AMA AMERICAN MEDICAL ASSOCIATION

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Federal Stark Law waivers during COVID-19

A strategic guide for physician practices

The American Medical Association presents this high-level overview in order to introduce physician practices and other stakeholders to the temporary blanket waivers of sanctions under the federal physician self-referral law, commonly referred to as the "Stark Law," that have been issued by the federal government and apply during the COVID-19 federal public health emergency (PHE) declarations ("Temporary Stark Law Blanket Waivers").[1] Although many states have statutes similar to the federal Stark Law and the federal Anti-Kickback Statute (AKS), this resource does not address those laws. The intended audience for this guide is physicians and practice managers. If, upon reviewing this information, a reader wishes to pursue any of the opportunities and/or options described herein, the AMA strongly recommends consultation with health care counsel experienced in the federal Stark Law and the AKS, as well as the applicable state's fraud and abuse laws, prior to taking any actions in reliance on the Temporary Stark Law Blanket Waivers and AKS flexibilities discussed in this guide.

The U.S. Centers for Medicare & Medicaid Services (CMS) and the U.S. Department of Health and Human Services (DHHS) Office of the Inspector General (OIG) published final rules designed to update the Stark Law and AKS on Dec. 2, 2020. These new rules do not have a direct impact on the Blanket Waivers. However, the combination of the Blanket Waivers and the new rules creates an opportunity for physicians to have a head start in benefiting from the new Stark and AKS rules. Physicians may be able to build relationships and infrastructure under the protection of the Blanket Waivers, and then leverage that foundation to create arrangements that may meet the requirements under the new Stark and AKS rules. The AMA cannot overemphasize that the waivers described herein are **temporary** and that physicians and/or practices should anticipate needing to unwind arrangements, that are only permissible because of the waivers, when the PHE ends.

The Stark Law and the AKS have long precluded physician practices from engaging in certain payment and care delivery models with other health care entities. As the COVID-19 pandemic required ever-more innovative relationships among providers and other health care entities to meet patient needs, however, federal regulators recognized the need to provide flexibility in the application of the Stark Law and issued the Temporary Stark Law Blanket Waivers that will continue in effect throughout the remainder of the U.S. Department of Health and Human Services (DHHS) declared PHE. The AMA has prepared a high-level overview of the Temporary Stark Law Blanket Waivers During COVID-19; however, this guide provides a comprehensive set of tools to assist in better understanding these laws and how recently announced flexibilities may be helpful to your practice during the PHE:

- Background on the Temporary Stark Law Blanket Waivers and the AKS Policy Statement
- Opportunities and options for practices and health systems
- Case studies: Application of Temporary Stark Law Blanket Waivers and AKS Policy Statement
- FAQs: Common questions on the Temporary Stark Law Blanket Waivers
- Stark Law/AKS 101: What the laws mean today

Background on the Temporary Stark Law Blanket Waivers and the AKS Policy Statement

In an effort to respond to the unique challenges of the COVID-19 pandemic, CMS has issued a variety of Temporary Stark Law Blanket Waivers adding flexibility under the Stark Law. On March 30, 2020, CMS issued a set of eighteen (18) such waivers of sanctions under the Stark Law.[2] The waivers were effective March 1, 2020, and may be used without notifying CMS. This was followed on April 21, 2020, by an Explanatory Guidance document further

1. Two prerequisites must be met before the Secretary of the U.S. Department of Health and Human Services may invoke the waiver authority. First, the President must have declared an emergency or disaster under either the Stafford Act or the National Emergencies Act. Second, the Secretary must have declared a Public Health Emergency under section 319 of the Public Health Service Act. Note that these federal actions are independent of any state actions that may be related to a public health emergency.
2. Available at, https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf

clarifying the Temporary Stark Law Blanket Waivers.[3] The Temporary Stark Law Blanket Waivers temporarily waive sanctions if an arrangement is made in good faith and is solely related to a "COVID-19 Purpose."[4]

AKS flexibilities are not as expansive as those offered by DHHS for the Stark Law

On April 3, 2020, the OIG issued a Policy Statement exercising its enforcement discretion not to impose administrative sanctions under the AKS for remuneration arrangements, but *only* to the extent it fit within the scope of the Temporary Stark Law Blanket Waivers.[5] The OIG specified that, beginning on or after April 3, 2020, it will exempt additional arrangements that do not satisfy one of the AKS safe harbors so long as the arrangement satisfies all of the conditions and definitions of one of the remuneration arrangements covered by some of the Temporary Stark Law Blanket Waivers issued by CMS (but excluding some waivers, including those related to physician-owned entities and in-office ancillary services). The OIG further clarified in the Policy Statement that, for the exemption to apply to a remuneration arrangement, the parties must have acted in good faith, and that there not be a government determination of fraud and abuse. Importantly, an arrangement is only protected if it *exactly* matches a Stark Law exception—an arrangement will not be protected under these waivers if it is otherwise exempted from the Stark Law (such as arrangements between a physician and an ambulatory surgical center). And, because the AKS is an intent-based statute, an arrangement is not required to fit a safe harbor to avoid liability.

Opportunities and options for practices and health systems

The Temporary Stark Law Blanket Waivers provide protection for payments and other arrangements between physicians and other entities that would normally be prohibited under the Stark Law and AKS. While waivers associated with the PHE are time-limited, the Stark and AKS laws were recently updated to create more flexibility, particularly for value-based arrangements. Practices may consider leveraging Blanket Waivers to develop arrangements that could be modified or progressed to arrangements that may be protected under the new permanent rules. This outline identifies for physicians and practices some immediate key steps, opportunities, and strategically significant changes under the Temporary Stark Law Blanket Waivers.

Immediate key steps

- ✓ Review compensation terms in all coverage agreements to determine whether higher compensation is warranted during the PHE.
- ✓ Review equipment or supply needs to determine whether—because of COVID-19—a health system or other third party is able to help cover the costs of equipment or supplies.
- ✓ Identify opportunities for contracted third parties and/or referral sources, such as health systems, to provide financial relief to a practice to help it weather the PHE.

Opportunities

Under the Temporary Stark Law Blanket Waivers, the following scenarios are possible during the PHE if structured in a compliant manner with the help of experienced health care legal counsel:

- Health system provision of **free use of medical office space** on its campus to allow physicians to provide services to patients who come to the hospital but do not need inpatient care.
- Hospital **deployment of a hospital employee** to an independent physician practice to assist with staff training on COVID-19, intake and treatment of patients most appropriately seen in a physician office, and care coordination between the hospital and the practice.
- Health system coverage of a physician's contribution of donated **electronic health records (EHR) items and services** or other ongoing support services to continue the physician's access to patient records.
- Partner entity provision of **free telehealth equipment** to a physician practice to facilitate visits for patients who are observing social distancing or in isolation or quarantine.

3. Available at, https://www.cms.gov/files/document/explanatory-guidance-march-30-2020-blanket-waivers-section-1877g-social-security-act.pdf
4. To learn more about these Temporary Stark Law Blanket Waivers visit: https://www.ama-assn.org/practice-management/sustainability/temporary-stark-law-waivers-during-covid-19
5. Available at, https://oig.hhs.gov/coronavirus/OIG-Policy-Statement-4.3.20.pdf

- Creative **office sharing arrangements** that permit patients to receive timely and convenient services that would enhance care coordination and yield potential cost savings.
- Arrangements involving the provision of **telehealth, remote monitoring, and other digital health technologies** to facilitate telehealth visits and care coordination, improve quality of care for chronic disease management and post-discharge care, and lower the cost of care.

Significant changes

DHHS made significant changes to the way that it evaluates components of the Stark Law in the Temporary Stark Law Blanket Waivers. Here are some material issues to understand:

- **CMS waived the "fair market value" requirement under the Stark Law for arrangements involving services personally performed by a physician. This means:**
  - » A hospital or other entity can pay a physician either above or below the fair market value for services the physician actually performs. This is a vital modification given that public health measures taken to combat the pandemic precluded some physicians from providing medical services for part of the year (causing their fixed compensation to arguably exceed the value of their services), while other physicians delivered far more care than predicted (arguably causing existing compensation relationships to be below fair market value).
  - » "Hazard pay" relationships in which physicians are paid above fair market value may be permissible if all other provisions of applicable exceptions apply—for example, compensation cannot vary with the volume or value of designated health services (DHS) referrals.

- **CMS modified the fair market value requirement in several other provisions of the Stark Law, so that a physician can pay below fair market value for rentals of space, equipment, or purchases of items or services from an entity.** Similarly, an entity can pay below fair market value for leasing space or equipment or items or services from a physician. In its commentary to the fair market value rule, CMS notes this could mean a hospital could provide free space to a physician during the pandemic, so long as the other elements of applicable exceptions are met.

- **CMS also allows entities like hospitals to provide benefits, under the Stark Law, that are more favorable than those normally offered to physicians.** For example, hospitals can provide additional valuable medical staff incidental benefits and nonmonetary compensation. Entities can also provide loans to physicians at interest rates below fair market value or on terms more favorable than other lenders. Physicians can also provide loans at favorable terms to other partner entities. CMS also clarified that such loans can be repaid even after the end of the PHE, and that physicians or hospitals can repay these loans in-kind (for example, through services).

- **CMS modified some of the Stark Law rules around in-office ancillary services, allowing physicians to provide DHS in new locations including patient homes, assisted living facilities, or independent living facilities.** The modified rules relaxed some of the requirements of the "same building" or "centralized building" definitions in the in-office ancillary services exception, allowing physician's greater flexibility to provide necessary DHS to patients in more locations. For example, if a patient is not able to travel to the physician's practice due to illness or increased risk related to COVID-19 exposure, the physician could nonetheless provide medically necessary DHS, such as imaging or lab services, at the patient's place of residence or other site outside of the physician's practice location without violating the in-office ancillary services requirements.

Strategy tip: Compensation
CMS's Temporary Stark Law Blanket Waivers clarified DHHS's longstanding guidance that compensation could only be modified if the amended compensation did not take into account the volume or value of referrals or other business generated by the physician and the overall arrangement remained in place for at least one year following the amendment. In effect, this meant compensation could only be changed once every year. CMS has clarified that compensation could be changed multiple times so long as the parties intended the arrangement to continue for one year at the time of each amendment. CMS has left open the possibility that this could mean a party could modify compensation during the PHE and then resume the earlier terms after the resumption of normal business trends.

Case studies: Application of Temporary Stark Law Waivers and AKS Policy Statement

The following six case studies illustrate some of the ways that the Temporary Stark Law Blanket Waivers can be utilized by physician practices.

1. Rent holiday for remote practitioners

In March 2020, "Medical Practice A" urgently moved a significant share of its patient visits onto a telehealth platform. In late summer 2020, Medical Practice A surveyed its providers and found that many of them anticipate furnishing some telehealth services from a remote location on a permanent basis. Patients have also indicated a desire to be seen via telehealth even after medical offices are fully reopened.

Medical Practice A had some excess office space before the PHE began, and the potential of providers working remotely increases the amount of office space that is likely to be unused. Medical Practice A concludes that it could obtain cost savings if it decreased the size of its office.

Medical Practice A is the lessee of office space in a medical office building owned by a health system. Medical Practice A and the health system revise the office lease to provide: (1) a rent holiday for specific offices that are not currently in use because Medical Practice A providers are working remotely; and (2) an option for Medical Practice A to return all, or an identified portion, of the space subject to the rent holiday when the PHE ends.

The rent holiday and lease revisions are permitted under Temporary Stark Law Blanket Waiver #5.

2. Expansion and co-branding of home health

"Medical Practice B" has seen that obtaining necessary home health services for its patients is more challenging than ever. Medical Practice B raised this issue with "Local Home Care," one of the home health agencies that it commonly works with and learned that Local Home Care likely could increase its capacity with extra funding and marketing/branding assistance. Medical Practice B and Local Home Care decide that they should establish a joint venture during the PHE. Medical Practice B agrees to purchase a 40 percent stake in Local Home Care, and Local Home Care agrees to invest the additional capital into staff recruiting and company operations. The parties also agree to develop co-branded marketing materials (both patient and potential employee directed) and a process for care coordination.

Medical Practice B and Local Home Care understand that they will likely have to unwind the joint venture after the Temporary Stark Law Blanket Waivers expire, so they agree to a process—including relevant financial terms—to unwind the venture after the PHE ends.

The ownership interest in a home health agency is permitted under Temporary Stark Law Blanket Waiver #14. Joint venture ownership of a home health company can be structured to comply with the OIG guidance, under the AKS, on joint ventures.

3. Elective procedures moratorium and quality metrics

"Surgical Practice C" has a professional services agreement with "General Hospital." The agreement includes a variety of quality metrics tied to significant financial incentives.

The PHE included a temporary prohibition on "elective" procedures, which directly impacted the number and acuity of patients covered by the quality metrics. Surgical Practice C reviewed its patient case load data and found that both during and after the moratorium on elective procedures, the characteristics of its patient population were significantly different from its historical patient population. As such, Surgical Practice C

concluded that the agreed upon quality metrics benchmarks were based upon data and assumptions that no longer applied during the PHE and the moratorium effectively made the quality metrics irrelevant and unattainable.

Surgical Practice C and General Hospital agree that, during the PHE, the practice will be paid the full financial incentives assigned to the quality metrics, regardless of quality metric outcomes. The practice agrees to continue to track data related to the metrics and patient population so that the parties can re-set the quality metrics benchmarks and targets after the PHE ends.

Full payment on unmet metrics is permitted under Temporary Stark Law Blanket Waiver #1.

4. PPE purchase

"Medical Practice D" has an in-office procedure room and has seen an increase in its use as patients have sought services outside of a hospital or surgery center setting. At times, Medical Practice D's vendors fail to deliver shipments of personal protective equipment ("PPE"). The missing shipments, combined with increased use, have created genuine shortage concerns. Medical Practice D discussed this shortage with "Health System" and Health System has agreed to sell PPE to the practice at a significantly reduced price, including some PPE for no charge. The sale of PPE is not conditioned on the practice's use of or referral to Health System's facilities.

The Health System's sale of PPE at a price below fair market value is permitted under Temporary Stark Law Blanket Waivers #6, #9 and example 7.

5. Telehealth infrastructure initial development

To date, "Medical Practice E" has been able to operate without implementing a telehealth option; patient visits have taken place in-person in the office or in a hospital setting. Sensing that telehealth is here to stay, the practice wants to offer telehealth services to clinically appropriate patients. Medical Practice E is not currently equipped with the technology necessary to perform telehealth visits, has not implemented the necessary processes, and needs to train and educate staff on telehealth regulatory requirements and proper billing.

"Health System" offers to sponsor the up-front costs of implementing a telehealth service line at the practice by providing IT equipment including interactive audio and video telecommunication systems, software licenses and infrastructure as well as training on the platform. While the practice's medical records will be separate from the health system's, they will be integrated into Health System's IT system. Health System will train Medical Practice E physicians and staff and map out telehealth processes that identify clinically appropriate patients.

The health system's provision of IT equipment, licenses, and training to the practice is permitted under Temporary Stark Law Blanket Waivers #6, #9 and examples 6, 8.

6. Telehealth: From stop gap to long term

"Medical Practice F" urgently created a stop gap telehealth program at the onset of the PHE to ensure continuity of care for patients while limiting exposure risk. The practice would like to expand its current telehealth program for permanent, long-term use by updating technology, implementing permanent processes, and exploring various reimbursement models from both private and public payors.

The practice's physicians currently perform telehealth visits using the audio and video functions on their cell phones (e.g., Apple FaceTime) or the video chat functions on Skype and Google. The practice intends to move to a dedicated telehealth platform with greater security and HIPAA compliance measures and to no longer rely on the substitute technologies currently used.

After discussions with the health system, the practice decides that its best option is to adopt the IT telehealth infrastructure used by the health system. To facilitate the practice's adoption of telehealth infrastructure that can be fully integrated with its IT systems, the health system agrees to provide the practice with: loaner equipment, staff training, access to its IT help desk, software licenses (during the PHE) and an interest-free loan during the PHE to allow the practice to purchase equipment from a third-party vendor.

Health system assistance with the practice's telehealth infrastructure is permitted under Temporary Stark Law Blanket Waivers #6, #9 and examples 6, 8.

FAQs: Common questions on the Temporary Stark Law Blanket Waivers

1. What happens when the PHE expires?

The Temporary Stark Law Blanket Waivers are explicitly linked to the PHE, so when the PHE expires the waivers are expected to no longer have any effect. At that point, any financial relationships must come back into line with existing Stark Law exceptions and the AKS. CMS indicates any revisions and termination of the Temporary Stark Law Blanket Waivers will be on a prospective basis. However, the Stark Law and AKS rules were recently updated to create additional flexibility, particularly with respect to value-based care arrangements. Physicians may be able to modify arrangements that were permissible under a PHE waiver so that it may be protected by new Stark Law exceptions and AKS safe harbors. Competent health care legal counsel should be consulted in structuring any such modified arrangement.

2. How can we change existing agreements?

The Temporary Stark Law Blanket Waivers may support a variety of modifications to existing agreements between physicians and other entities. For example, CMS states the waivers will cover relationships like paying physicians above a previously contracted rate for delivering professional services in hazardous or challenging environments, providing free hospital space to physicians or leasing it to them for a discounted rate, providing free telehealth equipment to physicians to support social distancing efforts, donating PPE to physician practices or selling it at a discount, providing care coordinators or other hospital staff to physician practices, providing support services like childcare or meals to medical staff physicians, or providing loans at favorable rates (which may be repaid through in-kind services). CMS also further clarified the parties' ability to amend existing agreements.

3. How do I proceed in an area that is not clear?

While review of the Temporary Stark Law Blanket Waivers can be a useful starting point, a significant amount of gray area remains. Due to the significant liability associated with violation of the AKS and Stark Law, parties should be careful when establishing relationships under these waivers. CMS has stated it is open to providing additional feedback through its mailbox at 1877CallCenter@cms.hhs.gov. CMS is also authorized to issue new, facility-specific waivers if parties believe their situation is not directly covered by the Temporary Stark Law Blanket Waivers. These waivers are binding on CMS but not necessarily any other government agency; however, CMS states it will work with the U.S. Department of Justice to address whistleblower suits under the False Claims Act where parties using the Temporary Stark Law Blanket Waivers have a good faith belief that their remuneration or referrals are covered by a Temporary Stark Law Blanket Waiver.

In addition to the Policy Statement, the OIG established a new website compiling frequently asked questions (FAQs). This website functions as something like an expedited Advisory Opinion process to resolve questions regarding the application of the AKS and Federal civil monetary penalty (CMP) provision prohibiting inducements to beneficiaries (Beneficiary Inducements CMP).[6] Under the OIG FAQ process, providers may submit questions related to how the OIG would view an arrangement related to COVID-19 to OIGComplianceSuggestions@oig.hhs.gov.[7] While the FAQs resemble the Advisory Opinion process, they are intended as *informal feedback*. FAQ responses are not binding on OIG and will not result in prospective

6. 42 U.S.C. § 1320a-7b(b).
7. https://oig.hhs.gov/coronavirus/authorities-faq.asp

immunity or protection from the OIG administrative sanctions or federal criminal law. Parties must obtain a formal Advisory Opinion if they wish to have an answer that is binding on OIG.[8]

4. Will the waivers be made permanent?

The Temporary Stark Law Blanket Waivers and AKS flexibilities described above are scheduled to expire at the conclusion of the PHE, but the federal government is also moving forward with a potentially significant, permanent set of changes to these laws. CMS has not indicated that the Temporary Stark Law Blanket Waivers will be made permanent. However, CMS and the OIG recently finalized rules to "modernize" the Stark Law and modify the AKS. The new rules do not specifically mimic or address the Blanket Waivers, but they do create opportunities under new exceptions and safe harbors that may offer some arrangements protection after the PHE ends. CMS has extended the timeline for the publication of the Stark Law Final Rule to Aug. 31, 2021. The OIG is not required to provide notice to the public regarding an extension of the timeline for publication of its final rule, but we anticipate the timelines will be the same. DHHS intended the proposed rules to both AKS and Stark Law to work together to incentivize value-based arrangements and patient care coordination by expressly permitting certain activities that could be deemed problematic under the current laws. OIG's proposed changes to the AKS generally tracked those in the CMS proposed rule, particularly with respect to value-based arrangements. The AMA provided extensive comments on the proposed rule changes regarding the Stark Law and the AKS.

5. This is confusing—is there another way to do this, or another waiver we can use instead?

Parties are not required to use the Temporary Stark Law Blanket Waivers in any way. They are intended to assist parties to respond to the sudden and significant changes to health care relationships due to COVID-19. Parties are still able to structure relationships using traditional Stark Law exceptions or AKS safe harbors. Finally, during the PHE, parties can reach out to CMS or the OIG to obtain guidance on a potential financial relationship.

6. I am scheduled to take on risk next year in my value-based program; can these waivers help me?

The Temporary Stark Law Blanket Waivers may provide additional assistance to help members of ACOs or other value-based programs prepare to take on risk, especially if they are currently being impacted by the COVID-19 pandemic. For example, if physicians and hospitals collaborate in a value-based care program, hospitals may want to provide free or discounted resources such as care coordination services, electronic health records, or other infrastructure. The PHE may allow a hospital to provide more immediate support and furnish those items in a more efficient way, so long as they are linked to COVID-19 purposes. The new value-based Stark exceptions and AKS safe harbors may also provide some protection to allow hospitals to continue that support after the PHE. You should consult with experienced health care counsel to discuss your specific situation.

Stark Law/AKS 101: What these laws mean today

Traditional Stark Law and AKS analysis

The Stark Law is a strict liability civil law that regulates financial relationships between physicians and entities furnishing certain "designated health services" (DHS).[9] Violations of the Stark Law are punishable by large financial penalties and may trigger application of the federal False Claims Act, punishable by additional penalties of up to three times the amount of federal health care reimbursement. The law regulates compensation relationships (such as leases, employment contracts, medical directorships, or other personal service agreements) as well as ownership relationships (such as a physician's ownership in an in-office clinical

8. https://oig.hhs.gov/faqs/advisory-opinions-faq.asp
9. 42 U.S.C. § 1395nn. DHS includes radiology and other imaging services; clinical lab services; durable medical equipment, prosthetics, orthotics, and related supplies; outpatient prescription drugs; inpatient and outpatient hospital services; physical, occupational, and speech therapy; radiation therapy; home health services; and certain other items and services..

lab). It is administered by CMS, which has created a variety of exceptions to the law to protect common arrangements. The law is "strict liability," meaning the intent of the parties does not matter for purposes of identifying a violation. This means that, if the Stark Law applies, a relationship will automatically violate the law unless it meets each and every element of an exception.

By contrast, the AKS is a criminal law that prohibits the knowing and willful offer, payment, solicitation, or receipt of anything of value, directly or indirectly, to induce or reward referrals for items or services for which payment may ultimately be made under a federal health care program.[10] Penalties under the AKS may include financial penalties and criminal penalties including exclusion from federal health care programs or even imprisonment. The AKS is *not* a strict liability law; it will only be violated if the parties offered, paid, solicited, or received things of value with the intent to induce referrals or other business. However, the AKS applies to any item or service covered under the federal health care programs, not just DHS. The DHHS OIG has established a variety of safe harbors protecting certain arrangements. As with the Stark Law, an arrangement will only be protected if it meets each and every element of a safe harbor. Unlike the Stark Law, an arrangement does not necessarily *violate* the law if it fails to satisfy a safe harbor. An arrangement will only violate the AKS if the parties acted with the required intent.

10. 42 U.S.C. § 1320a-7b(b)

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