

Happiness is a Warm Blanket: The Stark Law COVID-19 Blanket Waivers

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Agenda

- Overview
- COVID-19 Purposes
- Term, Termination, and Record Keeping
- Specific Waivers
- Examples
- What's Not Covered?
- Employment Issues
- Questions

The Blanket Stark Law Waivers

- CMS has the authority to issue 1135 waivers for the Stark Law during periods of national emergency
- President Trump's emergency declaration triggered the agency's waiver authority
- Historically CMS has only issued Stark Law waivers on a case-by-case basis
- Blanket Stark Law waivers issued March 30 are unprecedented

How big is your blanket?

- Blanket Stark Law waivers issued March 30
 - Retroactive to March 1, 2020
- National in scope
- Cover remuneration “solely related to COVID-19 Purposes” between DHS entity and physician/immediate family member
- Remain in effect during the period of the COVID-19 national emergency
 - Then they take your blanket away

How big is your blanket?

- 18 separate waivers issued
- All conditions of the waiver must be satisfied
- Waivers automatic: no applications necessary
- Records relating to provider's use of waivers must be furnished to the Secretary upon request
- Will not apply if there is a determination of fraud or abuse

COVID-19 Purposes

Blanket waivers apply only to financial relationships and referrals “that are related to the national emergency that is the COVID-19 outbreak in the United States”

“COVID-19 Purpose” defined as:

- Diagnosis or medically necessary treatment of COVID-19 for any individual, whether or not the individual is diagnosed with a confirmed case of COVID-19 (NARROWEST)
- Securing services of physicians and other healthcare professionals to furnish medically necessary services in response to the COVID-19 outbreak
- Ensuring the ability of healthcare providers to address patient and community needs due to the COVID-19 outbreak

COVID-19 Purposes, cont.

- Expanding the capacity of healthcare providers to address patient and community needs due to the COVID-19 outbreak
- Shifting the diagnosis and care of patients to appropriate alternative settings due to the COVID-19 outbreak
- Addressing medical practice or business interruption due to the COVID-19 outbreak to maintain the availability of medical care and related services for patients and the community (BROADEST)

Term, Termination, and Record Keeping

- Blanket waivers are expected to end when the public health emergency ends
- CMS may narrow or terminate the waivers earlier but will always do so prospectively
- Argument that agreements do not have to be terminated as long as the aspect of the arrangement that relies on the waiver ends (i.e., above/below FMV compensation)
- Tip: include precise change in law provision for flexibility

Question:

Do you agree that all arrangements and amendments that rely on Stark Law blanket waivers must end on or before the precise date when the waivers expire?

Agree

Disagree

Term, Termination, and Record Keeping

- Must maintain records to provide to Secretary upon request
- Important to document COVID-19 Purposes contemporaneously
- Best practice to establish a process for keeping track of waived arrangements
 - Suggest designating a point person to handle all physician arrangement requests during this period
 - Ensures consistent assessment and documentation of COVID-19 Purposes
 - Will help the organization address waived arrangements when the blanket gets pulled

Specific Waivers:

Employment and Personal Services

- Waiver permits payments by an entity to a physician that is above or below FMV for services personally performed by the physician
 - e.g., hazard pay; restructuring procedure-based compensation methodologies
- Warning! TEO issues should be considered with below FMV charges
- Anti-Kickback Statute risk should also be considered
 - However, on April 3, 2020 the OIG issued a Policy Statement indicating that it will not impose administrative sanctions under the AKS for the vast majority of arrangements that fit within the blanket Stark Law waivers

Employment Law Aside

- **Remember:** An employment agreement or personal services agreement with a physician is still a contract
- The blanket Stark Law waivers do not waive contract rights or other legal obligations surrounding employment or services agreements
- More later . . .

Specific Waivers:

Office Space and Equipment Rentals

- Rental charges paid to a physician for lease of space/equipment may be below FMV
 - Example: hospital uses MOB space occupied by independent physician for surge capacity of COVID-19 patients
 - Example: hospital uses off-campus office space of an independent physician for non-COVID-19 patients
- Rental charges paid by a physician for lease of space/equipment may be below FMV
 - Example: hospital allows independent physicians to use office space located on hospital campus to assess potential COVID-19 patients
 - Example: hospital reduces or abates rent during public health emergency
 - Tip: try to determine long-term plan for these arrangements at the time you invoke the waiver
- Warning! TEO issues should be considered with below FMV charges

Specific Waivers:

Purchased Items or Services

- Waiver allows below FMV payments for items and services purchased by the entity from the physician
- Waiver also permits below FMV for items or services purchased by a physician from the entity
- Consider before pursuing a waiver:
 - FMV may be affected by COVID-19 crisis – so is the blanket waiver actually needed?
 - TEO issues and state law issues
 - AKS risk

Specific Waivers:

Loans

- Blanket waiver permits loans to a physician or physician group
 - At an interest rate that is below fair market value
 - On terms that are unavailable from a disinterested lender
- Example: Hospital loans money to the anesthesia group with which it has an exclusive contract to cover the physicians' lost income due to the cancellation of elective surgeries to ensure Hospital has anesthesia services needed for COVID-19 patients

Specific Waivers:

Loans, cont.

- Blanket waiver also permit loans from a physician to DHS entity
- Example: physician owner of a hospital can loan money to hospital to cover staffing expenses during COVID-19 surge
- Question: if a hospital makes a below FMV loan to physician group during blanket waiver period, what should it do when the waivers end?
 - Must the loan documents demand immediate repayment when national emergency ends?
 - What if the interest rate adjusts to FMV rate at that point?
- TEO issues should be considered when a non-profit DHS entity is making a non-FMV loan

Specific Waivers:

Type of Facility

- Physician-owned hospitals: may expand number of rooms and beds
- Physician owners of an ASC that temporarily converts to a hospital through streamlined enrollment and certification process after March 1 may still refer if conversion is consistent with the state's Emergency Preparedness or Pandemic Plan
 - Also possible for a freestanding ED to enroll as an ASC and then convert
- **Warning!** Only temporary – after crisis is over waiver ends . . .

Specific Waivers: Group Practice

Blanket Waiver adds flexibility to group practice location requirement:

- The in office ancillary services exception can still be used to protect referrals by a physician in a group practice for medically necessary DHS:
 - In a location that does not qualify as a “same building” or “centralized building” (mobile van, trailer, e.g.); or
 - To a patient in his or her private home, an assisted living facility, or independent living facility so long as the referring physician’s principal medical practice does not consist of treating patients in their private home
 - Means a physician can order radiology services for self-isolating Medicare beneficiary

Specific Waivers: Comp. to Physicians

- Medical Staff Incidental Benefit Exception
 - \$36 cap per item/service waived
 - DHS entities could provide to members of Medical Staff meals, childcare, change of clothes, etc.
- Non Monetary Compensation Exception
 - \$423 annual per physician limit waived
 - Allows DHS entity to fund
 - CME for COVID-19 training
 - PPE, supplies, etc.
 - Isolation related needs (housing, meals, childcare, transportation)
 - Provision of support personnel to physician offices to assist with COVID-19 staff training, facilitate patient screening in physician offices

Specific Waivers: Writing Requirements

- CMS permits arrangements to commence prior to satisfaction of writing and signature requirements, so long as all other requirements of applicable exception are satisfied
 - Examples: Call coverage starts prior to signing agreement for same; delivery of supplies prior to execution of purchase agreement
- Providers using a Blanket Waiver must make available to CMS, upon request, records relating to the use of the blanket waivers
 - No specific documentation is required
 - No requirement for advance notice to Secretary
- Important to document the COVID-19 purpose and other information that supports the proper purpose and scope of the arrangement

What Stark Issues Are Not Waived?

- Indirect arrangements
- Set in advance
- Commercial reasonableness
- Volume or value
- Per click compensation for rental arrangements
- Physician recruitment arrangements

Practical Implications

- If set in advance requirement of Personal Services Arrangement exception and Fair Market Value arrangement exception not waived, can a Hospital amend a services contract to pay physicians more for call coverage during COVID-19 crisis if compensation terms in existing agreement have not been in place for a year?
 - Could suspend or terminate existing contact and enter into a new arrangement
 - Probably can amend prospectively citing change in circumstances and services
- If hospital uses volume-based criteria to determine which physicians it will provide financial accommodations the agreements may not fit within the waivers because they are based on the volume of the physicians' referrals
 - Note AKS risks as well

Examples: YES

- Hospital agrees to pay some employed physicians based on their 2019 production because of the cancellation of elective procedures
 - But are there limits? Should Hospital ask for accommodation?
- Hospital sends personnel to community physicians' offices to assist with COVID-19 screening
- Hospital provides isolation related needs (such as temporary lodging, childcare, meals) for emergency physicians who do not want to return to their families after shifts

Examples: NO

- Indirect arrangements are not covered
 - Arrangements with ACOs, CINs, etc.
 - BUT consider definition of “indirect” – volume or value comp
- Per-click rental charges still prohibited
- No changes to physician recruitment exception
- Set in advance requirement and volume or value standards still in effect
- Commercial reasonableness not waived, but COVID-19 Purposes relevant?

Individual Waivers

- DHS entities can apply for individual 1135 waivers for unique situations
- Send request to 1877CallCenter@cms.hhs.gov and include the words “Request for 1877(g) Waiver” in the subject line
- Outline specific scenario that doesn’t meet exception for which waiver is necessary
- Tip: include COVID-19 Purpose in request
- Responses take up to 1 week; CMS aiming for quicker whenever possible
- Retro to March 1 if granted

Beyond Stark

- The Federal Anti-kickback Statute
 - But see: April 3, 2020 OIG Policy Statement indicating that agency will not impose administrative sanctions under the AKS for the vast majority of arrangements that fit within the blanket Stark Law waivers
- Tax Exempt Issues
 - Private inurement (insiders involved)
 - Private benefit
 - Bond Financing Restrictions
- State Law restrictions
 - Kickback, Stark, Anti-rebate
- Governmental Entities
 - Prohibitions on the gift of public funds

State Law Issues

- Not waived by CMS: application of state “mini Stark” laws and other state-level fraud and abuse laws
 - State-level waivers may exist or are being sought
 - Consider practical enforcement risk
- Not waived by CMS: state licensing laws (e.g., facility licensing requirements, practitioner licensing requirements such as those affecting telemedicine)

Collateral Considerations

- Whether the blanket Stark Law waiver is needed may be affected by the actions of state and local officials
 - Executive Orders
 - State law moratoria
 - Local emergency measures
- Example: if the Governor issues an executive order requiring rent abatement during the COVID-19 emergency, a formal lease amendment may not be necessary

Too many blankets?

- The blanket Stark Law waivers will allow DHS entities flexibility to adjust financial arrangements with physicians and physician groups during the COVID-19 pandemic
- The breadth of the waivers both is a blessing and a curse
- Financial considerations may prevent DHS entities from offering all of the financial assistance/relief requested
- When deciding which requests to accommodate and which to deny
 - Adopt consistent, defensible decision-making criteria
 - Avoid considerations related to the volume or value of the physicians' referrals
 - AKS risks

Employment Law Considerations

- Blanket waiver of Stark requirements does not waive existing contractual obligations
- Contract may need to be amended, renegotiated, or terminated to change compensation structure or duties

Employment Law: Contract Terms

- Key contract provisions:
 - Termination/amendment provisions
 - Notification obligations
 - Specific time commitment by provider or specific location
 - Productivity pay
 - Change in funding
 - Force majeure clause

Employment Law: Strategies

- Other legal strategies
 - Frustration of purpose: Contractual obligations can be excused where the purpose of the contract has been undermined (by unforeseen events)
 - Impossibility: Contractual obligations may be excused where they become impracticable (due to unforeseen difficulty or expense)

Beyond the Contract . . .

- Waiver does not waive other employment-related requirements
 - Paid time off requirements
 - Safe worksite
 - Discrimination/retaliation concerns
 - Obligations to union
 - Document business decisions related to changes

Thank you



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