VIEWPOINT

Physician Self-referral
Regulation by Exceptions

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On June 2, 2014, the Government Accountability Office (GAO) released its fourth and final report on the national state of physician self-referrals.[1] Commissioned in 2010 by a bipartisan and bicameral congressional contingent, the GAO reports represent the latest audit of physicians who refer their patients to service facilities wherein they (or an immediate family member) have a financial interest.[1] Limited to self-referred services in the advanced imaging, anatomic pathology, radiation therapy, and physical therapy arenas, the GAO reports examined recent (2004-2010) growth rates in service utilization and the effect on Medicare Part B spending.[1] In this Viewpoint, we discuss the findings of the GAO, revisit the premise of physician self-referral, survey the relevant statutory and regulatory framework, and explore potential solutions to this vexing and costly challenge.

Relevant to the advanced imaging sector, the GAO audit found that the growth rate of self-referred services outpaced non–self-referred counterparts by a 7:1 margin for magnetic resonance imaging and a 3.5:1 margin for computed tomography.[1] Specifically, between 2004 and 2010, the number of magnetic resonance imaging services increased from about 380 000 to 700 000 for self-referred and from 1.97 million to 2.21 million for non–self-referred. Similarly, the number of computed tomography services increased from about 700 000 to 1.45 million for self-referred and from 1.90 million to 2.48 million for non–self-referred.

> Furthermore, it was the conclusion of the GAO that "financial incentives for self-referring providers were likely a major factor driving the increase in referrals."

Comparable findings were reported for anatomic pathology wherein increases in self-referred services (driven by the specialties of dermatology, gastroenterology, and urology) exceeded non–self-referred counterparts by a margin of 3:1.[1] Specifically, the number of services increased from about 1.06 million to 2.26 million for self-referred and from 5.64 million to 7.77 million for non–self-referred. Observations on self-referrals of intensity-modulated radiation therapy (IMRT) services for the treatment of prostate cancer were particularly disconcerting. The utilization of self-referred IMRT services (driven by urology groups) increased by as much as 356% (from about 80 000 to 366 000) at a time when the utilization of the non–self-referred variety decreased by 5% (from about 490 000 to 466 000).[1] No significant increments were noted in the utilization of self-referred physical therapy services.[1]

Taken together, the GAO audits reveal that in 2010 alone, the excess number of self-referred advanced imaging, anatomic pathology, and IMRT services increased Medicare Part B expenditures by approximately $300 million.[1] Furthermore, it was the conclusion of the GAO that "financial incentives for self-referring providers were likely a major factor driving the increase in referrals."[1]

The subject of contentious debates for over a quarter of a century, physician self-referral remains controversial. To its proponents, physician self-referral is a patient-centered care-improving proposition intent on facilitating authorization and scheduling, timely diagnosis and treatment, same-day one-stop convenience, and continuity of care in familiar settings. To its detractors, physician self-referral constitutes a cynical representation of capitalism at its worst, the divided loyalties of which are liable to compromise the ethical character of the medical profession and its all-important public trust. Characterized as potentially unnecessary and occasionally harmful, physician self-referral has been repeatedly shown to increase the use of the services offered and the related attendant overall costs.[2,3] It is this latter reality that has thrust physician self-referral into the national health care debate in which "bending the cost curve" remains an overriding imperative.

The initial surge of the self-referral model occurred against the backdrop of the Anti-Kickback Statute of 1972. The latter, a criminal construct that requires proof of intent to defraud to establish a violation, precludes the exchange of anything of value in return for referrals.[4] However, following an adverse administrative decision (*Hanlester Network v. Shalala*), the notion of relying on the Anti-Kickback Statute in the prosecution of illegal physician self-referral arrangements has been abandoned.[4] In the context of this relative statutory vacuum, Congress enacted the Stark I (Physicians Ownership of, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services) provision (also known as the Ethics in Patient Referrals Act) under the Omnibus Budget Reconciliation Act of 1989.[4] The more expansive Stark II (Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships) provision followed suit under the Omnibus Budget Reconciliation Act of 1993.[4]

The Stark provisions (later modified by numerous additional statutory and regulatory entries) prohibit a physician from referring designated health services pay-

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able by Medicare or Medicaid to an entity with which he or she (or an immediate family member) has a financial relationship.[4] However, enforcement of the Stark provisions has been compromised by multiple exceptions (35 in all) relevant to ownership interest and compensation arrangements.[4] Among those, the so-called In-Office Ancillary Service exception has been widely used to circumvent the Stark laws.[4] A strong case can be made for the argument that the multiplicity of extant statutory and regulatory exceptions has rendered the Stark provisions ineffective in reducing fraud and abuse.[4] Some of the same concerns apply to the more recent voluntary Self-Referral Disclosure Protocol established by the Affordable Care Act (section 6409), which tends to encourage amicable out-of-court settlement of potential violations.[5]

By most accounts, the persistent increase in physician self-referrals (as documented by the GAO) is due to inadequate statutory and regulatory oversight in the face of ongoing incentives afforded by the fee-for-service reimbursement model. It follows that optimal redress of the physician self-referral challenge will require the institution of novel payment mechanisms whereby the fee-for-volume environment has been replaced by fee-for-value alternatives like accountable care organizations in which physicians are rewarded for cost-effective care. The promise of payment model revision notwithstanding, the enormity of the transformation required suggests that this approach is unlikely to yield near-term relief for the self-referral challenge. It would thus appear that meaningful and timely redress of physician self-referrals will require regulatory or legislative relief. Support for legislative is substantial. Consensus recommendations of a broad swath of health policy experts called for the closure of "loopholes for in-office imaging, pathology laboratories, and radiation therapy."[6] Comparable recommendations were made by the Washington, DC–based Bipartisan Policy Center.[7]

Moreover, the 2015 budget of the Department of Health and Human Services (HHS) called for "amending the in-office ancillary services exception to prohibit certain referrals for radiation therapy, therapy services, advanced imaging, and anatomic pathology services . . . as defined by the Secretary."[8] The Congressional Budget Office estimated that implementation of the amendments in question will yield a total of $6 billion in savings over the next decade.[8] The only congressional bill aligned with the HHS plan—Promoting Integrity in Medicare Act of 2013 (HR 2914)—has yet to be considered by the House Subcommittee on Health.

A 1992 editorial singled out self-referral as a prime example of the "growing encroachment of commercialism on medical practice" previously characterized as the "medical-industrial complex."[9] Regrettably, more than 2 decades later, this observation of the failing of responsible professionalism still rings true. The recent GAO analysis reaffirms the inescapable effects of physician self-referral on increasing Medicare Part B spending.[1] Viewed in this light, the GAO reports must be seen as nothing less than a call for action. Congress should address the relative shortcomings of the well-meaning if ineffective Stark provisions and enact simpler and enforceable ordinances in its stead. Failure to do so would constitute a costly opportunity missed.

ARTICLE INFORMATION

Published Online: January 12, 2015. doi:10.1001/jama.2014.16600.

Conflict of Interest Disclosures: Both authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr Kocher reports being a member of the board of directors of Aledade; receiving personal fees from Gates Foundation, Healthcare Financial Management Association, National Institute for Health Care Management, and Premera; receiving travel support from the Institute of Medicine, America's Health Insurance Plans, and the University of Southern California; being the co-chair of the planning committee for the Health Data Consortium; and holding stock in Castlight. No other disclosures were reported.

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