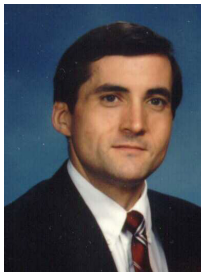

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In January 2008, *"concerned that the definition of 'office of the billing physician or other supplier' may not be entirely clear and could have unintended consequences"*, CMS promulgated a new "final rule" which delayed the implementation of the new anti-markup provisions until January 1, 2009. The *"Delay Rule"* would apply in all but two circumstances: (1) in cases where anatomic pathology diagnostic testing is furnished in space that is utilized by a physician group practice as a *"centralized building"*; and, (2) anti-markup provisions would still apply to the technical component of purchased tests as this provision has existed since the inception of the *Anti-Markup Rule* in 1992, and prior to the recent expansion.[3] The *Delay Rule* was quickly challenged by a group of urologist plaintiffs who objected to CMS' decision to not delay the portion of the Delay Rule that applied to services performed in a *"centralized building"*. Through their action (Atlanta Urological Associates, P.A., et al. v. Leavitt, D.D.C, No. 1:08-cv-00141), the plaintiffs were able to obtain a *preliminary injunction* which prohibited the Department of Health and Human Services (HHS) from applying the Anti-Markup Rule to services provided in a centralized building, based on the reasoning that HHS issued the Delay Rule without going through the formal notice and comment procedures, which made it *"arbitrary and capricious rulemaking"*.[4]

HHS challenged the injunction, however, and obtained a *dismissal* of the plaintiffs' action on May 5, 2008. The court granted the agency's motion to dismiss and vacate the injunction on the grounds that the plaintiffs lacked standing because they could not show that they had suffered an injury that was likely to be redressed by a favorable decision and because the plaintiffs *"overstate[d] their case"*, reasoning that the *Anti-Markup Rule* is merely a limit on Medicare reimbursement, and not a termination of participation.[5] Further, any challenge to the *Anti-Markup Rule* itself (as opposed to this challenge against the *Delay Rule*) by Medicare participants should be addressed through the administrative process before going to the courts.

Part of the reason HHS carved out the exception for pathology services performed in a *"centralized building"* is due to its growing concern over *"pod laboratories"*, which were defined by the judge in this case

In addition to this ongoing debate, many general hospitals have come under scrutiny by *antitrust* authorities for engaging in potentially *exclusionary practices* in what general hospitals cite as, an effort to respond to the negative financial impact POFs have on general hospitals. In situations where POFs are owned in whole or in part by physicians with privileges on the medical staff of a general acute care hospital, and where the POF competes with that hospital either on an inpatient or outpatient basis, many hospitals have engaged in activities that attempt to shut the POF (e.g,, specialty hospital) out of the market. Some of these practices include refusing to assist or cooperate with specialty hospitals; pressuring other members of the medical staff and/or community physicians to not do business with the specialty hospital; pressuring payors to exclude specialty hospitals from the payors' networks; and, limiting or terminating physician-investors' privileges and medical staff membership (*"conflict of interest credentialing"*).[3] In response to these practices, some POFs have initiated antitrust suits, claiming that the general hospitals are engaging in illegal exclusionary boycotts. The two most common claims are that hospitals have denied or restricted staff privileges to physicians that have an ownership interest in a POF that competes with the hospital and that hospitals have engaged in exclusive arrangements designed to restrict the POF's access to payors.[4]

Despite increased antitrust scrutiny in this sector, cases initiated by POFs have repeatedly failed to proceed to trial because they are generally difficult to prove and therefore cannot survive summary judgment. The first case that was able to survive summary judgment challenge was *Heartland Surgical Specialty Hospital v. Midwest Division, Inc.*, in which the plaintiff *surgical specialty hospital* (SSH) alleged horizontal conspiracies between multiple health plans and multiple hospitals, as well as vertical conspiracies between the hospitals and payors directly, resulting in pressure on payors, as well as direct agreements with them, to exclude the SSH from their networks.[5] This lawsuit is unique in that it alleges horizontal conspiracies in the POF context, since most lawsuits center around exclusive contracts or the denial or restriction of staff privileges for physicians

clients nationwide. He has developed and implemented hospital and physician driven MSOs and networks involving a wide range of specialties; developed a physician-owned ambulatory surgery center; participated in the evaluation and negotiation of managed care contracts, performed valuations of a wide array of healthcare entities; participated in numerous litigation support engagements; created pro-forma financials; written business plans and feasibility analyses; conducted comprehensive industry research; completed due diligence analysis; overseen the selection process for vendors, contractors, and architects; and, developed project financing.

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as *"a centralized collection of numerous small laboratories that are housed in adjacent cubicles (the 'pods') in a building subdivided and leased to several unrelated medical practices [E]quipment in each pod is separately owned by each physician group practice that refers specimens to the centralized location. A single pathologist and staff then rotate among the various pods, performing pathology services which in each pod on the patient specimens referred by the physician group that owns the medical equipment."*[6] Pod laboratories were a response to the promulgation of the Stark self-referral laws which provide an exception for a physician practice that directly performs its own clinical laboratory services as part of its group practice. In essence, *pod laboratories* are an attempt by physician practices to fit into this Stark exception while still having a separate pathologist perform the testing. With this most recent decision on the challenges to HHS' *Anti-Markup rules*, pod laboratories may no longer be as appealing now that the billing physician has no control over what prices may be charged for the services provided.

However, just as all of these issues appeared to have been decided, CMS issued another proposed rule on June 30, 2008,[7] in which it explores two alternatives to the original *Anti-Markup Rule* provisions promulgated in 2007. The first alternative, tests and services performed in a centralized building (or the same building, as defined under Stark law) would not be subject to *Anti-Markup Rule* provisions if they were performed by a physician who *"shares a practice"* with the billing physician or physician organization. However, if the physician performing the test provides services to more than one physician or physician organization, that physician would then not fall into the *"shares a practice"* exception. The second alternative proposes three amendments to the definition of the term *"office of the billing physician or other supplier"*, whereby the definition would include: (1) space located in the *"same building"* in which the billing physician or other supplier regularly provides patient care; (2) more than one location where a physician regularly furnishes patient care; or (3) the office where the *ordering* physician provides most of his or her services in the context of a physician organization. Under the second alternative, the Anti-Markup Rule would apply to the technical component services conducted or supervised outside the

with interests in POFs. Part of the reason that the *Heartland* case was the first of its kind to be allowed to continue to trial is because antitrust law enforcement has been *"pretty protective"* of hospitals that have taken measures to combat *"cream skimming"* by specialty hospitals.[6] However, antitrust laws still protect against entities with market power from using that market power to pressure others (here, other hospitals and payors) into agreeing to exclude a competitor from the market, and that is where the hospital defendants in this case ran into trouble.

The *Heartland* case eventually settled in Spring 2008 for an undisclosed amount.[7] What *Heartland* demonstrates, however, is how antitrust challenges by POFs will not always fall on the side of the general hospitals. While this precedent has now been established, there are still important and unresolved issues that the courts have yet to determine. One of the most important elements of any antitrust challenge is the requirement of an *agreement between competitors in the restraint of trade*. In a majority of these cases, the allegations of agreement are launched at hospital boards that are in supposed agreements with their medical staffs. The circuits are split on whether or not a hospital and members of its medical staff can be considered separate entities for the purposes of forming an agreement to restrain trade.[8] Some circuits argue that the medical staffs are simply a subpart of the larger hospital entity and therefore cannot be judged as making decisions as separate entities. Another important consideration courts are facing is the determination as to whether a hospital's staff privilege decision is merely a *"unilateral act"* rather than any form of conspiracy, as such unilateral decisions are legal (assuming the unilateral activity is not predatory). Finally, courts are also split on the question of whether certain actions taken by hospitals in response to POFs can be considered to have legitimate business justifications (the last step in any rule of reason in antitrust analysis), i.e., if a general hospital can show that its actions are in pursuit of a legitimate business goal, such as protecting its ability to cross-subsidize unprofitable services so that it may continue to provide those services to the community or to protect from *"cream-skimming"*, then some courts may find the actions justified, even if detrimental to the POF.[9] These

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OIG Issues Open Letter Regarding Refinements to Provider Voluntary Self-Disclosure Protocol

On April 15, 2008, the *Office of Inspector General* (OIG) of the Department of Health and Human Services issued an *"Open Letter to Health Care Providers"*[1] *("2008 Open Letter")* which updated the provisions of the *OIG Provider Self-Disclosure Protocol*

office of the billing physician, and the technical component would not be purchased from an outside supplier if the technical component if it is supervised by someone in the office of the billing physician. The new proposed rule, with the new alternatives, is open for comment starting July 7, 2008 through August 29, 2008.[8]

[1] "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Delay of the Date of Applicability of the Revised Anti-Markup Provisions for Certain Services Furnished in Certain Locations," Volume 73 Fed. Reg. 404 (Jan. 3, 2008).
[2] "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Delay of the Date of Applicability of the Revised Anti-Markup Provisions for Certain Services Furnished in Certain Locations," Volume 73 Fed. Reg. 404 (Jan. 3, 2008).
[3] "Court dismisses Urologists' Challenge to Anti-Markup Rule and Vacates Injunction," Sonnenschein, Nath, & Rosenthal, LLP, Health Care E-Alert, May 8, 2008, http://www.sonnenschein.com/practice_areas/healthcare2/pub_detail.aspx?id=44933&type=E-Alerts (accessed 6/16/2008).
[4] Atlanta Urological Associates, P.A., et al. v. Leavitt, Memorandum Opinion, Civil Action No. 08-141 (RMC), p. 8 (D.D.C. March 31, 2008).
[5] Atlanta Urological Associates, P.A., et al. v. Leavitt, Memorandum Opinion, Civil Action No. 08-141 (RMC), p. 13, 18 (D.D.C. May 5, 2008).
[6] Atlanta Urological Associates, P.A., et al. v. Leavitt, Memorandum Opinion, Civil Action No. 08-141 (RMC), p. 3-4, 18 (D.D.C. May 5, 2008). [7] "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Proposed Rule," 72 Fed. Reg. 38545 (July 7, 2008).
[8] "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Proposed Rule," 72 Fed. Reg. 38545 (July 7, 2008).

Physician Antitrust Update: Fifth Circuit Affirms FTC's Decision in North Texas Specialty Physicians

Three years after the Federal Trade Commission (FTC) ruled that the *North Texas Specialty Physicians (NTSP) independent practice association (IPA)* was engaging in *illegal price-fixing*,[1] the Fifth Circuit Court of Appeals affirmed the decision, stating that negotiation (on behalf of physician members) that doesn't involve risk sharing with payors or any form of improved efficiency arising out of clinical integration, runs afoul of *antitrust laws*.[2] The FTC originally examined the NTSP arrangement under a *"quick-look"* analysis. Under such an analysis, if the FTC finds that there is *inherently suspect conduct*, the respondent must then provide a *procompetive business justification* for the conduct. In this case, NTSP's joint contracting activities neither saved money nor improved quality, leading the FTC to the conclusion that they constituted illegal price-fixing under Section 1 of the Sherman

questions will be considered repeatedly in the coming year as multiple cases proceed to trial, and it will be critical for all healthcare provider enterprises to stay abrest of the legal developments in this ever-expanding area of antitrust law.

[1] "Antitrust Implications of Competition Between Physician-Owned Facilities and General Hospitals: Competition or Exclusion?" By William E. Berlin, Esq., The Health Lawyer, American Bar Association, Volume 20, No. 5 (June 2008), pg 6.
[2] "Antitrust Implications of Competition Between Physician-Owned Facilities and General Hospitals: Competition or Exclusion?" By William E. Berlin, Esq., The Health Lawyer, American Bar Association, Volume 20, No. 5 (June 2008), pg 6.
[3] "Antitrust Implications of Competition Between Physician-Owned Facilities and General Hospitals: Competition or Exclusion?" By William E. Berlin, Esq., The Health Lawyer, American Bar Association, Volume 20, No. 5 (June 2008), pg 3-5.
[4] "Antitrust Implications of Competition Between Physician-Owned Facilities and General Hospitals: Competition or Exclusion?" By William E. Berlin, Esq., The Health Lawyer, American Bar Association, Volume 20, No. 5 (June 2008), pg 3-5.
[5] Heartland Surgical Specialty Hospital, LLC v. Midwest Division, Inc. d/b/a HCA Midwest Division, et al., 527 F.Supp. 2d 1257 (D. Kan. 2007)
[6] "Physician-owned hospital can pursue antitrust lawsuit," By Amy Lynn Sorrel, AMNews, Nov. 12, 2007, http://www.ama-assn.org/amednews/2007/11/12/gvsa1112.htm (accessed 6.30.2008) (quoting Thomas L. Greaney, Professor of Antitrust Law at Saint Louis University in St. Louis, Missouri).
[7] "Antitrust Implications of Competition Between Physician-Owned Facilities and General Hospitals: Competition or Exclusion?" By William E. Berlin, Esq., The Health Lawyer, American Bar Association, Volume 20, No. 5 (June 2008), pg 5.
[8] "Antitrust Implications of Competition Between Physician-Owned Facilities and General Hospitals: Competition or Exclusion?" By William E. Berlin, Esq., The Health Lawyer, American Bar Association, Volume 20, No. 5 (June 2008), pg 5.
[9] "Antitrust Implications of Competition Between Physician-Owned Facilities and General Hospitals: Competition or Exclusion?" By William E. Berlin, Esq., The Health Lawyer, American Bar Association, Volume 20, No. 5 (June 2008), pg 9; see e.g. Williamson v. Sacred Heart Hospital of Pensacola, 1993 WL 543002 (N.D. Fla. 1993).

Stark Law Update: Recent Developments

Over the past several months, the Centers for Medicare & Medicaid Services (CMS) has issued various *proposed rules* and *advisory opinions* on issues related to the Stark Law provisions. Most notably, CMS is currently revisiting one of the provisions in the Stark II, Phase III rule it finalized in September 2007, i.e., the provision requiring physicians with financial interests in physician organizations to *"stand in the shoes"* of such organizations for the purposes of complying with *self-referral laws*. Additionally, CMS has issued an advisory opinion dealing with the Stark implications of providing customized software to members of hospital medical staffs for the purpose of *remote access to patient information*.

Status of the *"Stand in the Shoes"* Provision

In September 2007, CMS issued the third

(SDP). Since its inception in 1998, the SDP has offered detailed instructions for how healthcare providers can voluntarily report potential fraud in their dealings with federal health care programs. Originally, the SDP guidelines did not make any commitment as to how a self-disclosed case would be handled. However, since 1998, the OIG has issued multiple Open Letters that have consistently increased incentives for providers to self-disclose by *diminishing the severity of penalties imposed after self-disclosure*. For example, in 2001, the OIG departed from its practice of imposing five-year *Corporate Integrity Agreements* (CIAs) in favor of three-year *Certification of Compliance Agreements* (CCAs),[1] and in 2006, the OIG stated that it would ordinarily forego its exclusion powers for providers that self-disclosed and would impose monetary penalties that were *"near the lower end of the damages continuum."* [3]

With the goal of increasing efficiency and benefiting providers who self-disclose, the OIG has once again improved incentives for providers to participate in the SDP. In the 2008 *Open Letter*, the SDP has been refined so that participants who submit complete and informative disclosures; quickly respond to OIG's requests for further information; and, perform accurate audits will *"generally [not be] require [d] to enter into a Corporate Integrity Agreement or Certification of Compliance Agreement."* The OIG will also continue to impose monetary penalties near the lower end of the damages continuum to participants that fully cooperate.

In exchange for these increased incentives, which the OIG hopes will reward providers that are truly committed to integrity in the delivery of healthcare, the new SDP refinements have added *additional pieces of information* that the initial SDP submission must contain, in an effort to improve and streamline the disclosure process. In addition to the Basic Information required by the 1998 SDP, *a complete submission must now contain the following*: (1) a complete description of the conduct being disclosed; (2) a description of the provider's internal investigation or a commitment regarding when it will be completed; (3) an estimate of the damages to the Federal health care programs and the methodology used to calculate that figure or a commitment regarding when the provider will complete such estimate; and, (4) a statement of the

Antitrust Act.

NTSP is not the first, and is unlikely to be the last, IPA that has faced antitrust scrutiny and has been found to be in violation. Traditionally, IPAs have been able to negotiate on behalf of their members if the joint-contracting agreement has an element of risk-sharing built into it, or if the IPA has embarked on a clinical integration scheme to improve efficiency among its members (and even under this latter exception, only two clinically integrated IPAs have successfully survived antitrust challenges).[3] The significance of the NTSP decision for future IPA activities is the FTC and the Court's interpretation of the IPA's use of the "messenger model", which NTSP used to poll members to find out minimum fees they would accept before negotiating with insurers.[4] The *"messenger model"* has traditionally been a way for physician networks to use a single agent to relay contract information between the group and a payor, but has never allowed the group to set contract terms or negotiate on behalf of the group. NTSP argued that there are actually *"spillover"* effects from previous risk-sharing contracts that helped improve quality, and that the FTC failed to consider these *"spillover"* effects carefully enough when making its decision.

Even though the Fifth Circuit affirmed the FTC's decision as a whole, the Court did rule that the portion of the decision in which the FTC prohibited NTSP from facilitating any contract negotiations on behalf of its members was overbroad. While there is a delicate balance between the ability of IPAs to facilitate easier negotiations between member physicians and payors and activity that verges on being anticompetitive, it is important for physicians to be able to negotiate with payors, particularly in those instances in which physicians face a disproportionate disadvantage against *"large, sophisticated payors"*.[5] In order to combat this disadvantage at the bargaining table, physicians have to hope that joining an IPA will help bolster their negotiating leverage, and critics of the decision argue that it is *"likely to prevent doctors from trying to come up with efficient and innovative ways of coming together to practice medicine."*[6]

NTSP is considering appealing the Fifth Circuit decision, which may or may not get a court to look at the clinical efficiencies that it

installment of the federal self-referral law, more commonly referred to as Stark II ("Phase III").[1] In the Phase III installment, CMS included a provision that would now consider physicians who have an ownership interest in a physician organization to *"stand in the shoes"* of the physician organization for the purpose of Stark laws, i.e., the physician would *"collapse"* into the physician organization, resulting in the the physician organization no longer being considered an *intervening entity* for the purpose of establishing an *indirect compensation arrangement* with a *designated health service* ("DHS"). Under the new provision, any physician member, employee or contractor of the physician organization will be considered to have the same compensation arrangement with the DHS that the physician organization has as a whole. The effect of the *"stand in the shoes"* provision is that many more physicians will be considered to have direct compensation arrangements with DHS entities, therefore falling under a different set of exemption provisions to Stark.[2]

The final implementation of the *"stand in the shoes"* doctrine that concerned *academic medical centers* ("AMCs") and *nonprofit integrated health system* settings was delayed in November 2007, until December 2008, so that CMS could address such concerns as: (1) compensation arrangements between a faculty practice plan and another component of the same AMC; and (2) compensation arrangements between an affiliated DHS entity and the affiliated physician practice in the same nonprofit integrated health care system.[3] Following this delay, CMS issued the proposed rule regarding the *Hospital Inpatient Prospective Payment System* ("IPPS") for FY 2009 ("Proposed Rule"), in which CMS solicited comments on two alternatives to address the *"stand in the shoes"* provisions for AMCs and integrated health systems going forward. The first alternative would create *exceptions* from the provision for physician-employees or contractors whose compensation arrangement satisfies the *employment, personal services, or fair market value exception*, or where the compensation arrangement is between an AMC component and a physician organization affiliated with the AMC through a written agreement to provide services required to satisfy the AMC's obligations under the *Medicare Graduate Medical Education rules*.[4] The

laws potentially violated by the conduct. Finally, a provider must be in a position to complete the investigation and damages assessment within months.[4] These additional requirements are not expected to be a problem for most SDP participants as it is expected that most participants will have already conducted an internal investigation prior to self-reporting.

The purpose of the SDP is to *"facilitate resolution of matters that potentially violate federal criminal law, civil law, or administrative laws for which exclusion or civil monetary penalties are authorized,"* and it is not intended to penalize *"mere billing errors or overpayments,"* which should be submitted directly to the appropriate claims-processing entity.[5] While it is the goal of the OIG to make the SDP process more efficient and fairer towards self-disclosing providers, the *2008 Open Letter* continues to state nothing regarding how the Department of Justice will approach penalizing the violations that are self-disclosed. Nevertheless, Inspector General Daniel R. Levinson believes that the presumption in favor of not requiring compliance agreements *"appropriately recognizes the provider's commitment to integrity,"* and that the new approach *"benefits both disclosing providers and the Government and furthers our efforts to strengthen the integrity of the Federal health care programs."*[6] The new program rewards providers that submit a complete and accurate disclosure; respond promptly to OIG informational request; and, perform an adequate internal investigation of the underlying issues, while facing the prospect of no *integrity agreement*, a penalty which can prove onerous and extraordinarily expensive for the provider. The new refinements to the SDP give self-disclosing providers significant advantages over providers who do not self-disclose, which the OIG hopes will not only streamline the self-disclosure process, but will also make providers more efficient by allowing them to save money as they are working to correct the problem.

[1] "An Open Letter to Health Care Providers," By Daniel R. Levinson, Inspector General of the Dept. of Health and Human Services , April 15, 2008, http://www.oig.hhs.gov/fraud/docs /openletters/OpenLetter4-15-08.pdf (Accessed 6/9/08).
[2] "An Open Letter to Health Care Providers," By Janet Rehnquist, Inspector General of the Dept. of Health and Human Services, November 20, 2001, http://www.oig.hhs.gov/fraud/docs/ openletters/openletter111901.htm (Accessed 6/9/08).
[3] "An Open Letter to Health Care Providers," By Daniel R. Levinson, Inspector General of the Dept. of Health and Human Services , April 24, 2006, http://www.oig.hhs.gov/fraud/docs/ openletters/Open%20Letter%20to%20Providers%202006.pdf

argues are present. Regardless of what happens in this particular case, the important lesson for other IPAs to take away is that the more obscure the procompetitive benefits of an IPA's joint-contracting practice are, the less likely it will be able to withstand antitrust scrutiny.

[1] "Opinion of the Commission: In the Matter of North Texas Specialty Physicians, a corporation," by Thomas B. Leary, Commissioner, Federal Trade Commission, Dec. 1, 2005, http://www.ftc.gov/os/adjpro /d9312/051201opinion.pdf (Accessed 6.30.08).
[2] North Texas Specialty Physicians v. Federal Trade Commission, 2008 WL 2043040 (5th Cir. 2008).
[3] See Letter from Jeffrey W. Brennan, Assistant Director, Federal Trade Commission Bureau of Competition, to John J. Miles, Law firm of Ober, Kaler, Grimes & Shriver, Staff Advisory Opinion: MedSouth, Inc., February 19, 2002, http://www.ftc.gov/bc/adops/medsouth .shtm (Accessed 4.18.08); Letter from Markus H. Meier, Assistant Director, Federal Trade Commission Bureau of Competition, to Christi J. Braun and John J. Miles, Law firm of Ober, Kaler, Grimes & Shriver, Greater Rochester Independent Practice Association, Inc., Advisory Opinion, September 17, 2007, http://www.ftc.gov/bc/adops/ gripa.pdf (Accessed 4.18.08).
[4] "Texas IPA's contract talks are price-fixing, appeals court rules," By Amy Lynn Sorrel, AMNews, June 23/30, 2008, http://www.ama-assn. org/amednews/2008/06/23/gvsc0623 .htm (accessed 6.30.08).
[5] "Texas IPA's contract talks are price-fixing, appeals court rules," By Amy Lynn Sorrel, AMNews, June 23/30, 2008, http://www.ama-assn. org/amednews/2008/06/23/gvsc0623 .htm (accessed 6.30.08) (quoting Bruce A. Blefeld, attorney for Litigation Center of the American Medical Associate and State Medical Societies and the Texas Medical Association).
[6] "Texas IPA's contract talks are price-fixing, appeals court rules," By Amy Lynn Sorrel, AMNews, June 23/30, 2008, http://www.ama-assn. org/amednews/2008/06/23/gvsc0623 .htm (accessed 6.30.08) (quoting Bruce A. Blefeld, attorney for Litigation Center of the American Medical Associate and State Medical Societies and the Texas Medical Association).

second alternative provides that CMS would not change the current *"stand in the shoes"* provisions, but instead would develop a new exception for certain *mission support* and similar payment arrangements between and among DHS entities, physician organizations, and physicians.[5] The Proposed Rule also provides for revising the Stark Law such that a DHS entity would be deemed to *stand in the shoes* of any organization in which it has a 100% ownership interest so that the DHS entity would be deemed to have the same compensation arrangements (i.e., with the same parties and on the same terms) as does the organization that it owns.[6] The Proposed Rule also clarified how to apply physician- and entity-side *collapsing rules* so that the referring physician and the DHS entity will not ever become the same person/ entity for analytical purposes.[7]

With the revisions of the *"stand in the shoes"* provision, CMS also proposed revising the definitions of *"physician"* and *"physician organization"* so that the determination as to whether a direct or indirect compensation agreement exists would be clearer. Under the proposed definitions, physicians will be deemed to *"stand in the shoes"* of: (1) another physician who employs the physician; (2) his or her wholly owned professional corporation; (3) a physician practice that employs or contracts with the physician or in which the physician has an ownership interest; or (4) a group practice of which the physician is a member or independent contractor.[8]

Advisory Opinion: Remote Electronic Access of Patient Information

Additionally, CMS has recently published a new Stark Law *advisory opinion* on the topic of remote electronic access of patient information by the medical staff of a hospital system.[9] CMS advised an inquiring hospital system that providing *customized software* to members of the medical staffs would not give rise to a *compensation arrangement* between and among the physicians and the hospital under the Stark Law. Under section 1877 of the Social Security Act, a *compensation arrangement* includes all arrangements between a physician (or immediate family member) and an entity which involve remuneration, except those arrangements which involve only *"the*

(Accessed 6/9/08).
[4] "An Open Letter to Health Care Providers," By Daniel R. Levinson, Inspector General of the Dept. of Health and Human Services, April 15, 2008, http://www.oig.hhs.gov/fraud/docs/openletters/OpenLetter4-15-08.pdf (Accessed 6/9/08).
[5] "An Open Letter to Health Care Providers," By Daniel R. Levinson, Inspector General of the Dept. of Health and Human Services, April 15, 2008, http://www.oig.hhs.gov/fraud/docs/openletters/OpenLetter4-15-08.pdf (Accessed 6/9/08).
[6] "An Open Letter to Health Care Providers," By Daniel R. Levinson, Inspector General of the Dept. of Health and Human Services, April 15, 2008, http://www.oig.hhs.gov/fraud/docs/openletters/OpenLetter4-15-08.pdf (Accessed 6/9/08).

provision of items, devices, or supplies that are used solely to order or communicate the results of tests or procedures for such entity."[10] Because the provision of free equipment solely to communicate the results of exams does not have independent value apart from the service being provided, it does not constitute prohibited remuneration.

[1] "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III)," 72 Fed. Reg. 51012 (Sept. 5, 2007).
[2] "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III)," 72 Fed. Reg. 51028 (Sept. 5, 2007).
[3] "Medicare Program; Delay of the Date of Applicability for Certain Provisions of Physicians' Referrals to Health Care Entities With Which they Have Financial Relationships (Phase III)," 72 Fed. Reg. 64161 (Nov. 15, 2007).
[4] "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physicians Self-Referral Rules; Proposed Collection of Information Regarding Financial Relationships Between Hospitals and Physicians," 73 Fed. Reg. 23686 (Apr. 30, 2008).
[5] "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physicians Self-Referral Rules; Proposed Collection of Information Regarding Financial Relationships Between Hospitals and Physicians," 73 Fed. Reg. 23687 (Apr. 30, 2008).
[6] "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physicians Self-Referral Rules; Proposed Collection of Information Regarding Financial Relationships Between Hospitals and Physicians," 73 Fed. Reg. 23689 (Apr. 30, 2008).
[7] "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physicians Self-Referral Rules; Proposed Collection of Information Regarding Financial Relationships Between Hospitals and Physicians," 73 Fed. Reg. 23689 (Apr. 30, 2008).
[8] "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physicians Self-Referral Rules; Proposed Collection of Information Regarding Financial Relationships Between Hospitals and Physicians," 73 Fed. Reg. 23690 (Apr. 30, 2008).
[9] "Advisory Opinion No. CMS-AO-2008-01" By Jeffrey B. Rich, M. D., Director, Center for Medicare Management, May 28, 2008, http://www.cms.hhs.gov/PhysicianSelfReferral/Downloads/CMS-AO-2008-01.pdf (Accessed 6.30.08).
[10] 42 U.S.C. 1395nn(h)(1)(A)-(C)(ii)(II) (2003).