement to the waiver's specific criteria.

The blanket waivers address both remuneration and referral arrangements that are related to the emergency period. However, only those waivers addressing remuneration will be discussed here. These waivers are retroactive to March 1, 2020, and are effective through the end of the emergency period. Generally, to meet the criteria to be eligible for a blanket waiver, the remuneration must be:

- Furnished in good faith;
- Absent of fraud or abuse;

- Solely related to “COVID-19 Purposes,” as defined in the blanket waivers;
- Carefully documented, as records must be made available to the HHS secretary upon request;
- An arrangement directly between an entity that furnishes designated health services (as defined in the Stark regulations) and (i) a physician or the physician organization in whose shoes the physician stands (as defined in the Stark regulations) or (ii) the physician’s immediate family member (physician’s family); and
- Related to one of the following:
 - Personally performed services: Remuneration from an entity to a physician or the physician’s family for services personally performed by the physician or the physician’s family that are *above or below* fair market value.
 - Lease of office space: Remuneration between an entity and a physician or the physician’s family for the lease of space that is *below* fair market value.
 - Lease of equipment: Remuneration between an entity and a physician or the physician’s family for the lease of equipment that is *below* fair market value.
 - Items or services: Remuneration between an entity and a physician or the physician’s family for purchased items or services that are *below* fair market value.
 - Use of premises: Remuneration from a physician or the physician’s family to an entity for the use of the entity’s premises that are *below* fair market value.
 - Loans to a physician: Remuneration from an entity to a physician or the physician’s family resulting from a loan to the physician or the physician’s family (1) with an interest rate *below* fair market value or (2) on terms that are unavailable from a lender that is not a recipient of the physician’s referrals or business generated by the physician.
 - Loans to an entity: Remuneration from a physician or the physician’s family resulting from a loan to the entity (1) with an interest rate *below* fair market value or (2) on terms that are unavailable from a lender that is not in a position to generate business for the physician or the physician’s family.
 - Medical staff incidental benefits:^[4] Remuneration from a hospital to a physician, in the form of medical staff incidental benefits, in an amount that exceeds the limits set forth in 42 C.F.R. § 411.357(m)(5) , which is less than \$36 for each occurrence of the benefit in calendar year 2020.^[5]
 - Nonmonetary compensation: Remuneration from an entity to a physician, or the physician’s family, in the form of nonmonetary compensation that exceeds the limit set forth in 42 C.F.R. § 411.357(k)(1) , which is an aggregate amount of \$423 for calendar year 2020.

Adhere to the federal AKS OIG policy statement

In addition to the blanket waivers issued by the HHS, OIG issued a complementary policy statement that indicates that it will not impose administrative sanctions related to the federal AKS for remuneration arising from a COVID-19–related arrangement that satisfies all of the criteria of one of the blanket waivers.^[6] The policy statement does not extend to arrangements implicated by the federal AKS but not addressed by the above blanket waivers. The policy statement only applies to arrangements that may otherwise violate the Stark Law, so a

physician must be a party to an arrangement before the OIG's statement will apply.

The policy statement regarding administrative sanctions will apply to conduct occurring in conformance with the blanket waivers on or after April 3, 2020, and shall be valid through the end of the emergency declaration.

Post-pandemic compliance

The blanket waivers are only applicable during the emergency period. Therefore, compliance officers should plan for post-pandemic compliance at the time of entering into the arrangement covered by a blanket waiver.

Adhere to current policies and procedures

Even if a waiver applies, an arrangement is still required to satisfy all nonwaived requirements of an applicable Stark Law exception in order to avoid the referral and billing prohibitions.^[7] It is therefore important for compliance officers to continue to follow policies and procedures for reviewing arrangements and discussing the compliance of arrangements with counsel. For example, under the blanket waivers, it is permissible for the remuneration between an entity and a physician for the lease of space to be below fair market value.^[8] A compliance officer's analysis of such an arrangement should continue to include all of the nonwaived requirements of the "Rental of office space" exception, including that the arrangement otherwise be "commercially reasonable."^[9]

Know when to terminate or amend agreements

Agreements entered into during the emergency period that are noncompliant with the Stark Law will not be compliant as soon as the public health emergency declaration has ended. Agreements entered into during the emergency period should include provisions to revert to Stark Law compliance upon the expiration of the emergency period. An agreement entered into during the pandemic, under a blanket waiver, may be modified at the termination of the emergency period to bring it into compliance.^[10] Revisions to compensation arrangements are permitted within the agreement's original term provided the parties ensure the following:

- "All requirements of an applicable exception are satisfied,"^[11]
- "the amended remuneration is determined before the amendment is implemented,"
- "the formula for the amended remuneration does not take into account the volume or value [of] referrals or other business generated by the referring physician, and"
- "the overall arrangement remains in place for at least 1 year following the [modification or] amendment."^[12]

An amendment to an existing agreement may not be necessary if the parties enter into a new arrangement during the emergency period that is separate from any existing agreement between the parties. For example, a hospital may have leased space to a physician prior to the pandemic. A hospital may require personal services of the physician during the crisis. It could temporarily enter into a separate personal service arrangement. At the end of the emergency period, the separate agreement would be terminated without requiring any amendment to the terms of the existing lease. However, if the parties elect to defer or reduce the rental payment during the emergency period, the lease agreement would require amendment to memorialize the modification and link it to a COVID-19 purpose during the emergency period.

Document compliance with the blanket waivers

Each arrangement covered by a blanket waiver must be properly documented to support that the waiver requirements have been satisfied.^[13] Such documentation must be provided upon request of the HHS secretary. Detailed documentation will assist the organization in defending against future inquiries. Compliance officers should develop policies and procedures for maintaining records of arrangements covered by the blanket waivers. It will be especially important for compliance officers to maintain documentation to support how the remuneration of each arrangement was solely related to “COVID-19 Purposes,” as required and defined by the blanket waivers.

Counting on compliance

Compliance officers have an obligation to support their organizations to comply with regulatory requirements. During the emergency period, organizations may be required to respond to evolving events rapidly as the organization makes arrangements to address shortages in resources or personnel. Compliance officers will play a major role in tracking changes in regulatory guidance, educating leadership, and ensuring that policies and procedures are modified to ensure compliance with the blanket waivers, to understand when they are applicable, and to ensure preparation of the documentation required to substantiate compliance. Compliance officers should anticipate the resumption of compliance with applicable laws and regulations at the conclusion of the emergency period.

Note: This article is intended for educational purposes and should not be construed as legal advice or legal opinion. Readers should not act upon the information contained in this article without seeking the advice of legal counsel.

Takeaways

- Standard policies and procedures should be followed to ensure each arrangement satisfies all nonwaived requirements of an applicable Stark Law exception.
- Arrangements that are noncompliant with the Stark Law must be evaluated to determine whether a blanket waiver applies.
- Arrangements implemented pursuant to a blanket waiver should contemplate the expiration of the emergency period at the time the parties execute the arrangement.
- Arrangements implemented pursuant to a blanket waiver should also contemplate the resumption of full compliance by modification or termination in accordance with its terms.
- Once the emergency period ends, all remuneration arrangements must comply with all of the criteria of the applicable Stark Law exceptions.

¹ Centers for Medicare & Medicaid 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,” March 1, 2020, <https://go.cms.gov/2JuPI8a>.

² HHS OIG, “OIG Policy Statement Regarding Application of Certain Administrative Enforcement Authorities Due to Declaration of Coronavirus Disease 2019 (COVID-19) Outbreak in the United States as a National Emergency,” April 3, 2020, <https://bit.ly/2SjBWu8>.

³ Centers for Medicare & Medicaid Services, “Blanket Waivers of Section 1877(g).”

⁴ “CPI-U Updates,” Centers for Medicare & Medicaid Services, last modified December 20, 2019,

<https://go.cms.gov/3jzUv8U>.

5 Centers for Medicare & Medicaid Services, “Blanket Waivers of Section 1877(g).”

6 HHS OIG, “OIG Policy Statement.”

7 Centers for Medicare & Medicaid Services, “Explanatory Guidance: March 30, 2020 Blanket Waivers of Section 1877(g) of the Social Security Act,” April 21, 2020, <https://go.cms.gov/3f2W0KS>.

8 Centers for Medicare & Medicaid Services, “Blanket Waivers of Section 1877(g).”

9 42 C.F.R. § 411.357(a) .

10 Centers for Medicare & Medicaid Services, “Explanatory Guidance.”

11 Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Payments for Graduate Medical Education in Certain Emergency Situations; Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules; Updates to the Long-Term Care Prospective Payment System; Updates to Certain IPPS-Excluded Hospitals; and Collection of Information Regarding Financial Relationships Between Hospitals, 73 Fed. Reg. 48,434, 48,697 (August 19, 2008) .

12 Centers for Medicare & Medicaid Services, “Explanatory Guidance.”

13 Centers for Medicare & Medicaid Services, “Blanket Waivers of Section 1877(g).”

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