

AMERICAN MEDICAL ASSOCIATION PRIVATE PRACTICE PHYSICIAN SECTION

Resolution: 5
(1-23)

Introduced by: Daniel Choi, MD
Subject: Reforming Stark Law's Blanket Self-Referral Ban
Referred to: PPPS Reference Committee
(, MD, Chair)

1 Whereas, Current Stark law imposes inconsistent restrictions on physicians self-referral without
2 placing any limitations on hospital system self-referral practices with many health systems
3 requiring self-referral while physicians who self-refer face thousands of dollars in fines,
4 exclusion from Medicare and Medicaid, and possible jail time, thereby creating an unfair
5 competitive landscape within the healthcare industry^(1,2); and
6
7 Whereas, The unequal restriction on self-referral has contributed to a trend of consolidation and
8 vertical integration—including hospitals' and payers' acquisition of clinics, ambulatory surgery
9 centers (ASCs), and similar entities—exacerbating rising healthcare costs while degrading the
10 quality of patient care⁽³⁻⁵⁾; and
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12 Whereas, For the optimal performance of integrated care delivery platforms to be bot high-
13 quality and cost-effective while at the same time patient-centered depends on the alignment of
14 incentives for physicians and would require physicians have the opportunity to compete with
15 health systems and payer-providers; however, current Stark law effectively prohibits physicians
16 from competing with these vertically integrated healthcare entities in the delivery of integrated
17 care to our patients, further demonstrating the need to balance the benefits of integration with
18 the importance of preserving a fair and competitive environment for physicians; and
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20 Whereas, The prohibition of self-referral perpetuates challenges that can hinder patient access
21 to care by shifting the burden of quality assessment onto patients who may lack the necessary
22 information to make informed decisions⁶; and
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24 Whereas, The restriction on self-referral for Medicare and Medicaid patients may compel
25 physicians to refer patients to providers without sufficient knowledge of their particular quality or
26 capabilities, impacting patient outcomes; and
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28 Whereas, The current self-referral prohibition impedes the implementation of capitated, risk-
29 adjusted payment models within healthcare delivery, limiting the ability to explore innovative
30 care arrangements that prioritize cost-effective and patient-centered care; and
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32 Whereas, Our American Medical Association has a responsibility to investigate issues that
33 impact physicians and their patients; therefore be it
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35 Resolved, That our American Medical Association recognizes the substantial impact of the Stark
36 law's unequal restrictions on independent physicians, contributing to the growing trend of
37 hospital consolidation within the healthcare landscape (New HOD Policy); and be it further
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1 Resolved, That our American Medical Association supports comprehensive Stark law reform
2 aimed at rectifying the disparities by ending the blanket ban on self-referral practices,
3 particularly in the context of capitated, risk-adjusted payment programs such as Medicare
4 Advantage and Medicaid managed care (Directive to Take Action); and be it further
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6 Resolved, That our American Medical Association is committed to advocating for equitable and
7 balanced Stark law reform that fosters fair competition, incentivizes innovation, and facilitates
8 the delivery of high-quality, patient-centered care across the healthcare industry (New HOD
9 Policy).

Fiscal Note: TBD

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RELEVANT AMA POLICY

Stark Law and Physician Compensation H-385.914

Our AMA opposes and continues to advocate against the misuse of the Stark Law and regulations to cap or control physician compensation.

Citation: BOT Rep. 6, I-15

Physicians' Involvement in Commercial Ventures H-140.984

Our AMA opposes an across-the-board ban on self-referrals because of benefits to patients including increased access and competition, but proposes a list of standards to ensure ethical and acceptable financial arrangements:

- (1) Opportunity to Invest - The opportunity to invest in the medical or health care facility established by a health care service(s) (HCS) financial arrangement should be open to all individuals who are financially able and interested in the investment. This would include non-physicians. The only exception allowed would be for a sole community health care provider where ownership could be limited to potential referring physicians or their immediate family due to a lack of other individuals who have sufficient capital and interest to establish the facility.
- (2) Real Investment at Risk - Each investor should be undertaking a real financial risk similar to that which might occur in any other similar commercial investment. A referring physician should not be allowed to become involved in the HCS investment without incurring a real financial risk. The ability of a physician to refer patients must not be considered "capital" to become an investor in the facility. Each investor in the medical facility must be at risk by virtue of a binding commitment to capitalize the venture, such as a commitment to contribute money, property or services.
- (3) Patient Referral Requirement - No investor in the medical facility can be required or coerced in any manner to refer patients to the facility. No investor can be required to divest his or her investment for failure to refer patients. No investor can be required to divest because he or she moves from the area or ceases practicing medicine.
- (4) Distribution of Profit or Equity - Distribution should be based generally on the amount contributed to capital. Remuneration or profit distribution may not be related to patient referrals.
- (5) Disclosure of Ownership Interest - A physician or other health care professional or provider with an ownership interest in a medical or other health care facility or service to which the physician refers patients must disclose to the patients this ownership interest. A general disclosure can be made in a manner which is appropriate to his or her practice situation.
- (6) Request for Care - Each patient of a physician with an ownership interest (or whose immediate family member has an interest) must be provided with a physician's request for ancillary care to enable the patient to select a facility for such care. However, in accordance with the physician's ethical responsibility to provide the best care for the patient, the physician must be free to recommend what in the physician's judgment is the most appropriate facility, including his or her own facility.
- (7) Notification of Ownership Interest to Payer - If the physician (or immediate family member) has an ownership interest in a medical or health care facility or service to which he or she refers patients who are Medicare beneficiaries, this physician should identify the ownership interest on the Medicare claim form. If the Medicare carrier detects a pattern suggesting inappropriate utilization, the matter could be referred to the PRO for follow-up pursuant to the existing PRO

review process. Such PRO review would have to be conducted in a uniformly fair, open-minded manner.

(8) Internal Utilization Review Program - Each medical facility with referring physician owners (or immediate family members) must have an internal utilization review program to monitor referrals by such physicians. Regular reports from this internal program should be made available to the Medicare carrier on request.

(9) Compliance with Standards - Failure to comply with any one individual standard or compliance with all the standards, in and of itself, would not be sufficient to find that the arrangement is illegal. The entire arrangement needs to be examined to determine whether it is merely a sham arrangement to conceal a kickback scheme or whether it is "legal." Failure to comply with standards would subject the HCS investment arrangement to further scrutiny.

Citation: BOT Rep. ZZ, A-89; Reaffirmed: Sunset Report, A-00; Reaffirmed: Res. 201, I-00; Reaffirmation A-02; Reaffirmation I-04; Reaffirmation A-09; Reaffirmed: Res. 239, A-12; Reaffirmation A-15; [Reaffirmed: CMS Rep. 05, A-17](#)

Health Care Entity Consolidation D-383.980

Our AMA adopts the following Accountable Care Organization (ACO) principles:

1. Guiding Principle - The goal of an ACO is to increase access to care, improve the quality of care and ensure the efficient delivery of care. Within an ACO, a physician's primary ethical and professional obligation is the well-being and safety of the patient.

2. ACO Governance - ACOs must be physician-led and encourage an environment of collaboration among physicians. ACOs must be physician-led to ensure that a physician's medical decisions are not based on commercial interests but rather on professional medical judgment that puts patients' interests first.

A. Medical decisions should be made by physicians. ACOs must be operationally structured and governed by an appropriate number of physicians to ensure that medical decisions are made by physicians (rather than lay entities) and place patients' interests first. Physicians are the medical professionals best qualified by training, education, and experience to provide diagnosis and treatment of patients. Clinical decisions must be made by the physician or physician-controlled entity. The AMA supports true collaborative efforts between physicians, hospitals and other qualified providers to form ACOs as long as the governance of those arrangements ensure that physicians control medical issues.

B. The ACO should be governed by a board of directors that is elected by the ACO professionals. Any physician-entity [e.g., Independent Physician Association (IPA), Medical Group, etc.] that contracts with, or is otherwise part of, the ACO should be physician-controlled and governed by an elected board of directors.

C. The ACO's physician leaders should be licensed in the state in which the ACO operates and in the active practice of medicine in the ACO's service area.

D. Where a hospital is part of an ACO, the governing board of the ACO should be separate, and independent from the hospital governing board.

3. Physician and patient participation in an ACO should be voluntary. Patient participation in an ACO should be voluntary rather than a mandatory assignment to an ACO by Medicare. Any physician organization (including an organization that bills on behalf of physicians under a single tax identification number) or any other entity that creates an ACO must obtain the written affirmative consent of each physician to participate in the ACO. Physicians should not be required to join an ACO as a condition of contracting with Medicare, Medicaid or a private payer or being admitted to a hospital medical staff.

4. The savings and revenues of an ACO should be retained for patient care services and distributed to the ACO participants.

5. Flexibility in patient referral and antitrust laws. The federal and state anti-kickback and self-referral laws and the federal Civil Monetary Penalties (CMP) statute (which prohibits payments by hospitals to physicians to reduce or limit care) should be sufficiently flexible to allow physicians to collaborate with hospitals in forming ACOs without being employed by the hospitals or ACOs. This is particularly important for physicians in small- and medium-sized practices who may want to remain independent but otherwise integrate and collaborate with other physicians (i.e., so-called virtual integration) for purposes of participating in the ACO. The ACA explicitly authorizes the Secretary to waive requirements under the Civil Monetary Penalties statute, the Anti-Kickback statute, and the Ethics in Patient Referrals (Stark) law. The Secretary should establish a full range of waivers and safe harbors that will enable independent physicians to use existing or new organizational structures to participate as ACOs. In addition, the Secretary should work with the Federal Trade Commission to provide explicit exceptions to the antitrust laws for ACO participants. Physicians cannot completely transform their practices only for their Medicare patients, and antitrust enforcement could prevent them from creating clinical integration structures involving their privately insured patients. These waivers and safe harbors should be allowed where appropriate to exist beyond the end of the initial agreement between the ACO and CMS so that any new organizational structures that are created to participate in the program do not suddenly become illegal simply because the shared savings program does not continue.

6. Additional resources should be provided up-front in order to encourage ACO development. CMS's Center for Medicare and Medicaid Innovation (CMI) should provide grants to physicians in order to finance up-front costs of creating an ACO. ACO incentives must be aligned with the physician or physician group's risks (e.g., start-up costs, systems investments, culture changes, and financial uncertainty). Developing this capacity for physicians practicing in rural communities and solo-small group practices requires time and resources and the outcome is unknown. Providing additional resources for the up-front costs will encourage the development of ACOs since the 'shared savings' model only provides for potential savings at the back-end, which may discourage the creation of ACOs (particularly among independent physicians and in rural communities).

7. The ACO spending benchmark should be adjusted for differences in geographic practice costs and risk adjusted for individual patient risk factors.

A. The ACO spending benchmark, which will be based on historical spending patterns in the ACO's service area and negotiated between Medicare and the ACO, must be risk-adjusted in order to incentivize physicians with sicker patients to participate in ACOs and incentivize ACOs to accept and treat sicker patients, such as the chronically ill.

B. The ACO benchmark should be risk-adjusted for the socioeconomic and health status of the patients that are assigned to each ACO, such as income/poverty level, insurance status prior to Medicare enrollment, race, and ethnicity and health status. Studies show that patients with these factors have experienced barriers to care and are more costly and difficult to treat once they reach Medicare eligibility.

C. The ACO benchmark must be adjusted for differences in geographic practice costs, such as physician office expenses related to rent, wages paid to office staff and nurses, hospital operating cost factors (i.e., hospital wage index) and physician HIT costs.

D. The ACO benchmark should include a reasonable spending growth rate based on the growth in physician and hospital practice expenses as well as the patient socioeconomic and health status factors.

E. In addition to the shared savings earned by ACOs, ACOs that spend less than the national average per Medicare beneficiary should be provided an additional bonus payment. Many physicians and physician groups have worked hard over the years to establish systems and practices to lower their costs below the national per Medicare beneficiary expenditures.

Accordingly, these practices may not be able to achieve significant additional shared savings to incentivize them to create or join ACOs. A bonus payment for spending below the national average would encourage these practices to create ACOs and continue to use resources appropriately and efficiently.

8. The quality performance standards required to be established by the Secretary must be consistent with AMA policy regarding quality. The ACO quality reporting program must meet the AMA principles for quality reporting, including the use of nationally-accepted, physician specialty-validated clinical measures developed by the AMA-specialty society quality consortium; the inclusion of a sufficient number of patients to produce statistically valid quality information; appropriate attribution methodology; risk adjustment; and the right for physicians to appeal inaccurate quality reports and have them corrected. There must also be timely notification and feedback provided to physicians regarding the quality measures and results.

9. An ACO must be afforded procedural due process with respect to the Secretary's discretion to terminate an agreement with an ACO for failure to meet the quality performance standards.

10. ACOs should be allowed to use different payment models. While the ACO shared-savings program is limited to the traditional Medicare fee-for-service reimbursement methodology, the Secretary has discretion to establish ACO demonstration projects. ACOs must be given a variety of payment options and allowed to simultaneously employ different payment methods, including fee-for-service, capitation, partial capitation, medical homes, care management fees, and shared savings. Any capitation payments must be risk-adjusted.

11. The Consumer Assessment of Healthcare Providers and Systems (CAHPS) Patient Satisfaction Survey should be used as a tool to determine patient satisfaction and whether an ACO meets the patient-centeredness criteria required by the ACO law.

12. Interoperable Health Information Technology and Electronic Health Record Systems are key to the success of ACOs. Medicare must ensure systems are interoperable to allow physicians and institutions to effectively communicate and coordinate care and report on quality.

13. If an ACO bears risk like a risk bearing organization, the ACO must abide by the financial solvency standards pertaining to risk-bearing organizations.

Citation: Res. 819, I-10; Reaffirmation A-11; Reaffirmed: Res. 215, A-11; Reaffirmation: I-12; Reaffirmed: CMS Rep. 6, I-13; Reaffirmed: Sub. Res. 711, A-15; Reaffirmation I-15; Reaffirmation: A-16; Reaffirmation: I-17; Reaffirmation: A-19; Reaffirmation: A-23

9.6.9 Physician Self-Referral

Business arrangements among physicians in the health care marketplace have the potential to benefit patients by enhancing quality of care and access to health care services. However, these arrangements can also be ethically challenging when they create opportunities for self-referral in which patients' medical interests can be in tension with physicians' financial interests. Such arrangements can undermine a robust commitment to professionalism in medicine as well as trust in the profession.

In general, physicians should not refer patients to a health care facility that is outside their office practice and at which they do not directly provide care or services when they have a financial interest in that facility. Physicians who enter into legally permissible contractual relationships—including acquisition of ownership or investment interests in health facilities, products, or equipment; or contracts for service in group practices—are expected to uphold their responsibilities to patients first.

When physicians enter into arrangements that provide opportunities for self-referral they must:

(a) Ensure that referrals are based on objective, medically relevant criteria.

(b) Ensure that the arrangement:

(i) is structured to enhance access to appropriate, high quality health care services or products; and

(ii) within the constraints of applicable law:

a. does not require physician-owners/investors to make referrals to the entity or otherwise generate revenues as a condition of participation;

b. does not prohibit physician-owners/investors from participating in or referring patients to competing facilities or services; and

c. adheres to fair business practices vis-à-vis the medical professional community—for example, by ensuring that the arrangement does not prohibit investment by nonreferring physicians.

(c) Take steps to mitigate conflicts of interest, including:

(i) ensuring that financial benefit is not dependent on the physician-owner/investor's volume of referrals for services or sales of products;

(ii) establishing mechanisms for utilization review to monitor referral practices; and

(iii) identifying or if possible making alternate arrangements for care of the patient when conflicts cannot be appropriately managed/mitigated.

(d) Disclose their financial interest in the facility, product, or equipment to patients; inform them of available alternatives for referral; and assure them that their ongoing care is not conditioned on accepting the recommended referral.

Citation: CEJA Rep. 1, I-08; Reaffirmation A-15

Physician Ownership and Referral for Imaging Services D-270.995

Our AMA will work collaboratively with state medical societies and specialty societies to actively oppose any and all federal and state legislative and regulatory efforts to repeal the in-office ancillary exception to physician self-referral laws, including as they apply to imaging services.

Citation: Res. 235, A-04; Reaffirmed in lieu of Res. 901, I-05; Reaffirmed: BOT Rep. 10, A-15; Reaffirmed in lieu of Res. 213, A-15