RESOLVED, That the American Bar Association urges Congress to amend the Ethics in Patients Referrals Act of 1989, Section 1877 of the Social Security Act, 42 U.S.C. § 1395nn (commonly known as the “Stark Law”), to make changes to (a) clarify the application of the Stark Law and (b) address concerns of physicians and other healthcare providers that new alternative payment and delivery models promoted by the Centers for Medicare & Medicaid Services and other payers may result in violations of the Stark Law;

FURTHER RESOLVED, That the American Bar Association urges Congress to amend the Stark Law to remove the statutory prohibition against payment for services furnished pursuant to a compensation arrangement that failed to meet an exception to the Stark Law solely due to non-compliance with technical requirements of the statute;

FURTHER RESOLVED, That the American Bar Association urges Congress to amend the Stark Law to clarify the requirement that compensation must be consistent with fair market value, and to provide that a valuation from a nationally recognized healthcare appraiser or valuation consultant shall create a rebuttable presumption of fair market value for purposes of the Stark Law;

FURTHER RESOLVED, That the American Bar Association urges Congress to amend the Stark Law to provide greater clarity and consistency in the application of the prohibition on compensation arrangements that vary with or take into account the volume or value of physician referrals; and

FURTHER RESOLVED, That the American Bar Association urges Congress to adopt a statutory exception under the Stark Law for compensation paid under an alternative payment arrangement meeting specified requirements in order to encourage the adoption of collaborative healthcare delivery models without concerns of violating the Stark Law.
The purpose of this Resolution is to urge Congress to amend the Ethics in Patient Referrals Act, Section 1877 of the Social Security Act, 42 U.S.C. §1395nn (commonly known as the “Stark Law”), to provide clarification of critical requirements of the Stark Law and to address concerns of physicians and other healthcare providers who potentially face significant penalties under the Stark Law as a result of entering into collaborative healthcare delivery approaches and value-based incentive payment arrangements.

The Stark Law prohibits a physician from referring patients for “designated health services” (“DHS”) payable by Medicare to an entity with which the physician or an immediate family member has a financial relationship, and prohibits the entity from submitting a claim for such DHS to Medicare, to the patient or to any other payer, unless an exception applies. A financial relationship may be a direct or indirect ownership or investment interest, or a direct or indirect compensation arrangement. As more fully discussed below, the Stark Law is a strict liability law; if a financial relationship between a referring physician and an entity providing DHS is covered by the statute, it must fit precisely within an exception to the statute or else the referral is prohibited and payment for the DHS is prohibited, without regard to the intent of the parties or the medical necessity of the DHS being provided.

Congress initially enacted the Stark Law in 1989 to prohibit physician referrals for clinical laboratory services covered by Medicare, unless an exception applied, to address concerns that physicians’ financial relationships with clinical laboratories would unduly influence their clinical decision-making. In 1993, Congress expanded the definition of “designated health services” to include ten additional categories of DHS.

The categories of DHS subject to the Stark Law are: (1) clinical laboratory services; (2) physical therapy services; (3) occupational therapy services; (4) outpatient speech-language pathology services; (5) radiology and certain other imaging services; (6) radiation therapy services and supplies; (7) durable medical equipment and supplies; (8) parental and enteral nutrients, equipment and supplies; (9) prosthetics, orthotics, and prosthetic devices and supplies; (10) home health services; (11) outpatient prescription drugs; and (12) inpatient and outpatient hospital services.

There are over 30 exceptions to the Stark Law that are either included in the statutory language or that have been adopted by the Centers for Medicare & Medicaid Services (“CMS”) in the Stark Law regulations. The Stark Law exceptions are divided into three categories: (1) general exceptions applying to both ownership and compensation arrangements; (2) exceptions applying only to ownership/investment interests; and (3) exceptions applying only to compensation arrangements. The exceptions to the Stark Law were intended to permit the existence of legitimate business relationships.

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Section 1903 of the Social Security Act, 42 U.S.C. §1396b, prohibits payment of the federal share of Medicaid to states for services paid under Medicaid that would have constituted a prohibited referral under Medicare.
relationships that would otherwise have been prohibited under the statute; however, several exceptions contain criteria that have become increasingly complex, inflexible and impractical to satisfy, especially in light of the significant changes in healthcare delivery and payment since the original adoption of the statute.

The Stark Law is considered to be a strict liability statute because no intent to violate the law is necessary for a violation to occur. If a financial or other arrangement between a physician and a DHS entity, such as a hospital, does not meet precisely all of the requirements of an exception, any payments received for any DHS furnished pursuant to a referral prohibited by the Stark Law must be refunded to Medicare or the applicable payer – regardless of whether the DHS were medically necessary and regardless of whether the non-compliance was highly technical, such as failure to timely sign a contract or other document involved in the arrangements. In addition, for “knowing” violations, the parties may be subject to enormous civil monetary penalties, as well as exclusion from participation in federal and state healthcare programs and liability under the False Claims Act.

In recent years, Congress has created alternative payment models, such as the Medicare Shared Savings Program, and has authorized the creation of other models in which payment for healthcare services is tied to a value-based methodology and not simply based on volume or the number of services provided. Indeed, there is near-universal agreement that great collaboration and coordination among healthcare providers is critical both for improving health outcomes and for controlling healthcare costs. However, healthcare providers have been hesitant to enter into collaborative healthcare service delivery arrangements and innovative payment arrangements for fear of violating the complex requirements of the Stark Law. Congress has authorized limited waivers from the Stark Law for the Medicare Shared Savings Program and has authorized CMS to create waivers for any alternative payment programs initiated through the Centers for Medicare and Medicaid Innovation (“CMMI”). However, these waivers of the Stark Law only apply to certain Medicare innovative payment models, may be of limited duration, and may not be issued until the model is underway. Outside of the very limited scope of arrangements that are covered by these waivers, the fear of inadvertently violating the Stark Law still inhibits the collaboration and cooperation among providers that our evolving healthcare policy otherwise encourages, even compels.

Current State of the Law and Proposals for Change

There have been few amendments to the Stark Law statute itself; however, CMS has done extensive rulemaking since 1989 to implement the statute as well as to create additional exceptions. The extensive regulatory changes by CMS have added to the complexity of the Stark Law and sometimes have been impediments to the development of value-based payment models that reward providers for delivering higher-quality and more cost-effective healthcare services. Notwithstanding this complexity, the Department of Justice and whistleblowers have brought False Claims Act cases on the theory that because (in their view) the statute is clear, the alleged Stark violations at issue must have been knowing violations.

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The following sections identify some major areas where clarification of existing provisions of the Stark Law or amendments to those provisions would reduce the sometimes draconian impediments or elimination of the legal, implementation of value-based delivery models and greater coordination of care without presenting a material risk of fraud, waste or other harm to the Medicare program.

“Technical” violations not causing program integrity concerns

Many of the regulations promulgated under the Stark Law involve formal, technical requirements, the failure to comply with which does not in and of itself pose any material risk of abuse to the Medicare program or its beneficiaries (e.g., payment of Medicare funds for services that were inappropriate or medically unnecessary). For example, the Stark Law exception for personal service arrangements between a referring physician and a DHS entity requires that the arrangement be reflected in a written agreement signed by the parties that is in place before any services are rendered or any compensation paid. If, through clerical error or unavoidable errors (e.g., a required signature is on vacation or sick leave), a contract signature is delayed beyond the time permitted or omitted, any claims for services rendered before that deficiency is cured are prohibited, even if the claims were for appropriate, medically necessary items or services and even if Medicare would have paid the claims without question if the parties did not have a Stark-covered financial relationship. Similarly, if a written agreement for such an arrangement expires without being formally renewed but the parties nonetheless continue to perform in accordance with the contract, services rendered after the expiration date will give rise to a Stark Law violation, even if they would have been permissible if the parties had entered into a written extension.

Practitioners commonly refer to these types of violations as “technical” violations, because they do not result in claims to Medicare for items or services that are suspect from a program integrity standpoint (as distinguished from violations of the fair market value, commercial reasonableness and volume-or-value prohibition, which may indicate an arrangement that results in overutilization of services). However, CMS has consistently taken the position that there is no such thing as a technical Stark violation; any failure to meet the formal requirements of a Stark Law exception precisely is a violation subject to the same penalties as a failure to meet the substantive terms of an exception. Thus, the penalty for a late or missing signature on a contract is the same as the penalty that would apply if the contract provided for compensation that varied directly with the volume of referrals — any claim submitted to Medicare is prohibited by statute from being billed or paid, and the parties are subject both to repayment obligations and to penalties. In this context, the strict-liability nature of the Stark Law punishes both innocent errors and intentional misconduct with a sledgehammer approach.

Although CMS has offered some limited relief for temporary non-compliance with these sorts of formal requirements, that relief is quite narrow in scope. Given the ever-increasing complexities of the healthcare delivery system, the opportunity for non-substantive (technical) errors will likewise continue to increase. It is appropriate for the Stark Law to be amended to provide that the per se prohibition on payment for DHS

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referred under a financial relationship that does not meet all of the requirements of an exception does not apply to technical non-compliance with an exception. Such amendment would remove the threat of False Claims Act liability premised on the allegation by (chiefly) a relator or the Government that the technical non-compliance was a knowing violation, and would also obviate the legal obligation for a DHS entity that discovers the technical non-compliance to refund the payment for the DHS involved or, alternatively, to make a self-disclosure to CMS. Instead, such technical non-compliance would allow (but not require) CMS, upon audit, to deny payment retrospectively for such DHS if the DHS entity cannot establish that it met all technical requirements of an applicable exception.

Fair market value

A critical requirement of several exceptions to the Stark Law is that any compensation between a referring physician and a DHS entity must be “consistent with” fair market value; i.e., the Stark Law does not differentiate between arrangements in which the referring physician pays less than fair market value and those in which the referring physician receives less than fair market value. In contrast, for purposes of the Anti-Kickback Statute (“AKS”), 42 U.S.C. §1320a-7(b), the Government is rightly not concerned if the physician or other referral source is paid compensation that is less than fair market value, or conversely, pays the referral target in excess of fair market value. Accordingly, the ABA recommends that “consistent with fair market value” be clarified to mean that the referring physician pays at least fair market value for items and services furnished by a DHS entity and receives no more than fair market value for items and services provided to a DHS entity. (Thus, for example, a physician who rents office space from a DHS entity could not pay less than fair market value rent, and a hospital who contracts with a physician to provide medical direction services could not pay more than fair market value compensation for such services.)

The ABA also recommends that, in order to provide some assurance that the compensation paid or received will not be attacked by the Government or a relator as being more than or less than fair market value, where the parties to an arrangement seek a market valuation from an independent and competent valuator, that valuation should be presumed to be correct. This is especially important in the context of alternative payment arrangements in which the parties are attempting to arrive at the fair market value of a physician’s success in lowering costs and increasing quality and patient satisfaction.

Volume or value of referrals

Generally, the Stark Law prohibits any payment that varies with or otherwise takes into account the volume or value of referrals from the recipient of the payment to the payer. The test for whether compensation impermissibly takes into account the volume 2 The AKS makes it a felony to offer, pay, solicit or receive any remuneration, in cash or in kind, for referring a person for items or services which may be paid for by any federal healthcare reimbursement program, such as Medicare, Medicaid and Tricare.

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referred under a financial relationship that does not meet all of the requirements of an exception does not apply to technical non-compliance with an exception. Such amendment would remove the threat of False Claims Act liability premised on the allegation by (chiefly) a relator or the Government that the technical non-compliance was a knowing violation, and would also obviate the legal obligation for a DHS entity that discovers the technical non-compliance to refund the payment for the DHS involved or, alternatively, to make a self-disclosure to CMS. Instead, such technical non-compliance would allow (but not require) CMS, upon audit, to deny payment retrospectively for such DHS if the DHS entity cannot establish that it met all technical requirements of an applicable exception.

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or value of referrals has proven to be particularly vexing. For example, a hospital's payments to a physician for the bona fide performance of services may be considered by the Government or a relator to reflect the volume or value of referrals if the physician must admit a patient to a hospital in order to perform those services. The ABA recommends that Congress amend the Stark Law to clarify the interpretation and application of the "volume or value of referrals" prohibition in situations where there is ambiguity or inconsistency in the text of the statute or in the interpretations of the statute applied by CMS. The following paragraphs provide specific examples as to which the ABA believes amendments to the statute would provide greater clarity and consistency without undermining the policy goals of the Stark Law. Adoption of this Resolution will allow the ABA to address these and similar issues through appropriate outreach to Congress. First, the ABA recommends that Congress adopt the existing "safe harbor" in CMS's regulations for unit-based ("per click" or "per procedure") compensation and make it applicable through a statutory safe harbor to any type of compensation that is set in advance, including percentage compensation arrangements (e.g., compensation based on a percentage of revenue or percentage of collections). Such an amendment to the Stark Law would provide greater clarity to healthcare providers and would reduce the exposure of such providers to enforcement actions based on inconsistent interpretations of the Stark Law. For example, the ABA is aware of one case in which a health system was leveraged into a $25 million settlement because its percentage compensation arrangement was disallowed as taking into account the volume or value of referrals. Although CMS agrees that percentage compensation arrangements can meet its definition of "set in advance," and although the preamble language to CMS's regulations concerning the volume or value prohibition supported the health system's position, the safe harbor in the regulations does not include percentage compensation arrangements. Next, the ABA believes it is especially important that the "volume or value" standard be clarified in the context of alternative payment arrangements in which physicians are paid a share of per-case cost savings, as more referrals/more procedures by the physicians may result in more savings (but may also result in lower savings). These types of payment arrangements are critical to the sorts of value-based payment approaches that CMS is actively advocating, but their legal status under the Stark Law is very unclear.

Further, some of the Stark Law exceptions prohibit the taking into account the volume or value of referrals only for Medicare DHS, whereas others expand the prohibition to also include "other business generated between the parties" (which is everything else – Medicaid, commercial pay, Medicare and Medicaid managed care, etc.). Again, this creates inconsistent guidance for providers and the risk of inconsistent enforcement actions for alleged violations. Accordingly, the ABA recommends making the prohibition on the volume or value of referrals relate only to Medicare DHS, which would better reflect the initial legislative intent behind the Stark Law (i.e., protection of the Medicare Trust). Having a single, albeit more liberal, standard provides some flexibility and reduces the possibility that arrangements unwittingly violate the Stark Law because the parties are unaware that the "other business generated" standard applies. Also, to the extent that "the other business generated" standard is intended to prevent "swapping or value of referrals has proven to be particularly vexing. For example, a hospital's payments to a physician for the bona fide performance of services may be considered by the Government or a relator to reflect the volume or value of referrals if the physician must admit a patient to a hospital in order to perform those services. The ABA recommends that Congress amend the Stark Law to clarify the interpretation and application of the "volume or value of referrals" prohibition in situations where there is ambiguity or inconsistency in the text of the statute or in the interpretations of the statute applied by CMS. The following paragraphs provide specific examples as to which the ABA believes amendments to the statute would provide greater clarity and consistency without undermining the policy goals of the Stark Law. Adoption of this Resolution will allow the ABA to address these and similar issues through appropriate outreach to Congress. First, the ABA recommends that Congress adopt the existing "safe harbor" in CMS's regulations for unit-based ("per click" or "per procedure") compensation and make it applicable through a statutory safe harbor to any type of compensation that is set in advance, including percentage compensation arrangements (e.g., compensation based on a percentage of revenue or percentage of collections). Such an amendment to the Stark Law would provide greater clarity to healthcare providers and would reduce the exposure of such providers to enforcement actions based on inconsistent interpretations of the Stark Law. For example, the ABA is aware of one case in which a health system was leveraged into a $25 million settlement because its percentage compensation arrangement was disallowed as taking into account the volume or value of referrals. Although CMS agrees that percentage compensation arrangements can meet its definition of "set in advance," and although the preamble language to CMS's regulations concerning the volume or value prohibition supported the health system's position, the safe harbor in the regulations does not include percentage compensation arrangements. Next, the ABA believes it is especially important that the "volume or value" standard be clarified in the context of alternative payment arrangements in which physicians are paid a share of per-case cost savings, as more referrals/more procedures by the physicians may result in more savings (but may also result in lower savings). These types of payment arrangements are critical to the sorts of value-based payment approaches that CMS is actively advocating, but their legal status under the Stark Law is very unclear.

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arrangements,” in which favorable compensation terms may be offered on non-Medicare DHS business to induce the referrals of Medicare DHS, the AKS is available to address that, and is a more appropriate vehicle for that analysis because of the intent-based nature of AKS liability.

Finally, the ABA recommends that the statute be amended to clarify that the “volume or value” standard does not apply to personally performed services of the referring physician, even if those personally performed services are surgical procedures for which a hospital bills a facility fee. The ABA believes this recommendation is consistent with CMS’s policy, but dicta from the Fourth Circuit in the Tuomey case\(^3\) has caused some anxiety among hospitals and academic medical centers as to how they may properly compensate their physicians for services when those services, by their nature, result in additional revenues for the hospitals.

Conclusion

The Resolution herein requests that the American Bar Association urge Congress amend the Stark Law to address concerns described in this Report and provide greater clarity, consistency and fairness in the interpretation and enforcement of the statute.

The Health Law Section requests that the American Bar Association House of Delegates adopt this Resolution.

Respectfully submitted

Alexandria Hien McCombs
Chair, Health Law Section
August 2019

\(^3\) United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc., 792 F.3d 364, 395 n.10 (4th Cir. 2015).
1. **Summary of Resolution(s).**

The Resolution urges Congress to enact legislation to amend the Ethics in Patients Referrals Act of 1989, 42 U.S.C. § 1395nn (commonly known as the Stark Law), to modernize the law and encourage the adoption of value-based payment arrangements and other coordinated care arrangements that will lower costs to the Medicare program and improve the quality of services to its beneficiaries.

2. **Approval by Submitting Entity.**

The Council of the Health Law Section approved the filing of this Resolution and Report on May 5, 2019.

3. **Has this or a similar resolution been submitted to the House or Board previously?**

There has not been a similar resolution filed.

4. **What existing Association policies are relevant to this resolution and how would they be affected by its adoption?**

There are no known Association policies directly relevant to this Resolution.

5. **If this is a late report, what urgency exists which requires action at this meeting of the House?**

There is no current legislation pending proposing relevant changes to the Stark Law. However, there may be legislative activity soon, as we have been informed that the Senate Finance Committee is exploring statutory changes to Stark, and both HHS’s Centers for Medicare & Medicaid Services (CMS) and Office of Inspector General have recently issued Requests for Information concerning potential changes in the regulatory exceptions to the Stark Law and the Anti-Kickback Statute. Earlier this year, Congress made minor changes to the Stark Law, which it characterized as for the purpose of modernizing the law.

6. **Status of Legislation. (If applicable)**

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7. **Brief explanation regarding plans for implementation of the policy, if adopted by the House of Delegates.**

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The sponsoring entities will work with the ABA Governmental Affairs Office to actively engage in federal and state legislative activities related to this issue.

8. **Cost to the Association.** (Both direct and indirect costs)
   There are no known costs to the Association.

9. **Disclosure of Interest.** (If applicable)
   There are no known conflicts of interest.

10. **Referrals.**
    By copy of this form, the Resolution will be referred to the following entities:

    - Section of Administrative Law and Regulatory Practice
    - Section of State and Local Government Law
    - Section of Science and Technology Law
    - Law Practice Division
    - Law Student Division
    - Young Lawyers Division
    - Commission on Law and Aging
    - Commission on Disability Rights
    - Commission on Women in the Profession
    - Standing Committee on Ethics and Professional Responsibility
    - Standing Committee on Lawyers’ Professional Liability
    - National Association of Bar Executives
    - National Bar Association Inc.
    - National Conference of Bar Presidents

11. **Contact Name and Address Information.**
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    simeon.carson@americanbar.org

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12. **Contact Name and Address Information.** (Who will present the report to the House? Please include name, address, telephone number, cell phone number, and e-mail address.

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EXECUTIVE SUMMARY

1. Summary of the Resolution.

The Resolution urges Congress to enact legislation to amend the Ethics in Patients Referrals Act of 1989 (commonly known as the Stark Law) to modernize the law and encourage the adoption of value-based payment arrangements and other coordinated care arrangements that will lower costs to the Medicare program and improve the quality of services to its beneficiaries.

2. Summary of the Issue that the Resolution Addresses.

The Resolution would eliminate or reduce the penalties for certain technical violations of the Stark Law that do not reasonably present a risk of fraud and abuse in the modern physician payment context, especially given the proliferation of alternative and value-based payment arrangements. The proposed legislative amendments would further simplify compliance with the Stark Law, keeping in step with other recent regulatory changes and Centers for Medicare and Medicaid Services policy initiatives towards reduction of unnecessary regulatory burdens.

3. Please Explain How the Proposed Policy Position Will Address the Issue?

The Resolution would propose amendments to the existing Stark Law legislation including those that would (i) alleviate regulatory burdens associated with self-disclosure of certain Stark Law technical violations, (ii) simplify determinations of fair market value in transactions subject to the Stark Law, and (iii) eliminate certain technical issues associated with compensation “determined in a manner that takes into account the volume or value of referrals.”

4. Summary of Minority Views or Opposition Internal and/or External to the ABA Which Have Been Identified.

No minority views or opposition have been identified.

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