

LEGAL AND REGULATORY FORCES AFFECTING PATHOLOGY IN 2008

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NEW ANTI-MARK UP RESTRICTIONS

As part of the 2008 Medicare Physician Fee Schedule, the Centers for Medicare and Medicaid Services (“CMS”) included restrictions on the ability of referring physician practices and suppliers to mark up the price of technical component or professional component diagnostic services. The restrictions became effective for anatomic pathology services on January 1, 2008. CMS has delayed the effective date of the new restrictions for diagnostic services *other than anatomic pathology services* until January 1, 2009.

The new rules provide that if a physician practice or supplier bills the Medicare program for the technical component or professional component of a diagnostic test that was ordered by the physician practice or supplier and the diagnostic test is either (1) purchased from an outside supplier (an independent contractor who has not reassigned his or her right to bill to the physician practice or supplier) or (b) performed at a site other than the “same building” of the billing physician practice or supplier (as defined under this Stark law), anti-markup restrictions are applicable. Under both of these scenarios, the payment to the billing physician practice or supplier for the technical or professional component of the diagnostic test may not exceed the lower of the following amounts: (1) the performing supplier’s net charge to the billing physician practice or supplier; (2) the billing physician’s or supplier’s actual charge; or (3) the Medicare fee schedule amount for the service.

For purposes of this restriction, the “same building” is defined under the Stark law as a building in which the referring physician, or another physician who is a member of the physician’s group practice, furnishes physician services unrelated to the furnishing of designated health services, and in which all of the criteria in any of subsections (1), (2) or (3) below must be met:

- (1) The referring physician, or the physician’s group practice, has an office that is normally open to patients for medical services at least 35 hours per week; and the referring physician, or one or more of the members of the physician’s group practice, regularly practices medicine and furnishes physician services to patients in the office at least 30 hours per week. The 30 hours per week have to include physician services that are unrelated to the provision of pathology services, even if such physician services may result in an order for pathology services;
- (2) The patient receiving pathology services usually receives physician services from the referring physician or members of the physician’s group practice; and the referring physician or the physician’s group practice owns or rents an office that is normally open to patients for medical services at least eight hours per week; and the referring physician regularly practices medicine and furnishes physician services to patients at

least six hours per week. The six hours per week must include some physician services that are unrelated to the provision of designated health services, including pathology services, even though such physician services may result in the order of designated health services (including pathology services); or

- (3) The referring physician is present and orders the pathology services during a patient visit, or the referring physician or a member of the physician's group practice is present while the pathology services are furnished; provided, however, that the referring physician or the referring physician's group practice owns or rents an office that is normally open to patients for medical services at least eight hours per week; and the referring physician or one or more members of the group practice regularly practices medicine and furnishes physician services to patients at least six hours per week. The six hours per week must include some physician services that are unrelated to the provision of designated health services, including pathology services even though such physician services may result in the order of designated health services (including pathology services).

More specifically, this provision will target offsite locations that referring physician practices or suppliers may have established for their ancillary services under the "centralized building" criterion of the Stark law's in-office ancillary service exception.

The new regulation explains that the "net charge" must be determined without regard to any charge that is intended to reflect the cost of equipment or space that is leased to the performing supplier by or through the billing physician practice or supplier. The commentary that accompanies the new regulation provides additional guidance, explaining that if the billing physician practice or supplier has incurred overhead expenses for technical and/or professional component services performed at a site other than the office of the billing practice or supplier (such as in space that is leased by the billing practice or supplier that meets the "centralized building" definition in the Stark law's in office ancillary services exception), the billing practice or supplier will not be able to recoup the overhead. CMS writes that "If the billing [practices and] suppliers were able to recoup overhead incurred for TCs and PCs that are performed at sites other than their offices, the effectiveness of the anti-markup provisions would be undermined, because there would be an incentive to overutilize to recover the overhead incurred for purchasing or leasing space."

NEW STARK PHASE III REGULATIONS

The Stark Phase III regulations were published in the Federal Register on September 5, 2007, to be effective on December 4, 2007. One of the changes in the Stark III regulations which would have a particular impact upon certain pathology arrangements is a change to the definition of a "physician in the group".

Many referring non-pathology practices (such as gastroenterology and urology practices) contract with pathologists to perform professional interpretations on behalf of the referring physician practices. Under such arrangements, the referring practices often submit claims to the payors, including the Medicare and Medicaid programs, for such professional interpretations. The referring physician practices are only permitted to bill the Medicare and Medicaid programs for such professional pathology interpretations if the arrangements fall within the "physician services" exception under the Stark law.

The physician services exception of the Stark self-referral restriction permits the referring physician practices to refer and bill for the professional pathology interpretations if the services are performed by a member of the group practice or a “physician in the group”. Previously, a pathologist could be considered a “physician in the group” if the pathologist’s group practice contracted with the referring physician practice for the professional interpretations. The new Stark Phase III regulations, however, state that a “physician in the group” must have a direct contractual arrangement with the referring physician practice. The Preamble to the Stark Phase III regulations clarifies that such a direct contractual relationship is intended to encompass only employment or independent contractor arrangements with the individual interpreting pathologist, and not his or her group practice.

Arrangements between referring physician practices and pathology practices pursuant to which the referring physician practices bill for the professional interpretations will need to be modified no later than the December 4, 2007, effective date to comply with these new regulations. Either the pathology practices will need to bill the Medicare and Medicaid programs directly for the professional interpretations, or the contractual arrangements will need to be modified so that each arrangement is structured between the referring physician practice and the individual interpreting pathologist.

ACCOUNT BILLING

In this arrangement, no pathology services are provided by the referring physician practice. Account billing involves the purchase of technical component and/or professional component pathology services for non-government patients by a referring physician practice, at a discounted rate. The referring physician practice then marks up the price of the purchased pathology services and re-bills the services.

Account billing arrangements only cover private payor services, because the federal restrictions governing the government health plans do not permit any markups on the government payor work. The pathology provider will bill government payors directly for the pathology services. It is also important to note that many states have restrictions on account billing arrangements, including the following:

Direct Billing: Arizona, Rev. Stat. 32-3210, California, Bus. & Prof. Code Sec. 655.6 (cytology); Iowa, Iowa Code Sec. 147.105; Kansas, K.S.A. 65-2837; Louisiana, Rev. Stat. Sec. 1742; Massachusetts, Mass. Gen. Laws Sec. 118G (29), Montana, Montana Code Sec. 37-2; Nevada, Rev. Stat. Sec. 652.195 (cytology); New Jersey, Stat. Sec. 45:9-42.41A; New York, Pub. Health Law Sec. 586; Rhode Island, Gen. Laws Sec. 23-16.2-5.1; South Carolina, South Carolina Code Sec. 44-132-10 - 40.

Anti-Markup: California, Bus. & Prof. Code Sec. 655.5; Florida, Admin. Code, Rule 59A-7.037; Michigan, Comp. Laws Ann. Sec. 445.161; Oregon, Rev. Stat. Sec. 676.310.

Disclosure (markup allowed so long as physicians disclose the price they paid for the testing to patients and non-federal third-party payers): Arizona, Rev. Stat. Sec. 36-472; Connecticut, Gen. Stat. Ann. Sec. 1769; Louisiana, Rev. Stat. Ann. Sec. 37:1741; Maine,

Rev. Stat. Ann. Sec. 2033; Maryland, Health Occ. Code Ann. Sec. 14-404; North Carolina, Gen. Stat. 90-681, Pennsylvania, Admin. Code Sec. 5.48; Tennessee, Tenn. Code. Ann. Sec. 63-6-214(b)(22); Texas, Health & Safety Code Sec. 161.061; Vermont, 26 Vt. Stat. Ann. Sec. 1354.

From a fraud and abuse perspective, it is important that the discount given to the physician practice for the technical and/or professional component services with respect to private payors reflect only the reasonable cost-savings realized by the pathology provider as a result of the account billing arrangement. In other words, it is acceptable for the pathology provider to pass along cost-savings as a result of streamlined billing to the physician practice, recognizing the cost savings associated with not billing individual claims to payors and patients, as well as cost-savings associated with the prompt payment (and no collection follow up) associated with account billing arrangements. Discounts up to 30-35% below the Medicare allowable generally are recognized as being within this reasonable range.

Discounts that exceed 30-35% below the Medicare allowable raise more of a red flag under the fraud and abuse laws. Because the physician practice makes referrals to the pathology provider for Medicare and Medicaid services, a deep discount could be viewed as a kickback to the physician practice in exchange for its referrals of government payor work. This concern is highlighted in Office of the Inspector General Advisory Opinion 99-13, which warns against deeply discounted account billing arrangements.

TC/PC ARRANGEMENTS

In the TC/PC scenario, the referring physician practice contracts with the pathology provider or individual pathologist(s) on an independent contractor to perform the professional interpretations on behalf of the physician practice, or with one or more individual pathologists on an employment basis to provide the professional interpretations. If the referring physician practice wishes to bill government payors for the professional interpretations, the physician practice will need to comply fully with an applicable Stark exception. Besides paying the pathology provider fair market value for the professional pathology interpretations, compliance with the Stark law typically will require the interpreting pathologist to provide the professional interpretations in the offices of the referring physician practice. The new anti-markup restrictions also will require the services to be performed in the offices of the physician practice if the physician practices wishes to obtain the full Medicare allowable payment for the interpretations. The referring physician practice will be responsible as well for supplying a microscope and office space to the pathologist, as well as transcription services.

This option involves the performance of the technical component by an outside laboratory. The laboratory will bill payors and patients directly for the technical component services. It is also possible for the laboratory to enter into an account billing arrangement with the physician practice, as discussed in the preceding section, for the private payor technical component work.

If the referring physician practice wishes to bill for the professional pathology interpretations, the physician practice also incurs the professional liability associated with these services. In virtually all such arrangements, the referring physician practice must purchase additional malpractice insurance to protect the physician practice in the event of acts or omissions by the pathologist. It is important to note that pathologist's professional liability insurance only covers the pathologist, and not the physician practice. Compliance with the Stark law requires the referring physician practice to

take full responsibility for the professional pathology interpretations, which must be reported out under the name of the physician practice. If the referring physician practice attempts to disclaim responsibility for the professional interpretations, it will be destroying its compliance with the Stark law.

In order to implement this TC/PC arrangement, the parties should execute either an employment or an independent contractor agreement for the professional pathology services, outlining the responsibilities of each party as well as the compensation terms. Prior to commencing to bill for the professional pathology services, the referring physician practice must enroll the interpreting pathologist(s) under the physician practice's managed care contracts as well as its Medicare and Medicaid group numbers.

At the same time, both parties should speak with their respective malpractice carriers to insure that they are fully covered for all risk exposures. As explained above, the referring physician practice will need to confirm that it is covered for any acts or omissions of the pathologist that are provided under the independent contractor or employment agreement. Similarly, the pathology provider should insure that its malpractice insurance also covers the pathologist(s) when services are being rendered on behalf of the referring physician practice.

IN-HOUSE HISTOLOGY LABORATORY

Referring physician practices have an increasing interest in developing their own in-house histology laboratories so that they can bill payors directly for the technical component processing. The recent anti-markup restrictions make the establishment of an offsite pod laboratory unfeasible for most referring physician practices. In addition, offsite pod laboratories have been labeled as suspect under the Medicare and Medicaid anti-kickback law by the Office of the Inspector General in Advisory Opinion 04-17.

Under this scenario, the referring physician practice will place a technical component histology laboratory in its own offices, hire or lease the histotechs who will provide the services, contract with the pathology provider for medical director services, and contract with the pathology provider for the provision of professional pathology interpretations. The referring physician practice will bill patients and payors for its technical component services.

Direct billing by the pathology provider of its pathology services to patients and payors is preferable from a compliance standpoint. The Stark issues and malpractice issues discussed in the preceding section are avoided if the pathology provider bills payors directly for the professional pathology interpretations.

In order to effectuate this arrangement, the parties first would negotiate the terms of a three-part agreement. Pursuant to this agreement, the pathology provider will provide consulting services to assist the referring physician practice in establishing the laboratory. The referring physician practice will pay the pathology provider either a fixed fee or an hourly fee for these consulting services. The fraud and abuse laws require that this payment reflect fair market value.

The second part of the agreement would cover the CLIA medical director services provided by the pathology provider to the physician practice's laboratory. As with the compensation for the consulting services, the compensation for the medical director services can be a fixed fee or an hourly fee, and this compensation must reflect fair market value.

The third part of the agreement would cover the provision of the professional pathology services by the pathology provider. If the pathology provider will bill payors directly for its services, the referring physician practice will not be responsible for payment for these services.

If the referring physician practice will bill for the services of the pathologists, then the issues addressed with respect to the TC/PC arrangement must be considered, including malpractice liability insurance and payor credentialing.

DONATIONS OF ELECTRONIC HEALTH RECORDS TECHNOLOGY

On August 8, 2006, the Department of Health and Human Services' Office of Inspector General ("OIG"), and the Center for Medicare and Medicaid Services issued a new safe harbor under the federal anti-kickback law and an exception to the federal physician self-referral law that permits certain donations of electronic health records ("EHR") software or information technology and training services. As a preliminary matter, the requirements under the anti-kickback law safe harbor and Stark law exception are virtually identical.

The OIG's stated purpose for the new safe harbor and exception was to "lower perceived barriers to the adoption of health information technology" by promoting "the adoption of open, interconnected, interoperable electronic health record systems." The safe harbor and exception will both currently terminate on December 31, 2013.

Under the EHR safe harbor and exception, laboratories and other permitted donors can subsidize the cost of compliant EHR technology to physicians and other qualifying recipients at 85% of the cost of such technology. The EHR technology is not required to be certified by the OIG. However, the standards and criteria related to interoperability that are recognized by the Department of Health and Human Services should be consulted.

Persons and entities that are considering donating or receiving a donation of EHR technology are advised to review the rule and related supplementary information from the OIG very carefully. Assuming other safe harbor and exception conditions are met, the following requirements are set forth under the EHR technology safe harbor and exception:

Permitted Donors and Recipients:

Donors: The safe harbor and exception apply to protect any donor that is an individual or entity that provides patients with health care items or services covered by a federal health care program and submits claims or requests for payment for those items or services (directly or pursuant to reassignment) to Medicare, Medicaid, or other federal health care programs. This is a bright-line test designed to focus on those individuals and entities with a substantial and central stake in patients' EHR. Individuals and entities that can satisfy the test include, for example, laboratories, hospitals, group practices, physicians, nursing and other facilities, pharmacies, oncology centers, community health centers, federally qualified health centers, dialysis centers and health plans.

The OIG has, however, expressed concern about the potential for abuse by ancillary service providers and suppliers, including laboratories, and intends to monitor compliance with the safe harbor and exception. According to the OIG, among other things, it will be alert to patterns of increased utilization correlated with transfers of nonmonetary remuneration in the form of EHR

technology. The OIG also noted that, notwithstanding the safe harbor and exception, parties remain liable under various federal and state laws for billing abuses, including over-billing and billing for items and services that are not medically necessary.

Recipients: The final rule permits the donation of protected remuneration to any individual or entity engaged in the delivery of health care without regard to whether the recipient is on a medical staff, is a member of a group practice, or is in a network of a prescription drug plan organization or Medicare Advantage organization. Protected recipients include, among others, physicians, group practices, physician assistants, nurse practitioners, nurses, therapists, audiologists, pharmacists, nursing and other facilities, federally qualified health centers and community health centers, laboratories and other suppliers, and pharmacies.

The final rule permits donors to use selective criteria for choosing recipients, provided that neither the eligibility of the recipient, nor the amount or nature of the items or services, is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. If any one of seven selection criteria set forth in the final rule is met, the determination is deemed not to directly take into account the volume or value of referrals or other business generated between the parties. The selection criteria are as follows:

- A. The determination is based on the total number of prescriptions written by the recipient (but not the volume or value of prescriptions dispensed or paid by the donor or billed to a Federal health care program);
- B. The determination is based on the size of the recipient's medical practice (for example, total patients, total patient encounters, or total relative value units);
- C. The determination is based on the total number of hours that the recipient practices medicine;
- D. The determination is based on the recipient's overall use of automated technology in his or her medical practice (without specific reference to the use of technology in connection with referrals made to the donor);
- E. The determination is based on whether the recipient is a member of the donor's medical staff, if the donor has a formal medical staff;
- F. The determination is based on the level of uncompensated care provided by the recipient; or
- G. The determination is made in any reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated between the parties.

Covered Technology:

EHR Defined: Under the final rule, "electronic health record" is broadly defined as "a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions."

Software/Information Technology and Training Services: Only nonmonetary remuneration that consists of items and services in the form of software or information technology and training services that are necessary and used predominantly to create, maintain, transmit, or receive EHR are protected under the rule. Covered items and services include, interface and translation software;

rights, licenses and intellectual property related to EHR software; connectivity services, including broadband and wireless internet services (including connectivity fees); clinical support and information services related to patient care (but not separate research or marketing support services); maintenance services; secure messaging (i.e., permitting physicians to communicate with patients through electronic messaging); and training and support services (such as access to help desk services). Hardware (e.g., routers and modems) is not covered, nor is operating software that makes the hardware function; storage devices; software with core functionality other than EHR (e.g. human resources or payroll software, or other software focused primarily on practice management or billing); or items or services used by the recipient primarily to conduct personal business or business unrelated to the recipient’s clinical practice or clinical operations. The provision of staff to recipients or their offices is also not covered.

Necessary Requirement: Software and services are not “necessary” if the recipient already possesses equivalent software or services. Under the rule, if a donor knows that the recipient already possesses equivalent items or services, or acts in deliberate ignorance or reckless disregard of that fact, the donor will not be protected by the safe harbor and exception. Accordingly, prudent donors should make reasonable inquiries to recipients and document these communications. The rule does not preclude upgrades of items or services that enhance their functionality (e.g. a software upgrade).

Predominance Requirement: EHR functions must be predominant. The core functionality of the technology must be the creation, maintenance, transmission or receipt of individual patient’s EHR. The items and services cannot be used primarily to conduct personal business or business unrelated to the recipient’s clinical practice or clinical operations. The safe harbor and exception do protect arrangements involving software packages that include other functionality related to the care and treatment of patients (e.g., patient administration, scheduling functions, billing and clinical support).

Interoperability Requirement: The donated EHR software must be interoperable at the time it is provided to the recipient. “Interoperable” means that, at the time of the donation, the software is able to (i) communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings; and (ii) exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered. The donor (or any person on the donor’s behalf) cannot take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or EHR systems.

Interoperability must apply in various settings, meaning that the software must be capable of being interoperable with respect to systems, applications, and networks that are both internal and external to the donor’s or recipient’s systems, applications, and networks. Software is not interoperable if it can only communicate or exchange data within a limited health care system or community. Interoperability is to be evaluated given the prevailing state of technology at the time the items or services are provided to the recipient.

Parties must have a “reasonable basis” for determining that software is interoperable. Standards and criteria related to interoperability that are recognized by the Department should be consulted. Compliance with these standards will provide greater certainty to donors and recipients that products meet the interoperability requirement and may be relevant in any enforcement activities. To avoid uncertainty, parties can avail themselves of the “deeming” provision. This provides that software is deemed to be interoperable if a certifying body recognized by the Secretary

of the Department has certified the software within no more than 12 months prior to the date it is provided to the recipient.

Electronic Prescribing Required: The EHR software must contain electronic prescribing capability, either through an electronic prescribing component or the ability to interface with the recipient's existing electronic prescribing system that meets the applicable standards under Medicare Part D at the time the items and services are provided.

Other: For items or services that are of the type that can be used for any patient without regard to payor status, the donor cannot restrict, or take any action to limit, the recipient's right or ability to use the items or services for any patient.

Value of Technology:

The final rule offers protection only if the recipient pays 15% of the donor's cost of the technology. This payment is required to be made before the recipient's receipt of the items and services being donated. All donated software and health information technology and training services are subject to the cost-sharing requirement. Any updates, upgrades, or modifications to the donated EHR system that are not covered under the initial purchase price for the donated technology are subject to separate cost sharing obligations by the recipient (to the extent that the donor incurs additional costs). Donors (and their affiliated individuals and entities) are prohibited from providing financing or making loans to recipients to fund the recipient's payment for the technology. Under the final rule, there is no cap on the amount of protected technology that can be donated.

Written Agreement Required:

The arrangement between the donor and the recipient must be documented in a written agreement that sets forth the following:

- A. Is signed by the parties;
- B. Specifies the items and services being provided, the donor's cost of those items and services, and the amount of the recipient's contribution; and
- C. Covers all of the EHR items and services to be provided by the donor (or any affiliate). This requirement will be met if all separate agreements between the donor (and affiliated parties) and the recipient incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary of the Department upon request. The master list should be maintained in a manner that preserves the historical record of agreements.