



800 10th Street, NW
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100 Phone
www.aha.org

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The Honorable Orrin Hatch
Chairman
Committee on Finance
219 Dirksen SOB
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance
219 Dirksen SOB
Washington, DC 20510

Dear Chairman Hatch and Senator Wyden:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to provide input on how to improve the physician self-referral (Stark) law. We welcome the Committees' focus on the law's challenges to implementing new payment models and the changes that experience shows would be essential to realizing their full benefit for improving quality, outcomes and efficiency in the delivery of patient care.

As the reimbursement landscape changes for hospitals, physicians and other health care providers, moving to a value-based paradigm from a volume-based approach, enforcement mechanisms and perspectives tethered to a by-gone era must be revisited, revised and, in some cases, abandoned to make way for innovation and improvement. Today, health care services are delivered through collaboration by multidisciplinary teams of professionals and providers in a growing variety of settings. Public and private payers increasingly are using incentives to drive behavior to achieve efficiencies and outcomes. To achieve those goals, the financial interests of members of the team need to be aligned. In this changing environment, it is imperative that laws affecting the ability of hospitals, physicians and others to work together should facilitate, rather than limit, those efforts.

As Congress recognized last year in the Medicare Access and CHIP Reauthorization Act (MACRA), the Stark law is not the only one that has created impediments to implementation of these new payment models. We applaud Congress's elimination of a barrier created by the "gainsharing" Civil Monetary Penalty (CMP). As interpreted by the Office of Inspector General (OIG), it prevented hospitals from sharing financial incentives with physicians for developing and implementing evidence-based care guidelines. In the MACRA, Congress made clear that a penalty was intended only if a hospital made payments to a physician to reduce or limit *medically necessary* care. As a result, hospitals and physicians can share the rewards for improving quality of care without risk of sanction under that law.



Below, we begin by addressing the two items identified as of primary interest in the Committees' request for input:

- What changes in the Stark law are needed to implement the MACRA in its current form, as well as accountable care organization (ACO)/shared savings programs; and
- Where to draw the line between technical and more serious violations of the law.

LEGAL IMPEDIMENTS TO IMPLEMENTATION OF NEW PAYMENT MODELS

We understand and echo the importance of focusing on the Stark law and removing the barriers it creates. The Stark law, however, is not the only legal barrier that needs to be addressed. Hospitals, physicians and other health care providers must break out of the silos of the past and work as teams to achieve the efficiencies and care improvement goals of the new payment models. To do that, a legal safe zone for those efforts is needed that cuts across the fraud and abuse laws (Stark, anti-kickback and certain CMPs).

In our view, the Stark law is not suited to the new models and should not be the locus of oversight for these new arrangements. The statute and its complex regulatory framework are designed to keep hospitals and physicians apart – the antithesis of the new models. Its core provisions micro-manage compensation arrangements on a strict liability basis that has proved unworkable. **To us the answer seems clear: Congress should adopt a single, broad exception that cuts across the Stark law, the anti-kickback statute and relevant CMPs for financial relationships designed to foster collaboration in the delivery of health care and incentivize and reward efficiencies and improvements in care. We recommend that the exception be created under the anti-kickback statute and arrangements protected under the exception be deemed compliant with the Stark law and relevant CMPs.**

The need to reset oversight of these arrangements is reinforced by Congress's repeated grant of authority to the Secretary of Health and Human Services (HHS) to waive their application in the various demonstrations, pilots and other innovation programs. For example, when crafting the Medicare Shared Savings Program (MSSP), Congress granted the Secretary authority to waive provisions of the anti-kickback, Stark and CMP laws to remove these impediments to the successful creation and operation of Medicare ACOs. It did the same to enable new models to be tested under the Innovation Center. The Secretary has made full use of that authority with the new models. We urge adoption of a new framework for oversight of these efforts so the benefits of the quality and efficiency improvements are available to all Medicare beneficiaries, not only those affected by a discrete programmatic initiative.

THE PROBLEM

The Stark law's oversight of compensation arrangements is anchored in a fee-for-service world where physicians were self-employed, hospitals were separate entities, and both billed for

services on a piecemeal basis. It presumes that compensation arrangements are suspect and attempts to micromanage the circumstances in which a compensation arrangement is permitted and the amount paid. Increasingly, public and private payers are holding hospitals accountable for reducing costs and improving quality, and using financial incentives to drive behavior. Payment models for physicians also are using financial incentives to drive behavior. Achieving Congress's goals for the government health care program and beneficiaries can be accomplished only through teamwork among hospitals, physicians and other health care providers across sites of care. An essential component for the success of their efforts is also the use of financial incentives – specifically, arrangements that align incentives.

Yet the ability to share the rewards of collaboration is different for hospital-physician relationships than when a physician practices alone or as part of a group. As interpreted today, the two “hallmarks” of acceptability under the Stark law – fair market value and commercial reasonableness – are not suited to the collaborative models that reward value and outcomes. Fair market value has become a rigid measure of hourly wage equivalents. Commercial reasonableness has been contorted to cap a physician’s compensation at levels that he or she could generate if he or she remained an independent seller of physician services, even if part of that compensation is paid for supervising non-physician members of a multidisciplinary team in the efficient delivery of quality care. And the statutory and regulatory caveat that compensation may not take into account or vary with the volume or value of referrals, as interpreted by law enforcement officials today, has become a “gotcha,” since compensation tied to successful outcomes almost necessarily includes some nexus to the number of patients whose treatment a physician oversees.

For example:

- A hospital and a primary care physician want to work together to expand access to primary care by adding a nurse practitioner and social worker to the practice. Each beneficiary would have a team for his or her care, and the practice would be able to serve additional beneficiaries. An individual newly released from the hospital would get assistance from the social worker in implementing and arranging for the follow-up care prescribed by the physician in the discharge plan. The nurse practitioner would follow-up to monitor the effect of medications. The physician, social worker and nurse practitioner would each be available to the beneficiary and collectively coordinate his care. Each beneficiary would have the benefit of the same coordinated care. The result: A beneficiary would have someone to call or an office to visit instead of a trip to the emergency department and avoidable readmissions would be reduced.
 - The problem: Compensation of the physician cannot recognize the quality of the services provided by the other team members and the clinical outcomes, nor increase to recognize the expansion of services he or she oversees.
- A hospital wants to engage physicians to improve clinical outcomes and the recovery time for certain hospitalized patients (e.g., those with an acute diabetic condition). The work would involve consensus building, research and study to select appropriate, evidence-based

clinical protocols. The hospital would like to use financial incentives to encourage and reward consistent implementation of those clinical protocols.

- The problem: Compensation of the physicians cannot recognize adherence to the protocol for individual patients or the achievement of clinical outcomes.
- A hospital wants to establish the electronic infrastructure for sharing medical record information among physicians and other providers and professionals who are part of the care team for a patient after discharge. Having real-time and complete information across the patient's care team will facilitate the care coordination to optimize the individual's recovery and health status.
 - The problem: A hospital may not bear the cost of the investment.

At the same time, Medicare is conditioning a portion of payment to hospitals on achieving goals that require the collaboration of hospitals and physicians across the care continuum (e.g., specific metrics regarding readmissions and hospital-acquired conditions, bundled payment for the Comprehensive Care for Joint Replacement model). Physician payment is undergoing a similar change. The MACRA ties a portion of most physicians' Medicare payments to performance on specified metrics, beginning in 2019. It also includes financial incentives to encourage physician participation in alternative payment models. While these changes in hospital and physician payments have been made on separate, but parallel, tracks, all are making shared performance objectives and financial incentives important among providers across the care continuum.

A SOLUTION: NEW EXCEPTION FOR TEAM-BASED CARE

We urge the creation of an exception under the anti-kickback statute for hospital-physician clinically integrated arrangements designed to achieve the efficiencies and care improvement goals of new payment models. There should be protection for shared savings and incentive programs, as well as any arrangement start-up or support contribution. Any arrangement covered by the exception would be deemed compliant with the Stark law and applicable CMPs.

The exception should establish the basic accountabilities for an arrangement: The shared savings or incentive payments should be part of a documented program; performance practices under each program must be supported by credible medical evidence; the program must have ongoing monitoring to protect against reductions or limitation of medically necessary care; and payments must reflect the achievements of the physician, the practice or the program. The exception should recognize existing quality improvement processes and the reporting and other quality and safety oversight within the Medicare program.

A new exception also would address the impediments created by the anti-kickback statute on implementation of new payment models. The enforcement landscape has effectively made any financial relationship between hospitals and physicians questionable. If a hospital rewards a physician for following evidence-based clinical protocols, the reward could be construed as violating the law, since technically such a reward could influence a physician's order for treatment or services. In acknowledgement that there are cases where the anti-kickback statute

thwarts good medical practices, Congress has periodically created “safe harbors” to protect those practices.

This is another occasion where the same is needed. Hospitals and physicians should not have to spend hundreds of hours or thousands of dollars in hopes of stringing together components from the existing exceptions and safe harbors or developing inefficient work-arounds to try to ensure that their efforts to achieve the goals of the new payment models are achieved and do not run afoul of such laws and regulations. The exception also should apply when an arrangement includes other providers and professionals.

DISTINGUISHING BETWEEN TECHNICAL AND SUBSTANTIVE VIOLATIONS AND OTHER STARK LAW CHALLENGES

While originally intended to provide a “bright line” standard to assure hospitals and others clear guidance, the self-referral law has evolved into a series of increasingly complex, confusing and continually changing rules. Many involve form and audit-type requirements that carry the same weight as the core requirements of a legitimate arrangement for compliance purposes. As a result, the Stark law places hospitals at risk for draconian compliance penalties that have no relationship to the harm, if any, to the Medicare program. As a strict liability statute, any violation is subject to the same penalty – return of any amount paid by the Medicare program for services provided to a beneficiary and billed to the program based on a physician’s “self-referral,” without regard to whether the services were medically necessary.

Congress recognized the difficulties created when all requirements in the law are given the same weight when it granted the Secretary authority to develop a self-referral disclosure protocol (SRDP) to enable providers to disclose actual or potential violations. Importantly, the Secretary also was granted authority to determine what, if any, repayment is due by a provider based on the individual facts and circumstances of the situation after consideration of certain factors: (1) the nature and extent of the improper or illegal practice; (2) the timeliness of the self-disclosure; (3) the cooperation in providing additional information related to the disclosure; (4) the litigation risk associated with the matter disclosed; and (5) the financial position of the disclosing party.

The AHA supported creation of an SRDP throughout the legislative process as a means to address the unintended consequences of a strict liability approach and restore fairness to a law that makes compliance a virtual impossibility. We urged, and continue to urge, that the amount of any repayment should be calibrated to the harm, if any, to the program. Distinguishing “technical” from “substantive” violations has become shorthand for identifying the types of violations for which there should be no repayment or only a nominal amount.

In principle, we believe that any requirement governing the form rather than the substance of an arrangement is a technical rather than substantive requirement. This would include: a requirement that an arrangement be set forth in writing; a requirement that the writing setting forth the arrangement be signed by one or more parties to the arrangement; and/or a requirement that an arrangement that expires according to the terms of the writing be extended under the

terms of a written amendment or new agreement. For example, arrangements involving missing signatures, or where a course of dealing demonstrates that parties had agreed to an economically compliant but undocumented, or improperly documented, arrangement would be covered.

We believe the statute should require that enforcement take into account mitigating factors when a violation does occur. These factors should include: whether the violation is “technical” or “substantive;” whether the parties’ failure to meet all the prescribed criteria of an applicable exception was due to an innocent or unintentional mistake; the corrective action taken by the parties; whether the services provided were reasonable and medically necessary; whether access to a physician’s services was required in an emergency situation; or whether the Medicare program suffered any harm beyond the statutory disallowance.

Regarding other Stark law challenges, the most consequential are the unpredictable and potentially catastrophic developments occurring in litigation. Punitive fines and penalties are threatened that bear no relation to the value or volume of the harm novel relationships may cause the federal health care programs. And even worse, the guidance issued by the Centers for Medicare & Medicaid Services to implement the law is being disregarded and has now been shown to be irrelevant as a defense to hospitals who relied on it. As described earlier in this letter, fair market value, commercial reasonableness and the volume/value prohibition are imbedded in the exceptions for compensation arrangements. The specter of relators and the relator’s bar taking control of how to interpret the Stark law in service of achieving the financial bounties available under the False Claims Act, will no doubt chill, and could extinguish, the development of new relationships essential to the success of the new reimbursement models.

Thank you for the opportunity to provide input on this important issue. We stand ready to provide additional detail on our recommendations. If you have any questions or would like additional information, please contact Maureen Mudron, deputy general counsel, at (202) 626-2301 or mmudron@aha.org or Robyn Bash, vice president of government relations and public policy operations, at (202) 626-2672 or rbash@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President

CC:

The Honorable Kevin Brady
The Honorable Sander Levin
The Honorable Peter Roskam
The Honorable John Lewis
The Honorable Patrick Tiberi
The Honorable James McDermott