

# Navigating Stark During COVID-19

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# Agenda

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- Introduction and Welcome
- Overview of the 1135 Stark Law Waivers
- What the Waivers Don't Address
- Practical Tips and Legal Considerations
- Fair Market Value and Related Considerations
- Examples of Waiver Application
- Questions

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# Overview of the 1135 Stark Law Waivers

# Background

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- January 31, 2020 declaration of public health emergency by HHS Secretary
- March 13, 2020 declaration of national emergency by President
- Actions permitted HHS to issue Section 1135 nationwide waivers
- **Goal of Stark Law Blanket Waivers, issued March 30:**
  - Ensure sufficient availability of health care items and services
  - Ensure providers furnishing items/services in good faith, but unable to comply with certain Stark Law requirements as a result of consequences of the COVID-19 pandemic, may be reimbursed and exempted from sanctions

# Overview of Stark Blanket Waivers

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## Timeline

- Can be relied on retroactively to March 1
- Until end of declared emergency or 60 days from waiver publication

## Applicability

- Direct financial relationships with physicians (or immediate family members) where remuneration is solely related to a “**COVID-19 Purpose**”
- Absent government determination of fraud or abuse
- Must comply with all elements of applicable Stark exception that are not waived

## Waivers

- 18 nationwide blanket waivers
- CMS provides multiple examples of scenarios to which a waiver could apply
- Providers could also seek individual waivers

## Other

- Must make available to CMS, on request, records relating to use of the waivers
- OIG Policy Statement (April 3) – enforcement discretion not to impose sanctions under AKS for remuneration covered by the first 11 of the 18 Stark Blanket

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

# COVID-19 Purposes

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- Diagnosis or medically necessary treatment of COVID-19, regardless of whether a case is confirmed
- Furnish medically necessary services in response to the COVID-19 outbreak

Other purposes due to the COVID-19 outbreak:

- Ensuring the ability, or expanding the capacity, of health care providers to address patient and community needs
- Shifting diagnosis and care to appropriate alternative settings
- Addressing medical practice or business interruption to maintain the availability of medical care and related services for patients and the community

# Overview of 18 Specific Waivers

<b>FMV Requirement</b>	<ul style="list-style-type: none"><li>• Payment for services personally performed by physician, above or below FMV (#1)</li><li>• Payment by DHS entity or physician for space or equipment rental, below FMV (#2, 3, 5, 6)</li><li>• Payment by DHS entity to physician for purchased items/services, below FMV (#4)</li><li>• Payment by physician to DHS entity for purchased items/services or use of entity's premises, below FMV (#7)</li><li>• Loan to DHS entity or physician with terms unavailable from bank/commercial lender or interest rate below FMV (#10, 11)</li></ul>
<b>Non-Monetary, Incidental Benefits</b>	<ul style="list-style-type: none"><li>• Provision of medical staff incidental benefits by hospital to physician that exceed current dollar limits (#8)</li><li>• Provision to physician of non-monetary compensation by DHS entity to physician that exceeds current dollar limits (#9)</li></ul>
<b>Group Practices/ IOAS exception</b>	<ul style="list-style-type: none"><li>• Referral for DHS furnished in location that doesn't qualify as the "same building" or "centralized building" (#15)</li><li>• Referral for DHS furnished to patient in their home, assisted living facility, or independent living facility (#16)</li></ul>

# Overview of 18 Specific Waivers

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## Physician-Owned Hospitals, ASCs, HHAs, etc.

- Referrals by physician-owners to hospitals that expand facility capacity (#12)
- Referrals by physician-owners to ASCs that convert to hospital space (#13)
- Referrals to physician-owned HHAs that do not qualify as rural providers (#14)
- Referrals to an entity with which the physician's immediate family member has a financial relationship, if the patient who is referred is in a rural area (#17)

## Writing/Signature Requirements

- Referrals to DHS entity where compensation arrangement does not satisfy applicable writing or signature requirements (#18)
- Can be used in combination with other waivers



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# What the Waivers Don't Address

# What's Not Covered by the Waiver?



Set in Advance  
Requirements – They  
Have Not Been Waived



Indirect Compensation  
Arrangements – Not  
Addressed



Issues related to one  
year terms – Not  
Waived



Retroactive changes in  
compensation -- Not  
Permitted By Waiver

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# Practical Tips and Legal Considerations

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1. Look for existing exceptions first
  - Use the Waiver Only When Needed
  - Remember: Hindsight is 20-20
2. Tracking Waiver Use/Documentation
  - Concurrent Documentation
  - Best Practices
3. Planning for the end of the waivers
  - Short Trigger v. “Automatic” Termination
  - Other Arrangements (e.g., loans)?
4. Interplay With Anti-Kickback Statute

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# Fair Market Value and Related Considerations

# Fair Market Value Considerations

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1. When commonly accepted valuation approaches and data sources are available, attempt to stay within FMV.
2. Commonly accepted valuation approaches may not be applicable. For example, can there be “fair market value” when paying no rent?
3. Even if you are relying on a waiver, it remains important to document why an exception is being made and the quantitative basis for the financial terms.
4. Waivers allow for flexibility on hazard pay, extra shifts, “locums” services, and more. However, consider establishing internal data-driven guidelines.
5. Valuation allows for normalization of data. Current events will have minimal impact on the value of services going forward.



# Commercial Reasonableness (CR) Considerations

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1. Waivers do not extend to CR.
2. Consider that attrition is likely not the same concern as it was before the PHE. Historical concerns around managing physician compensation to avoid attrition appear to be less pronounced than near term financial sustainability.
3. Consider applying support consistently based on what each doctor is doing (or not doing) during the PHE, and not on what they previously did or will do.
4. Avoid the tendency to favor the highest producing physicians. From a CR standpoint, modifications should not disproportionately benefit the highest producing and most highly paid physicians.
5. Example: Consider whether indexing pay based solely on historical production might be problematic both for reasons of CR and financial feasibility.

# Suggested Framework for Evaluating Modifications

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1. Establish priorities for financial support.
2. Be aware of what flexibility does or doesn't exist in your contracts. Identify the rights and obligations under the subject arrangement, and be cognizant of how the temporary arrangement will impact future payments when the situation normalizes.
3. First priority: Physician services for current patient care.
4. Second priority: Financial support for physicians whose workload has been reduced in programs necessary for licensure/certification or in services that would not otherwise be available to area patients.
5. Third priority: Individual requests to alleviate financial hardship.



# Implementation Strategies

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1. Develop communication materials to ensure consistent messaging and manage expectations.
2. Whenever possible, documentation and analysis should be related to a category of service, and not on a case-by-case basis.
3. Requests for modifications should require the use of a standard form or packet. Packets will help ensure that the relevant questions are asked and answered. Describe recommendation, rationale, and basis for approval.
4. Consider a separate packet for different categories of priorities.
5. Create a template amendment to accelerate and standardize modifications.

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# Examples of Waiver Application

# Rate Abatement, Reduction or Deferral

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- Example: financially distressed physician practice/tenant, which leases medical office space from hospital/landlord, is seeking financial relief
  - Deferral, Reduction, or Abatement?

# Loans to Physicians

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- Ambiguity in the waivers themselves?
- What do you do after the waivers?
- Alternatives?



# Payment for COVID-19 Response Services

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## Consider Engaging Physicians to Provide:

- Covid-19 Administrative Services,
- Triage Services in response to Surges
- Staying home when advised,
- Telehealth services
- Remaining in community and reporting back post-emergency

## New Agreement or Amendment?

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Questions?

# Contact

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