Stark Law Reform: Is It Time?

Kathy H. Butler

Examining the Health Care Regulatory Construct to Facilitate Health Care Reform

Fraud and abuse in the health care industry is a legitimate concern, and the federal government has enacted a number of laws designed to prohibit financial arrangements offered to providers that incent over-utilization of health care services for federal government payor program beneficiaries. Studies have demonstrated that physician referrals for health care services increase when the physicians receive a financial benefit based on the volume or value of those referrals. Specifically for this reason,[1] the federal government in 1989 passed the Stark law, which became effective in 1992.[2]

The Stark law is a strict liability law that was intended to create a bright line rule prohibiting physicians who have a financial relationship (direct or indirect) with a health care entity from referring Medicare patients for certain services *unless* the arrangement falls within a specific exception to the prohibition. Because it is a strict liability law, it does not matter whether a person or an entity intended to violate the law: A violation is a violation no matter how big or how small, intended or unintended, or whether there is actual harm caused to the public fisc.

Initially, the Stark law only applied to clinical laboratory services. In 1993, the law was expanded to include 10 additional "designated health services" or "DHS" in addition to laboratory services which significantly expanded the scope of the law.[3] Designated health services are broadly defined and cover a wide variety of services, including inpatient and outpatient hospital services.[4]

The Stark law prohibits a physician from referring Medicare patients to a DHS entity with which he or she has a direct or indirect financial relationship (which can include ownership and/or compensation relationships) and also prevents the DHS entity from billing for services referred by a physician provided to Medicare patients if the financial relationship does not fit within an exception. Exceptions are extremely technical and require compliance with terms that are not well-defined. The Stark law was meant to be a straightforward test

Kathy H. Butler is an Officer and the Manager of the Health Law Practice Group at Greensfelder, Hemker & Gale, P.C. Her practice focuses on representation of health systems, hospitals, physician groups, and other health care providers, with an emphasis on operational, compliance, and regulatory matters. She can be reached at 314/516-2661 or by email at khb@greensfelder.com.

to prevent inappropriate financial relationships between physicians and health care providers in exchange for referrals. However, application of the Stark law is anything but straightforward. As currently written, even minor technical noncompliance can result in onerous penalties.

The Stark law in its current state consumes an enormous amount of resources (lawyers, consultants, internal compliance staff, et cetera) to ensure compliance. In addition, the Stark law, because of its onerous penalties, has become an impediment to health care reform by stifling the innovations required between health care entities and physicians needed to transform the health care payment system from a fee-for-service system to a value-based payment system. Many of the actions required to align physician and health care entity incentives to achieve the quality and performance benchmarks that are the hallmark of health care reform are either prohibited by the Stark law or the Stark law's application is unclear. The potential devastating penalties that a health care entity could suffer for even a technical violation of the law make health care providers reluctant to participate in alternative payment models that could otherwise have a meaningful impact on health care reform.

Health Care Reform and Traditional Fraud and Abuse Regulations

Major health care reform legislation was passed in 2010 in the form of the Patient Protection and Affordable Care Act[5] and the Health Care and Education Reconciliation Act of 2010[6] (collectively referred to as the "Affordable Care Act" or "ACA"). These laws include various programs to transform the health care delivery system, improve quality, and encourage development of new patient care models. These models move away from traditional fee-for-service (FFS) models under which providers are paid based on the services they provide (without consideration of the quality or efficiency of the service) to new value-based or population-based payment models.

Value-based payment models reimburse providers not for the amount of service they provide but for the efficiency and quality of the services provided. Similarly, population-based health care delivery systems focus on an entire population's health status including the treatment of disease and prevention and health of the overall target population. Under the authority granted by the ACA, the Center for Medicare and Medicaid Innovation (CMMI) has created and oversees demonstration projects designed to implement the shift from FFS to value-based payment. These new payment programs will continue to evolve as the health care delivery system transforms, utilizing integrated delivery models to coordinate care in an effort to see health care delivered to Medicare beneficiaries in an efficient, cost-effective, and quality manner. The fundamental changes in the health care delivery models for Medicare beneficiaries will naturally also be applied to all patient populations, regardless of who is paying for the care, making the need to reform the complex regulatory structure important at both the federal and the state level.

One of the first programs mandated by the ACA is the Medicare Shared Savings Program (MSSP),[7] which outlined a new approach to the delivery of health care.[8] The Centers for Medicare & Medicaid Services (CMS) describes the program as one which will "facilitate coordination and cooperation among providers to improve the quality of care for Medicare Fee-For-Service (FFS) beneficiaries and reduce unnecessary costs. Eligible providers, hospitals, and suppliers may participate in the Shared Savings Program by creating or participating in an accountable care organization (ACO)."[9]

ACOs are groups of hospitals, physicians, and other health care providers who come together voluntarily to give coordinated, high quality care to their Medicare patients with the goal of ensuring that patients,

especially the chronically ill, get the right care at the right time while avoiding unnecessary duplication of services and preventing medical errors.[10] If the ACO succeeds in delivering high quality care in a cost-effective manner, it will share in the savings it achieves for the Medicare program, and the providers participating in those programs can receive a financial benefit for achieving quality and financial goals. There are a number of different programs currently in process. CMS issued a press release on August 25, 2016, announcing that Medicare ACOs are achieving their goals and have generated more than $1.29 billion in total Medicare savings since 2012.[11]

Waivers of Fraud and Abuse Laws Allow Provider Participation

The payment models authorized by the ACA require health care providers to coordinate care, deliver the care efficiently and without duplication, and achieve quality benchmarks to achieve the savings which will be shared with the participants, aligning the providers' clinical and economic incentives in the health care delivery process. As such, incentives that are present under an FFS payment system that can lead to over-utilization are no longer present as providers are not compensated for each service they provide. Congress, when it passed the ACA, recognized that the health care reform initiatives being implemented could be hampered by the existing fraud and abuse laws. As a result, Congress gave the Secretary of the U.S. Department of Health and Human Services (HHS) broad authority to issue waivers of a variety of fraud and abuse laws, including the Stark law, the federal anti-kickback statute or "AKS",[12] the prohibition on inducements to beneficiaries, and the prohibition on hospital payments to physicians to induce reductions or limitations of medically necessary services (the "gainsharing prohibition") under the Civil Money Penalties Law or "CMP Law,"[13] among others. The HHS Office of Inspector General (OIG) and CMS worked together to issue interim final waiver regulations in 2011[14] and final regulations in 2015.[15]

The final waiver regulations clearly acknowledge that the nature of the current fraud and abuse require financial separation between sources of federal health care program referrals and those seeking those referrals, while the MSSP focuses on coordinating care between and among providers, including those that are potential referral sources for one another. CMS and OIG note that stakeholders have expressed concern that the restrictions these laws place on certain coordinated care arrangements may impede some of the innovative integrated-care models envisioned by the MSSP. Stakeholders also believe that these laws inhibit shared savings and other incentives that they consider key to the success of an ACO — for example, arrangements involving the provision of electronic health record system, information technology (IT) services, or free care management personnel.[16]

The final waivers provide some protection from enforcement of the Stark law and other fraud and abuse regulations for MSSP participants and extend those protections to entities that provide items or services to support the MSSP participants. However, the waiver protections are program-specific and must be addressed on a program-by-program basis, which creates a compliance challenge for entities that participate in multiple programs. In addition, the CMMI waivers for demonstration projects are only available during the time the program is active, which is typically three to five years. After the program ends, there is little incentive and more than a minimal risk in a provider continuing a program that cannot comply with applicable fraud and abuse laws. This limitation on the applicability of waivers may cause some providers to avoid investing in the program re-design needed to participate in these programs. Furthermore, waiver protections are not broad enough to protect commercial payor

programs, which also may implicate the fraud and abuse laws.

Innovative payment programs continue to evolve and in the future will in all likelihood largely replace the FFS payment model. The CMMI Web site lists a number of other models currently in process and in various stages of development. The waiver process is not coordinated for purposes of the various health care reform models being implemented and is not keeping up with the pace of ongoing reform efforts.

A perfect example of why the Stark law has become an impediment to health care reform is the passage of the Medicare Access and CHIP Reauthorization Act of 2015[17] (MACRA), which permanently repeals the sustainable growth rate (SGR) applicable to physician payments, and proposes that it be replaced, effective for the 2019 physician payment adjustment, with a new single merit-based incentive payment system (MIPS) that makes it easier for physicians to earn rewards for providing high-quality, high-value health care, and supports and rewards physicians for participating in new payment and delivery models to improve the efficiency of care.[18] MACRA also gives CMS the authority to implement alternative payment models (APMs) which will provide financial incentives to providers who participate in these innovative reform programs. Proposed rules were released on May 9, 2016,[19] and the industry was provided the opportunity for comment.

MACRA itself does not provide the Secretary of HHS with waiver authority that is present in the ACA, so in order to participate in the programs enacted under MACRA providers must try to fit within the waivers granted by the Secretary under the ACA. Given the serious penalties associated with violating the fraud and abuse laws, especially a strict liability law like the Stark law, failure to provide relief from potentially onerous penalties that could result from allegations of violation of the fraud and abuse regulations will inhibit provider participation in innovative health care delivery models.

Congressional Review of the Stark Law and its Effect on Health Care Reform

On December 10, 2015, the U.S. Senate Committee on Finance and the U.S. House Committee on Ways and Means convened a round-table discussion of subject-matter experts to discuss whether changes in the Stark law were necessary to implement some of the new payment reform legislation, and if so, what options would work best in the transitioning health care system. Following that meeting, the Senate Finance Committee Majority Staff issued a report released on June 30, 2016, entitled *"Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models"* (the "Report"), which summarizes the serious issues faced by health care providers caused by the current form of the Stark law and outlines suggestions for reforms that will encourage providers to participate in innovative payment programs.[20]

The Senate Committee on Finance held a hearing on July 12, 2016, at which the Committee heard testimony from several industry representatives about the Stark law's effect on the health care industry, whether the law was achieving its intended purpose, and what reforms were needed to allow health care providers to fully participate in health care reform activities without fear of penalty under the Stark law.[21] Three witnesses who had participated in the round table testified, and each had a unique perspective on the subject. The first was Troy A. Barsky,[22] partner at Crowell & Mooring, LLP, Washington, D.C., and former director of the Division of Technical Payment Policy at CMS, who for the last four years of his tenure was responsible for Stark law policy and other payment issues, including those related to the implementation and creation of new value-based payment models created under the ACA. Barsky's testimony reflected issues

from the perspectives of both the provider and CMS.

The second witness was Ronald A. Paulus, MD,[23] president and chief executive officer, Mission Health System, Ashville, N.C. Paulus described his extensive experiences in leading large health systems through the transformation necessary to create a value-based health system and how the Stark law impacts their delivery system. The third witness was Peter B. Mancino, deputy general counsel, The Johns Hopkins Health System Corporation, Baltimore, Maryland.[24] Mancino's testimony reflects the issues faced by any health care attorney advising a client on the Stark law. Johns Hopkins system includes academic and community hospitals, physician groups, Medicare and Medicaid managed care plans, and other related businesses.

All three witnesses supported common-sense reforms to the Stark law to free providers to participate in innovative payment systems that will improve the quality of care, patient satisfaction, and the health of the population in an efficient, cost-effective manner without fear of ruinous penalties that can be assessed against providers under the strict liability Stark law regime.

Input from Stakeholders

The Report outlines suggestions for changes to the Stark law after considering input from the round-table discussion on December 10, 2015, and post-meeting input from round-table members and others who were invited to share their views on the Stark law. Input was received from Stark law experts, academics, attorneys in private practice who work with hospitals and/or physicians, attorneys in the private sector who previously served in government and regulatory agencies, hospital systems, electronic health record providers and associations representing hospitals, physicians, medical device manufacturers, accountable care organizations, and several types of ancillary service providers.[25]

The round-table participants were asked to consider an array of known issues, including the current Stark law environment, health care reform implementation, costs associated with compliance and disclosures, possible fixes under both FFS and alternative payment models, and CMS's limited authority to create exceptions and to issue advisory opinions. Round-table participants were then asked to specifically focus on (1) changes to the Stark law to implement health care reform, specifically MACRA, and (2) the distinction between technical and substantive violations.

After consideration of the input received, the Senate Finance Committee issued the Report. In short, the Executive Summary portion of the Report states:

> The Stark law has become increasingly unnecessary for, and a significant impediment to, value based payment models that Congress, CMS, and commercial health insurers have promoted. The risk of overutilization, which drove the passage of the Stark law, is largely or entirely eliminated in alternative payment models. When physicians earn profit margins not by the volume of services but by the efficiency of services and treatment outcomes, their economic self-interest aligns with the interest to eliminate unnecessary services.[26]

The Report provides a detailed discussion that highlights the thoughtful consideration and viewpoints of the round-table participants and other contributors, and the difficulty of balancing provider needs and government enforcement priorities. This article will highlight some of the substantive recommendations that were received.

Recommendations for Reforms Related to Payment Models[27]

The round-table participants were asked for recommendations on Stark law changes

necessary to implement health care reforms promoting alternative payments model, including suggestions for options that would work in both FFS and alternative payment models. The recommendations included:

1. Repeal

Many commenters felt the AKS in its current form can address the type of concerning conduct the Stark law is intended to prevent or, alternatively, that the Stark law should sunset once Medicare had meaningfully transitioned to alternative payments models.

2. Repeal Compensation Arrangement Prohibitions

A larger group of commenters believed that repealing the compensation arrangement prohibitions would address many of the concerns from both the health care reform perspective and the technical compliance perspective. Some commenters noted that the AKS also can be enforced in a civil context through both the False Claims Act (FCA) and the CMP law. Others commented that the compensation prohibitions were included to avoid circumvention schemes to give physicians the benefits, and dangers, of ownership without equity.

3. New Risk Revenue Waiver/Exception

Two commenters recommended creating a waiver from the Stark law once a health care entity's risk revenue reaches a certain majority percentage of its total revenue. One commenter framed the exception of terms of a broad waiver from the Stark law for a health care system that derives no less than 50 percent of its health care revenue from alternative payment methodologies. Some commenters believed the complexity of this type of exception would continue to present risk to participants.

4. Create New or Expand Currently Restricted Waivers

Most commenters suggested extending to all payors the waivers that are currently mostly limited to CMS-run programs. Some urged that the same protections be provided to physicians operating in alternative payment models that were provided through ACOs eligible for MSSP, including the pre-participation period. Those commenters believe this would recognize the variety of alternative payment models that use different mechanisms and structures to encourage efficient care. One commenter stated that, ideally, Congress would make the current CMMI waivers permanent and available to all new adopters of similar models in the future, as well as permanent programs established under the CMMI's authority. Commenters also agreed that Congress should give HHS broader authority to create regulatory waivers. Other suggestions included creating a new Stark law exception applicable to alternative payment models or a waiver for such models modeled on the current Stark law exception for Medicare prepaid plan enrollees.

5. Create New Exceptions

Many commenters suggested the creation of a new exception to enable financial arrangements that involve risk-sharing and gainsharing in alternative payment models when appropriate safeguards are in place. Some recommended that such an exception (the "APM Exception") apply to all MACRA alternative payment model financial arrangements and expressly allow for compensation arrangements that take into account the volume or value of referrals, and that it not impose a "fair market value" requirement. At least one commenter recommended a new exception for quality-based payments to physicians, provided that such payments are not tied to the volume or value of referrals. Other comments on the new exception recommendation focused on ensuring that the exception be designed to foster collaboration and incentivize true value-based arrangement, that it apply to all the providers participating in the integrated delivery of care, and the need to protect shared savings and incentive programs, including start-up and support

contributions. One commenter suggested a new compensation exception to the Stark law using conditions already used to qualify other ACOs and risk-sharing arrangements under the Stark law and AKS.

6. Special Compensation Rule

The majority of comments touched on potential changes to how the Stark law treats compensation arrangements. As an alternative to an integrated delivery system waiver, some commenters recommended changing the fair market value requirement or the fair market value definition to accommodate alternative payment models. One commenter suggested a special compensation rule related to MACRA APM financial arrangements that would automatically deem such arrangements to (1) not take into account the volume or value of referrals, or other business generated between the parties, and (2) constitute fair market value, provided all MACRA alternative payment model programmatic requirements were otherwise met.

7. Modify Existing Exceptions

Commenters also suggested modifying existing statutory or regulatory exceptions to the Stark law to promote integrated care and aligned incentives. These comments included:

a. Broadening the Stark law prepaid plan exception, and expanding the Stark law risk-sharing arrangements exception to apply to Medicare and Medicaid FFS programs, or to incentive payment arrangements between a DHS entity and a physician participating in a qualified APM.
b. Advocating for consistency between the Stark law and the CMP law, stating that the Stark law should not prohibit any arrangement presently permitted under the CMP law, including changes to the gainsharing prohibition as amended by MACRA.
c. Clarifying that the volume and value standard under the Stark law is not implicated when a physician is incentivized to follow a standard hospital quality measure (*e.g.*, a care protocol) that includes ordering an item or service for a patient that will not result in any additional reimbursement to a hospital.
d. Clarifying the definition of an indirect compensation arrangement to exclude from the definition of "aggregate compensation" a direct compensation arrangement that does not necessarily rise as a direct result of more referrals or higher paying referrals.
e. Adopting CMS's deeming provision for per-click compensation arrangements and extend it to percentage compensation, and clarifying that arrangements which allow physicians to receive a percentage of savings can satisfy the FMV and commercial reasonableness requirements of an applicable exception. An alternative recommendation would be to allow an arrangement to be deemed FMV and commercially reasonable where the provider had relied in good faith on an opinion from a nationally recognized appraisal firm. Other suggestions in this regard required the inclusion of a cap or threshold standard to govern the amount that can be shared with physicians.

8. Expand the Secretary's Authority: Waivers, Exceptions, and Advisory Opinions

Some commenters noted that the Stark law and its regulations govern compliance for purposes of payment, and to be effective, the regulated community must be able to obtain timely and clear guidance. Suggestions in this regard included:

a. Expanding the Secretary's authority to create waivers, exceptions, and advisory opinions. Although some commenters suggested that the authority be limited to expanding waivers for participants in MSSP and other CMMI models, most recommended that the Secretary

be given express waiver authority that would apply to innovative payment models under MACRA and other health care reform laws.

b. Expanding the standard to be used by the Secretary to create new exceptions from one of an arrangement posing "no risk of program or patient abuse" to one that requires that an arrangement "not pose an undue or significant risk of program or patient abuse."
c. Strengthening the Secretary's authority to issue Stark law advisory opinions and promote timely agency guidance.
d. Streamlining the Self-Referral Disclosure Protocol and providing CMS with more discretion to settle Stark law violations, including giving CMS explicit authority to impose CMPs in lieu of compromising repayments based on the total repayment amount. One commenter suggested giving CMS discretion to determine whether to prohibit billing for referrals received under a noncompliant arrangement, which was noted would have far-reaching implications, including taking Stark law violations out of the realm of the FCA.

Some commenters were not in favor of creating additional waivers or exceptions because the law is already overly complex, or strengthening the Secretary's advisory opinion authority because the advisory opinion process is slow and only marginally helpful. These commenters believed Congress should revise the law in its entirety.

Recommendations for Reforms Related to Technical Violations[28]

Commenters generally agreed that "technical violations" should be subject to a separate set of sanctions that would not give rise to either FCA exposure or potentially ruinous repayment liability. The discussions touched a variety of issues but left some commenters questioning the complexity of drawing a distinction between substantive and technical violations in the overall regulatory scheme. For this group, the solution to the complexity issue was a recommendation to eliminate the compensation arrangement prohibition in its entirety.

1. Documentation Issues

Commenters generally agreed that technical violations were those involving the form, not substance, of an arrangement and referred to the definition of technical violations in the "Stark Administrative Simplification Act of 2015," which included unwritten arrangements, arrangements unsigned by one or more parties, and prior arrangements that expired but continued without a written amendment or new arrangement.[29]

2. Arrangements That Do Not Incentivize Referrals or Unduly Influence Health Care Decision-Making

In addition to documentation issues, some commenters included as technical violations those that are irrelevant to whether an arrangement incentivizes referrals. Outside of the ownership context, "substantive" violations would be compensation structures that induce or reward referrals.

3. Fair Market Value

Commenters had differing ideas on how to deal with fair market value issues with some suggesting that arrangements be divided into two categories: (1) where the compensation is in excess of fair market value (and perhaps commercial reasonableness) and/or is determined in a manner that takes into account the volume or value of referrals; and (2) those where compensation is not. The commenters recognized that the division is not clear cut, but many agreed that any meaningful change to the Stark law must address volume and value, and, to a lesser extent, fair market value.

4. Compensation Arrangements That Do Not Violate the AKS

Several commenters suggested that any compensation arrangement that did not

violate the AKS would be a technical violation. As such, prohibited ownership violations would be substantive noncompliance while compensation arrangement violations would be enforced through the AKS or the CMP law.

5. Creating an Exception for Technical Noncompliance

One commenter suggested that an exception be created for technical noncompliance without specifying how to differentiate between technical and substantive violations.

6. Determining Penalties for Technical Violations

Some commenters advocated giving the Secretary explicit authority to reduce penalties or apply CMPs in lieu of penalties, and that certain factors be considered, including (1) whether the violation is technical or substantive; (2) whether the parties' failure to meet all of the prescribed criteria of an applicable exception was due to an innocent or unintentional mistake; (3) the corrective action taken by the parties; (4) whether the services provided were reasonable and medically necessary; (5) whether access to a physician's services was required in an emergency situation; and (6) whether the Medicare program suffered any harm beyond the statutory disallowance.

General Recommendations Beyond MACRA and Defining Technical Violations[30]

Other comments were received on issues outside of MACRA and technical violations that were noted in the Report:

1. Aligning the Stark Law with AKS

Commenters noted the inclusion of AKS compliance standards within various Stark law compensation exceptions stacks the deck against hospitals trying to obtain predictability with Stark law compliance. Commenters believe that the Stark law should be aligned with the AKS, which could be accomplished by replacing certain Stark law exceptions with AKS exceptions [*e.g.,* the Stark law employment exception (which currently has a FMV requirement) would be identical to the AKS employee exception (which does not have a FMV requirement)] or determining that any arrangement that complies with an AKS safe harbor is exempt from the Stark law.

2. Reversing the Premise and Changing the Burden of Proof

One commenter suggested reversing the premise on certain compensation relationships that are "strict liability" and placing the burden on the government to show a violation. However, the Report notes that the argument against reversing the premise is the difficulty in defining a list of all illegal arrangements that could mask self-referrals.[31]

3. Simplify/Clarify Terms and Exceptions

Commenters recommended clarification of three key terms related to compensation arrangements: fair market value, "takes into account" the "volume or value" of referrals, and commercial reasonableness. There were a number of suggestions specific to the definitions, including removing the term "commercially reasonable," removing the "volume or value" restriction from the definition of "group practice," and narrowing the definitions of "remuneration" and "compensation arrangement" to state that fair market value exchanges do not implicate the Stark law.

Conclusion

The Report identifies many of the challenges faced by health care providers with respect to Stark law compliance from an operational perspective and how it affects their ability to fully engage in the creation of innovative health care payment models. Reform efforts have been discussed in the past, and while some changes have been

made to address issues, those efforts are *ad hoc* and incremental.

The passage of MACRA and the ongoing push for Stark law reform has forced Congress to more closely examine whether the Stark law in its current form has become an impediment to the changes necessary to fully implement meaningful health care reform. The answer from the commenters who participated in the round table and contributed to the Report is a resounding "yes," that it does stifle the industry's ability to fully participate in health care reforms, and creates an enormous compliance burden that diverts resources from productive efforts to improve the health care delivery system.

Hopefully the suggestions gleaned through this process will provide Congress with some concrete ideas for Stark law reforms that will ease the regulatory burden on health care providers and permit the innovations that have been shown to improve the quality, efficiency, and cost-effectiveness of the health care delivery system. It's time.

Endnotes:

1. 66 *Fed. Reg.* 856, 859 (January 4, 2001) ["Prior to enactment of section 1877, there were a number of studies, primarily in academic literature, that consistently found that physicians who had ownership or investment interests in entities to which they referred ordered more services than physicians without those financial relationships (some of these studies involved compensation as well)."]
2. Omnibus Budget Reconciliation Act of 1989, § 6204 (Pub. L. 101-239, Dec. 19, 1989); Social Security Act, § 1877 (codified at 42 U.S.C. § 1395nn (2010) and in implementing regulations at 42 C.F.R. § 411.350 *et seq.* (2015)).
3. Omnibus Budget Reconciliation Act of 1993, Pub. L. 103-66 (1993).
4. Designated health services (DHS) means any of the following services:
   - Clinical laboratory services
   - Physical therapy, occupational therapy, and outpatient speech-language pathology services
   - Radiology and certain other imaging services
   - Radiation therapy services and supplies
   - Durable medical equipment and supplies
   - Parenteral and enteral nutrients, equipment, and supplies
   - Prosthetics, orthotics, and prosthetic devices and supplies
   - Home health services
   - Outpatient prescription drugs
   - Inpatient and outpatient hospital services
5. Pub. L. No. 111-148 (March 23, 2010).
6. Pub. L. No. 111-152 (March 23, 2010).
7. Social Security Act § 1899 (1935)(as added and amended March 23, 2010), 42 U.S.C. § 1395jjj (2010).
8. CMS Shared Savings Program Web site, www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html?redirect=/sharedsavingsprogram/ (last visited Sep. 27, 2016).
9. *Id.*
10. CMS ACO Web site, www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ACO/index.html (last visited Sep. 27, 2016).
11. CMS Press Release, www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-08-25.html (last visited Sep. 27, 2016).
12. Social Security Act § 1128B(b)(1935)(as amended and updated Dec. 28, 2015); 42 U.S.C. § 1320a-7b(b) (West 2015).
13. Social Security Act § 1128A(a)(5)(as amended and updated April 16, 2015); 42 U.S.C. § 1320a-7a(a)(5) (West 2015) and Social Security Act §§ 1128A(b)(1) and (2)(as amended and updated April 16, 2015); 42 U.S.C. § 1320a-7a(b)(1) and (2)(West 2015).
14. Medicare Program; Final Waivers in Connection with the Shared Savings Program; Interim Final Rule – 76 *Fed. Reg.* 67992 (November 2, 2011), www.gpo.gov/fdsys/pkg/FR-2011-11-02/pdf/2011-27460.pdf.
15. Medicare Program; Final Waivers in Connection with the Shared Savings Program; Final Rule – 80 *Fed. Reg.* 66726 (October 29, 2015), www.gpo.gov/fdsys/pkg/FR-2015-10-29/pdf/2015-27599.pdf.
16. *Id.* at 66726.
17. Pub. L. No. 114-10 (April 16, 2015); 42 U.S.C. § 1395l (West 2015).
18. Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), H.R. 2, Pub. Law 114-10, AMA Summary, www.sdcms.org/Portals/18/Assets/pdf/ama/2015-05-07-hr-2-detailed-summary-branded.pdf (last visited Sep. 27, 2016).
19. 81 *Fed. Reg.* 28,161 (May 9, 2016).
20. Senate Committee on Finance Report, "Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models" (June 30, 2016), www.finance.senate.gov/imo/media/doc/Stark%20White%20Paper,%20SFC%20Majority%20Staff.pdf (last visited Sep. 27, 2016).
21. Examining the Stark Law: Current Issues and Opportunities Before the Senate Committee on Finance (the "Report"), 114th Cong., www.finance.senate.gov/hearings/examining-the-stark-law-current-issues-and-opportunities (last visited Sep. 27, 2016).
22. *Id. See also*, the written testimony of Mr. Troy Barsky, www.finance.senate.gov/imo/media/doc/Senate%20Finance%20Committee%20-%20Barsky%20Written%20Testimony%20on%20Stark%20Law1.pdf (last visited Sep. 27, 2016).

23. *Id.* See also, the written testimony of Ronald A. Paulus, M.D., www.finance.senate.gov/imo/media/doc/12jul2016Paulus.pdf (last visited Sep. 27, 2016).
24. *Id. See also*, the written testimony of Mr. Peter B. Mancino, www.finance.senate.gov/imo/media/doc/12jul2016Mancino.pdf (last visited Sep. 27, 2016).
25. *See,* Senate Finance Committee Report at 1-2.
26. *Id.* at 2.
27. *Id.* at 8-13.
28. *Id.* at 13-17.
29. H.R. 776, 114 Cong. (2015).
30. *See,* Senate Finance Committee Report at 17-19.
31. American Health Lawyers Association, A Public Policy Discussion: Taking Measure of the Stark Law, a publication of the American Health Lawyers Association Public Interest Committee, (2009), www.healthlawyers.org/hlresources/PI/ConvenerSessions/Documents/Stark%20White%20Paper.pdf.

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