



THE AMERICAN SOCIETY FOR CLINICAL PATHOLOGY
POLICY STATEMENT

SELF-REFERRAL, MARKUPS, FEE SPLITTING,
AND RELATED PRACTICES
(POLICY NUMBER 04-03)

POLICY STATEMENT:

ASCP strongly supports federal and state self-referral prohibitions, anti-markup requirements and other measures to prevent clinical providers from profiting on their patient referrals for anatomic pathology and clinical laboratory services.

BACKGROUND AND RATIONALE:

I. INTRODUCTION

Self-referral, the practice of referring patients for certain medical services in which the referring provider has an ownership or financial interest, and markups, the practice of a billing provider marking up the cost of services provided by others, are growing problems for patients and third party payers as well as clinical laboratories and pathologists. Increasingly, clinicians who rely heavily on anatomic pathology services are restructuring their practices so that they can capture revenues from anatomic pathology, clinical laboratory and other medical services generated by their patients.”¹ In general, these practices are illegal under Medicare and Medicaid and have been declared unethical by the American Medical Association.^{2, 3} Indeed, ASCP is concerned about the impact of abusive billing and contractual arrangements and practices on patient care and the health care system. As articulated by the Department of Health and Human Services Office of the Inspector General, these arrangements can adversely affect patient health and safety.

Profiting on patient referrals can cause a host of problems. Self-referral, markups and certain abusive contractual arrangements can distort rational medical decisions, lead to the overutilization of health care services and higher medical costs for patients and third party payers, and “cause unfair competition by freezing out competitors” unwilling to engage in such practices.^{4, 5, 6} They can also adversely affect patient welfare and clinical laboratories as well as undermine patient trust in the medical profession.^{7, 8, 9} Patients most likely to be affected by these inappropriate practices are often uninsured and those covered by private payers that have

not adopted safeguards similar to those designed to protect the Medicare program from abusive billing practices.

Provider self-referral and markups come in a number of permutations. In a nutshell, these involve clinicians or other health care providers acquiring anatomic pathology and clinical laboratory services at a discount to fair market value. Rather than passing these savings on to patients and payers, the ordering provider marks up the costs of the services to profit on their referral. In a 2005 article, the Wall Street Journal reported on the growing practice of clinicians marking up the cost of anatomic pathology and clinical laboratory services by utilizing “pod labs”¹⁰ and/or client billing arrangements.^{11,12} The article suggests that physician profiteering on work done by other providers can cost hundreds of dollars on a per patient/per visit basis.

As part of its proposed revisions to the Physician Fee Schedule for 2008, the Centers for Medicare and Medicaid Services established several new important anti-markup provisions to eliminate the potential for billing abuse by physicians utilizing “pod” labs (also known as “condo” labs) or other suspect billing practices to markup patient health care services.¹³ These rules, however, offer no protection against these practices to patients lacking insurance or covered by a private insurer. Unfortunately, the agency’s revisions to these provisions as part of the 2009 Physician Fee Schedule final rule may have inadvertently established several significant loopholes, which may spur overutilization and billing abuse.

As the U.S. Department of Health and Human Services has attempted to rein in abusive billing practices, clinicians have increasingly sought out other arrangements to evade the federal Stark and Anti-Kickback laws. For example, specialty physicians are increasingly establishing in-office laboratories to perform the technical and professional components of anatomic pathology services. Because the Stark law exempts in-office ancillary services, such as anatomic pathology, physicians are able to markup the costs of tests performed in their office. ASCP does not view anatomic pathology as an ancillary service but rather as an essential part of the practice of medicine.

II. ABUSIVE BILLING PRACTICES RESULT IN OVERUTILIZATION OF LABORATORY SERVICES

Abusive billing practices, such as markups, fee splitting and kickbacks, distort rational medical decisions as a result of an economic incentive to overutilize testing services.^{4,9} An incentive to overutilize laboratory services exists when the referring physician is in a position to profit on work performed by a clinical laboratory or pathologist.² Abusive billing practices, essentially relying on markups, increase the potential for harm to patients resulting from unnecessary testing and treatments.¹⁴ Moreover, these practices harm patients by unnecessarily raising the costs of health care and undermining patient trust in the medical profession.^{9,15}

This incentive is the same incentive addressed by the Anti-Kickback Statute and the Stark Law, which bars clinicians from referring patient specimens to laboratories in which they have a financial interest. Studies by the U.S. Department of Health and Human Services (HHS) and other government agencies have shown that referrals to entities in which physicians have a financial relationship encourage excessive use of services.¹⁴

Prior to enactment of the Stark law, an HHS Office of the Inspector General study found that physicians with a financial interest in the clinical laboratories to which they “referred Medicare patients [ordered] 45 percent more laboratory services than did physicians who did not have such financial interests.”¹⁵ In addition, the Center for Health Policy Studies found that laboratory charges per enrollee under private health insurance programs were 41 percent higher in non-direct billing states.¹⁶ This study also found that laboratory test utilization is higher in non-direct billing states. Direct billing laws require the individual or entity performing the services to bill for it, thus preventing ordering physicians from marking up the cost of the services they order.

In June 2007, OIG published three audits of physician group practices to examine their utilization of anatomic pathology services after entering into business arrangements, typically by utilizing a pod lab or contractual joint venture arrangement, to capture the revenues intended for the performance of the technical and professional components of anatomic pathology services.^{17, 18, 19} The OIG audits reveal an alarming increase in the utilization of anatomic pathology services once these group practices were able to capture the pathology-related revenues.

In the year after the three urology practices entered into arrangements allowing them to profit from their pathology referrals, their utilization of pathology services increased 699%, 230%, and 26%, respectively. One urology group practice increased its utilization of pathology services from one unit of service per patient to almost 9 units of service. With Medicare reimbursing the examination of a biopsy specimen at about \$110 per specimen this represents a cost increase of almost \$900 per patient. Another practice increased its utilization of pathology services from approximately 4 units of service to almost 12 units of service.

In addition, the OIG audits reveal that *all* of the audited physician groups billed significantly more biopsies than the carriers paid on average to other providers—124%, 65%, and 58%, respectively. It is difficult to justify such significant increases in utilization over a 2 year period on changes in “clinical practice,” considering the comparison with the billing practices of other providers. The OIG’s findings suggest that self-referral billing abuses of anatomic pathology services may be on par with the abuses that prompted the first Stark law.

III. ABUSIVE BILLING PRACTICES VIOLATE FEDERAL AND SOME STATE LAWS

With few exceptions, self-referral, markups, and fee splitting violate Medicare and Medicaid anti-kickback and federal self-referral laws. Federal self-referral laws prohibit physicians from referring Medicare patients for certain health care services, such as laboratory tests, to entities with which the physician or their immediate family members has a financial relationship. Federal anti-kickback laws prohibit payment, receipt, offering, or solicitation of remuneration in exchange for the referral of services or items covered by Medicare or Medicaid.¹⁵ Enforcement of the anti-kickback law requires proof of “knowing” and “willful” illegal remuneration, such as bribes or rebates, for patient referrals, and it can result in criminal sanctions.

Moreover, numerous states, such as Louisiana, California, New York, New Jersey, and Nevada have attempted to prevent abusive billing practices by establishing anti-markup or direct billing laws, which allow only the provider performing the service to bill for it.^{15, 20}

IV. ETHICAL IMPLICATIONS OF ABUSIVE BILLING PRACTICES

The American Medical Association (AMA) Council on Ethical and Judicial Affairs (CEJA) outlines the AMA's strong opposition to self-referral arrangements, markups, and fee splitting and related practices regarding clinician compensation for services performed by other providers, such as clinical laboratories and pathologists. In a recent report of the AMA Council on Ethical and Judicial Affairs, the Council wrote that the AMA "Code of Medical Ethics categorically prohibits compensation to physicians for referral of patients..."²¹

The following opinions are published in the AMA Code of Medical Ethics.

Opinion E-6.10 states "[a] physician should not charge a markup, commission or profit on the services rendered by others." In Opinion E-6.02, CEJA states "[p]ayment by or to a physician solely for the referral of a patient is fee splitting and is unethical." CEJA has also explained that if anatomic pathology services are provided at a discount, the purchasing physician *should not* [emphasis added] charge a markup.

AMA Opinion E-8.09(2) states, "[a] physician should not charge a markup, commission, or profit on the services rendered by others." This opinion describes a markup as "an excessive charge that exploits patients if it is nothing more than a tacked on amount for a service already provided and accounted for by the laboratory." The opinion does allow the clinician to bill "an acquisition charge or processing charge" but that the "patient should be notified of any such charge in advance." Moreover, this opinion states that a "physician who disregards quality as the primary criterion or who chooses a laboratory solely because it provides low-cost laboratory services on which the patient is charged a profit, is not acting in the best interests of the patient."

Additionally, CEJA favors direct billing of laboratory services in opinion E-6.09. This opinion states that "[w]hen it is not possible for the laboratory bill to be sent directly to the patient, the referring physician's bill to the patient should indicate the actual charges for laboratory services, including the name of the laboratory, as well as any separate charges for the physician's own professional services." CEJA Report 1-I-8 elaborates that "[i]n 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."¹⁸

It should be noted that CEJA has also addressed the practice of clinical laboratories engaging in fee splitting by compensating physicians for their referrals. In opinion E-6.03, CEJA states "clinics, laboratories, hospitals, or other health care facilities that compensate physicians for referral of patients are engaged in fee splitting which is unethical."

V. ECONOMIC IMPACT ON PATHOLOGISTS AND CLINICAL LABORATORIES

Over the past two decades federal and state reimbursements (Medicare and Medicaid) for laboratory services have declined significantly. Repeated erosions to the caps for laboratory fee schedule (known as the national limitation amounts) have declined 36 percent. Moreover, for almost 15 years now the annual adjustments for laboratory reimbursements haven't kept pace with inflation. In fact, the lack of a reliable annual update has further eroded laboratory reimbursements by over 20 percent. At the same time, the cost of providing laboratory services

has increased steadily, making it very difficult for clinical laboratories to provide state-of-the-art diagnostic facilities.

Many pathologists and clinical laboratories have also seen their revenues reduced, sometimes substantially, because they have lost contracts from clinicians who established their own laboratories, such as in-office laboratories or “pod” labs, to capture the reimbursements for these services. Because the practice of laboratory medicine is highly dependent on patient referrals, providers dependent on patient referrals, such as pathologists and clinical laboratories, have little ability to deter clinician markups or other abusive billing practices.

This inability to keep pace with the high costs of laboratory services is affectively undermining the ability of clinical laboratories to provide “accessible, efficient, and high quality testing.”²² Provider self-referral, markups and other similar practices are compounding the financial difficulties facing clinical laboratories today. The practice may force some clinical laboratories and pathology groups to reduce testing services, close or consolidate, thereby reducing patient access to care.²⁰ This could be particularly problematic for patients in rural and underserved areas. The impacts also affect laboratory staffing levels and may overtime contribute to personnel shortages.

VI. POLICY OPTIONS

The Society supports federal and state policy initiatives to eliminate or reduce the likelihood of inappropriate billing practices and patient abuse. Among the policy options available to federal and state policymakers are establishing or strengthening provider self-referral laws, anti-markup prohibitions, limitations on reassignment of billing rights, direct billing requirements, patient notification requirements, and exempting anatomic pathology services from the in-office ancillary services exception of the Stark law.

In general, self-referral laws prohibit physicians from referring patients for health care services in which they have an ownership stake or financial interest. Anti-markup provisions prohibit physicians from charging patients or providers more for a service than the physician was billed by the performing provider or entity.

Limiting billing rights can restrict the ability of individuals or entities performing a service to reassign their billing rights to providers that would markup the costs of those services. Direct billing requires the pathologist or laboratory to bill for the patient’s testing services. Patient notification requirements mandate that when physicians bill patients for testing services they do not perform, called client billing, that they inform the patient how much the physician was billed by the laboratory for the testing services. Exempting anatomic pathology services from the in-office ancillary services exception to the Stark Law would prevent clinicians from developing in-office anatomic pathology labs for the express purpose of profiting on their referrals.

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- ³ American Medical Association. Opinion E-6.10. Services Provided by Multiple Physicians. AMA Code of Medical Ethics. Chicago, IL: American Medical Association. 1994.
- ⁴ Special Advisory Bulletin: Contractual Joint Ventures. Office of the Inspector General. U.S. Department of Health and Human Services. April 2003. p. 2.
- ⁵ Report to the Congress: Medicare Payment Policy. The Medicare Payment Advisory Commission. March 2005. p. 143.
- ⁶ Goodell, S. Physician Self-referral and Physician Owed Specialty Facilities. Research Synthesis. Policy Brief 15. Robert Woods Johnson Foundation, June 2008. p.1.
- ⁷ Proposed Revisions to Payment Policies Under the Physician Fee Schedule. Centers for Medicare and Medicaid Services, U.S. Department for Health and Human Services. 72 Federal Register 38179. July 12, 2007.
- ⁸ Casalino, LP, Physician Self-referral and Physician Owed Specialty Facilities. Research Synthesis. Report 15. Robert Woods Johnson Foundation, June 2008.
- ⁹ Benjamin, R. Report of the Council of Ethical and Judicial Affairs: CEJA Report 1-I-08. American Medical Association. November 12, 2008. p. 2.
- ¹⁰ A typical “pod lab” arrangement for pathology services involves an entity that leases space in a medical building, subdivides it into separate cubicles or “pods,” equips each space with microscopes and other laboratory equipment, and leases out these limited labs to a physician group. The entity hires a histotechnologist to perform the technical component and arranges for a pathologist to perform the professional component. The entity charges the physician group a management fee that covers the space, equipment, and histotechnologist. The group practice compensates the pathologists on a per slide basis (a purchased test) or with a set fee. In this latter scenario, the pathologist reassigns his or her billing rights to the group practice. The group practice then bills for the professional component provided by the pathologist and the technical component provided by the histotechnologist.
- ¹¹ Client billing, also known as account billing, involves the ordering or referring provider purchasing the technical and professional component of a diagnostic services, usually at a discounted rate, and billing the patient or third party payer.
- ¹² Armstrong, D. Lucrative Operation: How Some Doctors Turn a \$79 Profit on a \$30 Test: Physician Groups Add Markup on Work Done By Others, Despite Ethics Concerns. Wall Street Journal. September 30, 2005. p. A1.
- ¹³ Revisions to Payment Policies Under the Physician Fee Schedule. Centers for Medicare and Medicaid Services, U.S. Department for Health and Human Services. 72 Federal Register 66306 November 27, 2007.
- ¹⁴ Hearing on Physician Self-Referral Regulations. Hearing before the Committee on Ways and Means Subcommittee on Health, U.S. House of Representatives. Testimony of Kathy Buto, Deputy Director, HCFA Center for Health Plans and Providers, U.S. Department of Health and Human Services. May 13, 1999.
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- ¹⁶ Dyckman, Z. Impact of Direct Billing Requirements For Laboratory Tests on Laboratory Charges, Utilization and Costs. Center for Health Policy Studies. March 1993. p. 15.
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- ²¹ Benjamin, R. Report of the Council of Ethical and Judicial Affairs: CEJA Report 1-I-08. American Medical Association. Adopted November 9, 2008. p. 2.
- ²² Statement of the American Clinical Laboratory Association. U.S. House Ways and Means Subcommittee on Health. April 20, 1993. p. 3.