THE FLORIDA BAR
Health Law Section Newsletter
THE RESOURCE FOR FLORIDA HEALTH LAW
The Florida Bar Health Law Section
Vol. XVII, No. 2 www.flabarhls.org Summer 2012

INSIDE:

State and Federal Action Creates New Antitrust Risks for Physicians

By David A. Ettinger, Esquire, Detroit, MI*

Historically, federal and state antitrust enforcement has focused for the most part on hospital transactions. However, a recent Pennsylvania consent order relating to a physician practice merger and the new antitrust Enforcement Statement for Accountable Care Organizations each raise significant antitrust issues for physicians involved in practice acquisitions or ACOs.

On September 1, 2011, the state of Pennsylvania entered into a consent order with a urology practice that was formed as a result of the merger of five smaller practices. *Commonwealth of Pennsylvania v. Urology of Central Pennsylvania, Inc., Urology Associates of Central Pennsylvania, P.C., Mid-Penn Urology, Inc. and Harrisburg Uro-Care Group* (M.D. Pa. Case No. 11-01625).[1] The order resulted from an investigation commencing two years after the merger occurred in 2005. A complaint filed with the order claimed that the practice had created a monopoly, but the consent order did not break up the merged practice, and imposed limited regulatory restrictions on the practice.

The Pennsylvania decision followed a recent antitrust investigation of a cardiology merger in Washington which led to the abandonment of the transaction.

On October 20, 2011, the Federal Trade Commission and Department of Justice issued their Enforcement Statement on antitrust issues applicable to Accountable Care Organizations. The Enforcement Statement raises concerns about the formation and operation of ACOs which possess a "high share" of virtually any hospital or physician specialty area.

The combination of physician practices has in the past rarely been the subject of antitrust review, in part because such transactions are usually too small to come to the federal government's attention under the Hart Scott Rodino pre-merger notification process. However, *Urology of Central Pennsylvania* illustrates that actions can be brought based on post-merger conduct, if that conduct generates complaints to enforcement authorities. Since physician practice mergers, as well as physician practice acquisitions by hospitals, are aggregating more physicians together, increasing antitrust enforcement is likely in the future. Significantly, while only the State of Pennsylvania ultimately pursued the consent order in the *Urology of Central Pennsylvania* case, the earlier investigation also involved the Federal Trade Commission.

The Enforcement Statement may have an even greater impact. Compliance with the Enforcement Statement is not mandatory in order to qualify for CMS approval of an ACO, but antitrust agencies will be receiving information directly from CMS on ACO applications, and will be in a position to directly monitor each such application. As a result, those combinations will likely receive a more careful antitrust review in the future.[2]

Market Issues

The threshold issue in evaluating a physician combination is the market share affected. Concerns are not likely to arise unless a combination results in a dominant share in a relevant geographic market. Even a 50% share may not be sufficient to raise concerns. The

continued, next page

ANTITRUST RISKS

from previous page

original proposed Antitrust Enforcement Statements imposed a 50% threshold, but the final statement only talks about a "high share."

The Enforcement Statement also provides for a "safety zone" market share of 30%, below which a government challenge is extremely unlikely. However, shares in the 30-50% range are also very unlikely to raise antitrust concerns. The government's safety zones are defined very conservatively, and most conduct outside of antitrust safety zones is never challenged.

In fact, physician mergers resulting in much higher shares have been approved where other factors offset the conclusion that competition has been eliminated. In particular, in *HTH Health Services, Inc. v. Quorum Health Group, Inc.*, 960 F. Supp. 1104, 1135 (S.D. Miss. 1997), physician shares as high as 70% were found insufficient to create an antitrust violation because the court found that entry of new physician competition could keep the market competitive. There is a long line of antitrust merger cases establishing that easy entry can serve as a defense to a claim based on high market shares. *See e.g. Image Technical Services, Inc. v. Eastman Kodak Co.*, 125 F.3d 1195, 1208 (9th Cir. 1997).

While entry of new physician practices into local markets has become relatively rare, entry of new physician competition in particular specialties through recruitment by hospitals and multispecialty groups is quite common. If that kind of entry is present in a market, it may serve to rebut an otherwise troublesome market share.

Arguably high market shares may also be more defensible for combinations involving physician specialties that are not routinely used by patients. That is because concerns typically arise in health antitrust cases based on the need by managed care plans to include particular providers in their panels in order to effectively market them to consumers. In that event, a merger of preferred groups can result in a "must have" group with the power to demand higher prices. *In re Matter of Evanston Northwestern Healthcare Corporation*, 2007 WL 2286195 (F.T.C.) at 10-11, 18-19, 20, 24.

Yet in many markets, clear preferences for particular groups may not arise except in the cases of hospitals and the most commonly used specialties, such as primary care and, perhaps, cardiology. Other, less routinely used, specialties may not be a matter of concern for potential subscribers, simply because their use is not sufficiently common to generate a demand that they be present in a particular panel. As a result, market power may not result from even a relatively high market share in some specialties, as long as some effective alternatives are still present in the market.

Market Definition

For this reason, as well, a combination of physicians in a specialty that is not routinely used by patients may not possess a high market share, once the geographic market is properly defined to include all the groups that are realistic alternatives. A managed care panel may be quite attractive to subscribers and their employers even where it requires some travel outside of an immediate area to access a specialty that is not routinely used. Subscribers may not be concerned about this prospect, simply because they are willing to accept the inconvenience in the (unlikely) event that they will need to use such a specialist.

More generally, relevant geographic markets for specialty physician care may be fairly large in scope. While the Enforcement Statement defines markets by reference to a 75% "primary service area" for the provider, this is described as only a "screening device." In fact, the antitrust case law with respect to both hospitals and specialty physicians generally supports broad geographic markets, often broader than what the government has argued. *Morganstern v.*

Editor's Note

by Thomas P. Clark, Esq., Fort Myers, Florida

Welcome to the latest edition of the Florida Bar Health Law Section e-newsletter. This edition contains four articles covering the following topics: (a) State and Federal Action Create New Antitrust Risks for Physicians; (b) Overpayment Rule Proposed; (c) Health Information Technology Top 10 Strategic Mistakes Hospitals Make in HIT Contracting and How to Avoid Them; and (d) Stark's "Set-In-Advance" Requirement.

On behalf of the Health Law Section, I would like to thank the staff at The Florida Bar for their assistance with this edition. I also would like to thank the authors who submitted articles for publication. Without their help and support it would not be possible to continue the newsletter.

If you are interested in submitting articles for publication, please submit them to me at thomas.clark@henlaw.com. I look forward to working with you.

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Wilson, 29 F.3d 1291, 1296-97 (8th Cir. 1994) (at least a 60 mile radius for cardiac surgery); *Patel v. Verde Valley Medical Center*, No. CV-05-1129-PHX-MHM, 25 (D. Ariz. March 31, 2009) (120 miles for cardiology); *United States v. Mercy Health Servs.*, 902 F. Supp. 968, 979, 983 (N.D. Iowa 1995), *vacated as moot*, 107 F. 3d 632 (8th Cir. 1997) (90 miles for inpatient hospital care).[3] Moreover, the market is properly defined, not by where patients currently travel, but by where they would travel if the merging parties attempted to exercise market power by raising prices. *In the Matter of Hospital Corporation of America ("HCA")* 106 F.T.C. 361 (1985) (emphasis added).

There will often be good evidence to help prove that geographic market applicable to a particular physician specialty area is broader than the physicians' primary or even secondary service area. The likely source of such evidence will be behavior in other physician specialties, where there has been an effort to exercise market power by refusing to participate in an insurer's panel. If such efforts have resulted in patients traveling farther for care, that can be evidence of a broader market potentially applicable to many specialties. Other useful examples that may apply across specialties can involve evidence of referral patterns over greater distances because of quality preferences.

The relevant market has both a geographic and a product component. Typically, government enforcers will look at a traditional physician specialty area as a product market, while treating primary care as one such market. But there can be room to argue in particular cases that the relevant product market is really broader than a single specialty, because physicians in other specialties provide competing services, and as a result the shares of any combining groups are smaller. Depending on the locale, there may be significant evidence, for example, that OB/GYNs provide general primary care to their patients; that family physicians compete with pediatricians; or that primary care physicians provide many of the services offered by pulmonologists, gastroenterologists or cardiologists. *See e.g. Pulmonary Assocs., Ltd.*, DOJ Business Review Letter (Oct. 31, 1994) (pulmonology not a market because of competition with general surgeons, cardiac surgeons and primary care physicians) and *CVT Surgical Center*, DOJ Business Review Letter (April 16, 1997) (in evaluating a merger of cardiovascular and peripheral vascular surgeons, market could include "cardiologists and other specialists"). However, the approaches taken by managed care will also be relevant. *See e.g. Gastroenterology Associates, Ltd.*, DOJ Business Review Letter (July 7, 1997) (gastroenterologists a relevant product market even though others performed some of same procedures because managed care plans need them in their panels). Such evidence will in each case depend on the practices in each area.

Per Se Violations

Some antitrust issues can be a concern regardless of the market position of the combined groups. The antitrust laws treat as *per se*, or automatic, violations, agreements on price or other direct limitations on competition between competitors outside of the context of financial, operational and/or clinical integration. For this reason, the antitrust enforcement officials have been concerned about whether particular physician "mergers" involve significant integration, or whether they are a little more than an effort to jointly negotiate managed care rates and set prices while maintaining separate, and separately-run, offices. Such an arrangement can be flatly illegal and potentially even criminal.

Similarly, the Enforcement Statement cautions against what are sometimes called "spillover effects" – agreements between competitors outside of the scope of an integrated ACO. An ACO should not be used as a vehicle to facilitate agreements that do nothing more than limit competition in other areas.

Ancillary Services

In *Urology of Central Pennsylvania*, the Pennsylvania attorney general alleged that the merged groups monopolized "radiation oncology services for prostate cancer" by utilizing their combined scale to build a radiation therapy center, and then referring their patients to their own center. Of course, these were only allegations. In fact, if merging parties are able to utilize their greater size to justify an expansion of services that is viewed under the antitrust laws as procompetitive, since new services, and new competition, are

continued, next page

ANTITRUST RISKS

from previous page

thereby introduced into the market. *Poller v. Columbia Broadcasting Systems, Inc.*, 386 U.S. 464, 485 (1962), *Belfiore v. New York Times Co.*, 826 F.2d 177, 181 (2nd Cir. 1987). Of course, improper referrals are the subject of other laws, not the antitrust laws.

Such an "ancillary services" theory has little or no basis in antitrust precedents. Significantly, the consent order in *Urology* case does not require any divestiture or limitation on the efforts of the new cancer center. It merely requires disclosures by the physicians to patients regarding their alternatives.

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Endnotes:

1 Mr. Ettinger litigated the *Urology of Central Pennsylvania* case.

2 For many years, federal antitrust agencies have frequently challenged physician hospital organizations and physician networks, especially where these organizations were not sufficient integrated. Examples in Florida include *U.S. v. Federation of Certified Surgeons and Specialists* (M.D. Fla. 1999), *Trauma Associates of North Broward, Inc.*, 118 F.T.C. 1130 (1994), *Southbank IPA, Inc.*, 114 F.T.C. 783 (1991).

3 The exception may be for primary care physician practices. It's plausible that patients will not travel very far for those kinds of services.

Overpayment Rule Proposed

By Myla R. Reizen, Esquire, Miami, FL*

On February 16, 2012, the Center for Medicare & Medicaid Services ("CMS") published a proposed rule for providers and suppliers as described below concerning the reporting and returning of overpayments under the Medicare program. This proposed rule implements Section 6402(a) of U.S. Patient Protection and Affordable Care Act ("PPACA") and will affect certain providers and suppliers. Comments to this rule were due by April 16, 2012. The proposed rule provides some answers, but also raises some questions.

Overview

Section 6402(a) of PPACA established a new section 1128J(d) of the Act titled "Reporting and Returning Overpayments." This provision requires a person who has received an overpayment to report and return it by the later of (1) the date which is 60 days after the date on which the overpayment is identified, or (2) the date any corresponding cost report is due, if applicable. It is important to note that this provision provides that any overpayment retained by a person after the deadline for reporting and returning an overpayment is an obligation under the False Claims Act, which has the potential for treble damages and penalties.

What is an Overpayment?

The proposed rule provides the definition for the term "overpayment," as " ...any funds that a person received or retains under title XVIII of the Act to which the person, after applicable reconciliation, is not entitled under such title." The preamble to the proposed rule provides some examples of an overpayment under this proposed definition, which includes the following:

- Medicare payments for noncovered services.
- Medicare payments in excess of the allowable amount for an identified covered service.
- Errors and nonreimbursable expenditures in cost reports.
- Duplicate payments.
- Receipt of Medicare payment when another payor had the primary responsibility for payment.

Additionally, the proposed rule and preamble provide some information about the applicable reconciliation in the cost report context.

When is the Overpayment Identified?

Under the proposed rule, a person has identified an overpayment, "if the person has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment." The preamble notes that "in some cases, a provider or supplier may receive information concerning a potential overpayment that creates an obligation to make a reasonable inquiry to determine whether an overpayment exists. If the reasonable inquiry reveals an overpayment, the provider then has 60 days to report and return the overpayment. On the other hand, failure to make a reasonable inquiry, including failure to conduct such inquiry with all deliberate speed after obtaining the information, could result in the provider knowingly retaining an overpayment because it acted in reckless disregard or deliberate ignorance of whether it received such an overpayment."

The preamble provides a number of examples of when an overpayment has been identified:

- A provider of services or supplier reviews billing or payment records and learns that it incorrectly coded certain services, resulting in increased reimbursement.
- A provider of services or supplier learns that a patient death occurred prior to the service date on a claim that has been submitted for payment.
- A provider of services or supplier learns that services were provided by an unlicensed or excluded individual on its behalf.
- A provider of services or supplier performs an internal audit and discovers that overpayments exist.
- A provider of services or supplier is informed by a government agency of an audit that discovered a potential overpayment, and the provider or supplier fails to make a reasonable inquiry.
- A provider of services or supplier experiences a significant increase in Medicare revenue and there is no apparent reason—such as a new partner added to a group practice or a new focus on a particular area of medicine—for the increase. Nevertheless, the provider or supplier fails to make a reasonable inquiry into

whether an overpayment exists.

Process

CMS proposes to use the existing voluntary refund process and rename it the "self-reported overpayment refund process."

With respect to the 60 day repayment time frame, there are certain provisions concerning the financial limitations of the provider to meet this time frame. If the provider is not able to meet this time frame due to financial limitations, the provider would use the Extended Repayment Schedule process.

One of the open issues that remains is that it sometimes takes the provider more than 60 days to determine the amount of the overpayment in order to make the refund. This varies based on a number of factors, such as the types and complexity of issues.

Look Back Period

The proposed rule provides for a 10 year look back period. Specifically, an overpayment must be reported and returned in accordance with this rule only if "a person identifies the overpayments within 10 years of the date that the overpayment was received." The preamble notes that this time period was chosen since this is consistent with the outer limit of the statute of limitations for the False Claims Act.

Other Disclosure Protocols

The proposed rule provides some guidance about the interplay of this rule with the current Medicare Self-Referral Disclosure Protocol ("SRDP") as well as the OIG Self-Disclosure Protocol and other OIG guidance. Additionally, the preamble seeks comments regarding the SRDP about the alternate approaches that would allow providers and suppliers to avoid making multiple reports of identified overpayments.

Anti-Kickback Statute

With respect to overpayments that arise from violations of the Anti-Kickback Statute, CMS acknowledges that the provider may be unaware of the kickback arrangement in certain circumstances. There is a discussion in the preamble regarding this issue.

Application

The preamble notes that the rule is proposing to implement the provisions of Section 1128J(d) of the Act only as they relate to Medicare Part A and Part B providers and suppliers. The preamble does note that other stakeholders, including MAOs, PDPs and Medicaid MCOs, will be addressed at a later date. Furthermore, CMS cautions all stakeholders about the current statutory requirements under PPACA and the potential False Claims Act liability, Civil Monetary Penalties Law liability, and exclusion from federal health care programs for the failure to report and return an overpayment.

Conclusion

As noted from above, this proposed rule has significant implications for providers and suppliers on a number of fronts.

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This newsletter is prepared and published by the Health Law Section of The Florida Bar.

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Health Information Technology

Top 10 Strategic Mistakes Hospitals Make in HIT Contracting and How to Avoid Them

By Brent A. Friedman, Esquire, Miami, FL*

You are a C-level executive of a hospital or health care system (the "Institution"). The Institution, under pressure from competing hospitals and your Institution's Board of Directors, wants to take advantage of Federal funds made available through the HITECH Act to upgrade your Institution's technology infrastructure. The Board of Directors desires to install a state-of-the-art, paperless system that will allow its physicians and nurses to enter orders, review patient status and access patient records wirelessly throughout the Institution. The Board also seeks to employ, among other things, RFID technology, to maximize utilization of the OR — its most profitable real estate.

The Institution's technology upgrade will include a new technology platform; new software for scheduling, materials management, physician order-entry, e-prescribing, pharmacy, decision-support and patient accounting; as well as a web portal to provide remote access to physicians and nurses. The Institution anticipates spending upwards of $35 million on its new system. The Board of Directors anticipates that the return-on-investment of the new system will allow it to achieve profitability, and wants to seize the opportunity to obtain HITECH reimbursement monies while they are still available.

Yet, there is risk. If the new system does not properly integrate with the Institution's existing technology, the Institution will lose millions of dollars of revenue, and its investment will have been for naught.

You are responsible for the project. The Institution is considering proposals from Cerner Corporation, Epic Systems, Siemens Medical Solutions, Allscripts Healthcare and McKesson Corporation. You have been asked to negotiate an "airtight" agreement with the chosen vendor. Yet, each vendor's form contract is different, some more favorable to the Institution than others. One uses a skeletal agreement that offers few contract protections. Another uses a more comprehensive form agreement, but will not make changes to it. A third uses a form agreement that is littered with legalese and HIT-speak, and is largely unintelligible. You must negotiate the best possible contract. What do you do? How do you prepare?

This article offers practical advice on how hospitals and healthcare systems may avoid the top 10 strategic mistakes made in HIT contracting. Obviating these missteps will prevent fatal and embarrassing mistakes, reduce liability, save your job and significant time and expense.

1. Obtain Required Approvals and Buy-Ins.

Before procuring a new HIT system, obtain appropriate approvals from state authorities, your Institution's board of directors, and physicians and nurses. Indeed, many states mandate that hospitals obtain a certificate of need ("CON") before procuring a new HIT system. Each state has its own criteria regarding the issuance of CONs. An excellent resource tool on CONs is "The U.S. Healthcare Certificate of Need Sourcebook," written by Robert James and Published by Beard Books.

Furthermore, obtain the support of your Institution's board of directors, who generally must approve the funds to pay for the system. A new HIT system represents a significant capital expenditure for any hospital or healthcare system. Any decision regarding a new system should be approved by your Board of Directors and other C-level executives, who must support the vendor selection and procurement process. Even more important, obtain approval from your Institution's physicians and nurses. The benefits of a new HIT system (i.e., enhanced workflows, cost savings, operational efficiencies and reduced medical errors), may only be achieved if the new system is used by physicians and nurses, whose "buy-in" is critical.

2. Formulate an Appropriate Contracting Team.

HIT contracting is exceedingly complex. What's more, hospitals generally procure new HIT systems only once every 8 to 10 years (i.e., a system's life cycle). Generally speaking, hospital executives underestimate the difficulty of HIT contracting, and rely on their CIO and general counsel to negotiate these deals, which they do only once every 8 to 10 years, if ever.

Conversely, a vendor's contracting team consists of experienced in-house HIT lawyers and sales persons — who transact hundreds of HIT deals annually.

To address this imbalance, assemble a team of experienced HIT professionals to assist your CIO and general counsel. A professional HIT lawyer and consultant will add years of experience to your team, and will negate the experience imbalance described above. The cost of utilizing outside professionals is de minimis compared to the cost of your new HIT system and failure to achieve appropriate contract protections. Furthermore, the cost of retaining outside professionals is justified by the savings that they will obtain for you in your new HIT contract.

3. Define Strategy.

Before commencing your HIT contract negotiations, carefully consider your Institution's goals, and define a contracting strategy. For example, decide what matters most to your Institution - a speedy HIT implementation or an air-tight HIT contract that consumes six (6) to eight (8) months of negotiations. While these concepts are not mutually exclusive, delineating a "risk-reward" strategy allows you to focus on what matters most. Paradoxically, spending months in HIT contract negotiations makes little sense if your Institution is bleeding millions of dollars in losses.

Deciding what matters most — and creating a thoughtful contracting strategy — will allow you to set realistic expectations with your senior management team and Board of Directors, and set realizable goals that are achievable.

4. Use a Term Sheet.

Historically, HIT vendors press hospitals

continued, next page

and healthcare systems to commence contract negotiations before key deal terms are known. This forces hospitals to become "vested" to the vendor and the contracting process. To avoid this trap, commence contract negotiations only after a final term sheet has been created. Utilization of a term sheets helps to focus your negotiations. Once a term sheet is completed, the vendor or your attorney may craft a contract that mirrors it. You must avoid falling prey to a vendor's sales techniques — that are intended to prevent you from shopping their deal, while costing your Institution time, money and expense (i.e., by forcing you to become wed to their sales process).

5. Whose Contract Should You Use?

In most instances, HIT vendors seek to use their form HIT contracts on each deal. Yet, their forms offer few protections to hospitals and healthcare systems. What's more, HIT vendors' forms are oftentimes intentionally vague, creating "wiggle room" in the event of disputes. Experienced HIT attorneys have negotiated many HIT agreements, and generally maintain their own forms with carefully crafted protections for hospitals and healthcare systems. By substituting all or a portion of your attorney's forms for a vendor's, your Institution will realize the protections that it needs. This will save time and expense, and will expedite the contracting process. This will also enable your Institution to reap the benefits of its new HIT system sooner, rather than later, by shortening the contracting process.

6. Why Re-Invent the Wheel?

When hiring an HIT attorney, ask whether your attorney knows of or would consider using a form contract recently negotiated by the same vendor with another hospital or healthcare system as a template. Significant time and expense can be saved if you commence your HIT negotiations using the same form of agreement that your vendor reached with another hospital or healthcare system represented by sophisticated, outside counsel. Stated otherwise, why reinvent the wheel? It defies logic that your Institution's legal and contracting needs are radically different from every other hospital's such that your Institution must start from scratch on contract negotiations with a vendor, at a cost of thousands of dollars in legal expense.

7. Do Not Be Misled; Financing Is Available.

Don't despair!!! Financing is available! Today, numerous parties will finance your Institution's HIT acquisition. For example, some HIT vendors offer subscription pricing (i.e., monthly payments over a period of 6 to 10 years), spreading the cost of your acquisition over an extended time. Moreover, traditional lenders (i.e., such as General Electric Capital Corporation) will also finance HIT acquisitions. What's more, HITECH Act stimulus monies and grants may be available from the Federal or state governments.

While new HIT systems are costly, sophisticated hospital executives must compare the costs of acquiring a new HIT system with the revenue lost in using an antiquated one. New HIT systems increase workflows, decrease

costs and increase hospital operating efficiencies. Alternatively, the use of antiquated HIT systems prevents hospitals and healthcare systems from collecting revenue, achieving operational efficiencies and attracting qualified physicians and nurses.

Because the ROI associated with the use of a sophisticated, state-of-the-art, HIT system pays for itself and the financing costs relevant thereto, financing of an HIT acquisition allows a hospital or healthcare system to realize the benefits associated with a new HIT system today, rather than years from now in a competitive health care marketplace.

8. Select a Back-Up Bidder; Maintain Leverage.

The sales cycle for an HIT system can reach 12 to 18 months. During this time period, hospital executives issue "RFI's" and/or "RFP's," interview hospital staff (i.e., to assess their needs), attend vendor site locations, analyze each vendor's products, and engage in a litany of other studies. Once a vendor is selected, contract negotiations begin. Yet, what happens if you cannot reach agreement with your vendor on a contract? Will you be relegated to re-initiating your sales cycle, adding an additional 12 to 18 months to the process?

Simply put, the answer is "no." To obviate this problem, consider holding dual contract negotiations with your top two vendors. This will enable you to maintain leverage and a "back-up" vendor should your negotiations fail with your primary one. Alternatively, you may engage in negotiations with one vendor, and keep a second "in-the-wings." In either scenario, you maintain leverage with your primary vendor, and avoid significant time delays should your negotiations fail.

9. Prepare for and Anticipate Contract Amendments.

Generally speaking, most vendors' contracts are not written to facilitate easy amendment. Therefore, as time evolves and your Institution's needs change, amendments to your Institution's contract will be required. A piecemeal approach to contract amendment creates confusion, and raises difficult contract interpretation issues. A well-written HIT contract makes for easy modification by allowing exhibits to be substituted for one another, as opposed to complicated amendments (swapping-out large portions of the original agreement),creating a virtual spider's web.

10. Negotiations Will Fill Time; Set Deadlines and Be Prepared To Walk Away!

An old adage teaches that "time grows to fill the space allotted." This is especially true in HIT contracting. Unless deadlines are set by which negotiations must end, negotiations will drag on. To avoid this result, establish time lines by which segments of your HIT deal must be completed, and hold your vendor's "feet to the fire." Among other things, establish dates and times each week that your negotiations will be held, and provide "homework" deliverables that each side must address between meetings.

Furthermore, avoid in—person meetings to save time and expense, and make as much progress as possible via telephone conference calls and the electronic transmission of drafts. Lastly, do not be afraid to terminate negotiations with your principal vendor (and to approach your back-up vendor), if you reach a major impasse. It is critical to remember that your Institution is spending millions of dollars on a new HIT system, and must obtain an HIT contract that it can live with.

Conclusion

This article identifies the top 10 strategic mistakes that hospitals make in HIT contracting. By following these rules and by avoiding these mistakes, you will save significant time and expense in your HIT contract negotiations.

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Stark's "Set-In-Advance" Requirement

By Bernabe A. Icaza, Esquire, Coral Springs, Florida*

Under Stark if a physician (or an immediate family member of such physician) has a financial relationship with an entity the physician is prohibited from referring certain designated health services to that entity and the entity is prohibited for billing for the services referred to by the physician unless an exception applies. If a financial relationship exists, the financial relationship must meet a Stark exception.

The consequence for violating Stark, even unintentionally, is severe. Medicare is not allowed to make payments for claims that are associated with prohibited referrals even if the services provided were medically necessary. Providers who submit claims are subject to overpayment liability that may be disproportionate to the severity of the violation.

Moreover, Stark is a per se statute. If Stark applies, failure to meet an applicable exception regardless of the reason creates Stark liability. These exceptions contain rigid requirements.

For instance, several Stark exceptions require that the compensation be "Set-In-Advance". Compensation will be considered "Set-In-Advance" if the compensation amount or the specific compensation formula is set in an agreement between the parties prior to the furnishing of any items or services. The formula for determining the compensation must be set forth in sufficient detail so that it can be objectively verified, and the formula may not be changed or modified during the course of the agreement.

The following Stark exceptions have a "Set-In-Advance" requirement: 1) Rental of Equipment; 2) Rental of Office Space; 3) Personal Service Arrangement; 4) Fair Market Value Compensation ("FMV Exception"); and 5) Academic Medical Centers.

Certain other exceptions such as the employment and in-office ancillary/group exceptions also have a Set-In-Advance requirement if the agreement requires that the physician refer patients to a specific provider (collective "Employment Exception"). Generally, the Employment Exception does not require that physician's compensation be set in advance. However, in Phase II, CMS created a limited exception under which an employer could require a physician to refer patients to a specific provider so long as the arrangement, in addition to meeting the requirements of the applicable exception, also met a number of other requirements such as the "Set-In-Advance" requirement. Therefore, to determine whether an employment agreement is required to meet the Set-In-Advance requirement it is important to first determine whether there is any language in the agreement requiring the physician to refer to a particular provider.

For comparison, several Anti-Kickback Statute ("AKS") safe harbors also contain a "Set-In-Advance" requirement. However, the AKS further requires that the '*aggregate'* compensation be set-in-advance. The safe harbor requirement is more onerous as it requires that prior to the furnishing of the services the parties determine the *aggregate* compensation for the entire term of the agreement. As a result, personal service agreements such as Emergency Department On-Call Agreements or Medical Directorships that may pay physicians on a per diem or hourly rate basis generally fail to meet all the prongs of the applicable safe harbor. Since the compensation will vary with the frequency of the services provided the *aggregate* compensation for the entire term of the agreement cannot be determined in advance. Fortunately, the AKS is not a per se statute and the parties' intent is relevant to determining whether a violation has occurred. Unlike Stark, the parties are not required to meet a safe harbor when entering into an arrangement. Under the AKS the parties cannot easily commit a technical violation since the parties' intent always plays a pivotal role in determining whether a violation of the AKS statute, which is a criminal statute, has occurred.

However, Stark is a *per se* statute and the parties' intent is irrelevant. A transaction covered by Stark must meet an exception. Failure to meet an exception is a *per se* violation. As a result, a technical violation, such as failing to meet the "Set-In-Advance" requirement of an applicable exception, subjects the parties to the transaction to Stark liability. The consequences of a Stark violation are draconian.

There are certain practices that, although permissible in ordinary business arrangements, may not be permissible in the health care industry. For instance, the practice of amending the financial terms of an arrangement may be permissible in ordinary business transactions but in the health care industry if not properly structured could easily lead to a violation of Stark. Also, providing services after the parties have reached a common understanding and then subsequent to the provision of some of these services executing the agreement may be more common in ordinary business arrangements but may be problematic in transactions governed by Stark.

The Final 2009 IPPS Rules ("IPPS Rules") helped provide certain flexibility to certain rigid requirements in Stark such as the "Set-In-Advance" requirement. Prior to the IPPS Rules, CMS took the position that an amendment to the compensation provision of the agreement at any time during the term of the agreement would violate the "Set-In-Advance" requirement. In a multi-year agreement the parties were required to wait at least one year prior to any amendment and then were required to terminate the agreement prior to entering into a new agreement with the revised compensation term.

The IPPS Rules loosened the "Set-In-Advance" requirement by permitting mid-term revisions to *certain* compensation arrangements. The IPPS Rules now allows parties the opportunity to renegotiate the compensation term of the agreement without having to terminate the existing arrangement or having to wait until the first year expired as was previously required. The new compensation does need to remain in place for at least one year and the new compensation term cannot be amended during this one-year period. In essence, despite the "Set-In-Advance" requirement of Stark, after the IPPS Rules, the parties could amend the compensation each year as long as the reason for the amended compensation is not in violation of the Anti-Kickback Statute, does not vary with the volume or value of referrals and the transaction overall meets the other prongs of the applicable exception.

According to the IPPS Rules, the compensation arrangements that this amendment applies to are those compensation arrangements that rely

on an exception that contains a *one year term* requirement. All of the exceptions referenced above that contain a "Set-In-Advance" requirement contain a *one year term* requirement except the FMV Exception and the Employment Exception. Thus, the pre-IPPS Rules requirements continue to apply to transactions that were structured to meet either the FMV Exception or the Employment Exception. The consequences for arrangements that were structured to meet either the FMV Exception or the Employment Exception are that the parties to these arrangements are not permitted to modify or amend the compensation (or the compensation formula) during the term of the agreement.

Parties need to be careful not to rely on the FMV Exception as their principal exception or when structuring their employment arrangements need to only use the referral requirement when absolutely necessary. Boilerplate agreements can create significant issues for practitioners who do not carefully scrutinize them and thoroughly think about the consequences prior to placing unnecessary provisions in the agreements such as a referral requirement. If the parties are considering amending the compensation term of the arrangement it is important to review the arrangement for language requiring the physician to refer to a particular provider. If the agreement contains referral language the parties will be precluded from amending the compensation during the term.

Note also that the reasons for the amendment to the compensation do not matter since Stark is not intent based. For purposes of Stark and the "Set-In-Advance" requirement, for instance, it does not matter that the modification to the compensation was not based on the volume or value of referrals ("vv"). This vv requirement is an additional requirement contained in the Stark exceptions and one that may help with defending against a potential violation of the AKS since this is intent based statute. In other words, even if the compensation is at fair market value, commercially reasonable and was not based on the volume or value of referrals, if the compensation term was not set in advance the parties to the transaction may still be subject to Stark liability. Stark is a per se statute and less flexible.

The IPPS Rule also adopted a signature exception that allowed parties thirty days or ninety days depending on whether the mistake was inadvertent. The IPPS Rule provided parties to a transaction with thirty days, if the failure to obtain the signature was 'not inadvertent' (i.e. knowing), or ninety days, if the failure was inadvertent, to obtain the parties' signatures. In other words, if the parties agreed to all of the essential terms of the arrangement, including the compensation, and the only item missing from the arrangement was the parties' signatures, the parties could proceed with providing the services under the terms agreed and subsequently sign the agreement. Note, that the parties are only allowed to rely on this exception once every three years.

Prior to the IPPS Rule, the parties were not allowed to provide the services and be compensated prior to the execution of the agreement. The exceptions above all require a written and signed agreement as well as require that the compensation be "Set-In-Advance". The practice of back-dating an agreement, while perhaps more common in other industries, subjected the parties to potential Stark liability for failure to meet the signature, writing, and Set-In-Advance prongs of the applicable exceptions.

Finally, it is important to note that the Patient Protection and Affordable Care Act ("PPAC") of 2010, directed the U.S. Department of Health and Human Services ("HHS") to develop a process for healthcare providers and suppliers to self-report violations of Stark that may otherwise have resulted in overpayment amounts significantly disproportionate to the severity of the violation. Prior to the PPAC, HHS had limited authority to compromise overpayments associated with technical violations of Stark. A provider or supplier who suspects that it may have committed a technical violation, such as violating the "Set-In-Advance" requirement, may want to consult the Medicare Self-Referral Disclosure Protocol. HHS has the authority under this protocol to reduce the amount due and owing for such violations if voluntarily disclosed.

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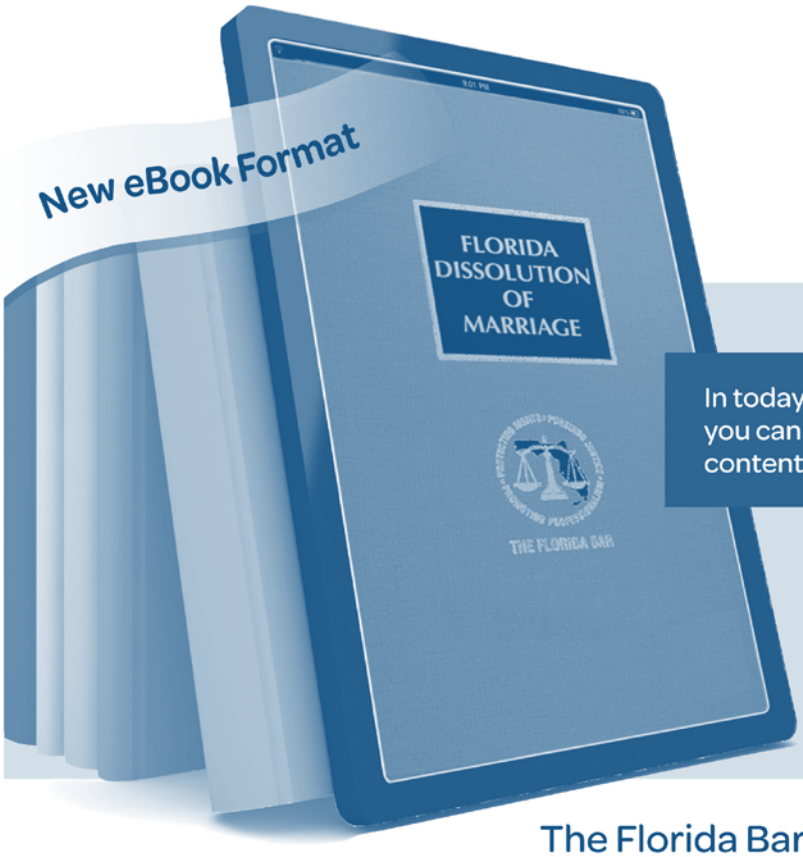

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