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A newsletter on the current legal issues facing today's health care industry

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Impact of Supreme Court's Health Reform Ruling

By William H. Maruca

The U.S. Supreme Court's June 28, 2012 ruling upholding most of the Affordable Care Act (the "ACA" or "Obamacare") by a narrow 5-4 margin took many experts by surprise. Chief Justice John Roberts wrote the majority opinion, joined by Justices Ginsburg, Breyer, Sotomayor and Kagan upholding the controversial individual insurance mandate and its associated penalties, not under the Constitution's commerce clause, but as a legitimate exercise of Congress' power to tax. Justice Anthony Kennedy, long considered the swing vote, joined Justices Alito, Scalia and Thomas in the primary joint dissent, and Justices Thomas and Ginsberg wrote additional separate opinions clarifying their positions on the law.

In the Court's only defeat for the Obama administration, the majority scaled back the ACA's penalties for States that resist the Act's expansion of Medicaid benefits. Using a constitutional scalpel, seven out of nine justices agreed to strike down only the penalty provision that would have cost noncompliant States all of their current federal Medicaid funds. The additional funding for states that implement the expanded coverage was upheld.

The ruling will undoubtedly impact the 2012 Presidential and Congressional races, and a Romney victory and sufficient GOP gains in Congress could result in rollbacks of some of the more unpopular portions of the ACA, but for now, it is the law of the land. How will the ruling affect healthcare providers in the coming years? A few predictions:

Less uncertainty. The Court's ruling upholding nearly all of the ACA means that providers will not be in the position of waiting for government agencies to untangle the complexities of a partial invalidation of the law. States who have held off on developing their insurance exchanges will accelerate the process, or else step aside in favor of fallback federal exchanges. Benefits that have already taken effect will not be rescinded or recouped. Popular ACA programs such as the Bundled Payment Initiative and the Shared Savings Program and Pioneer programs for Accountable Care Organizations will continue.

Reimbursement pressure. The ACA may stress the budgets of CMS and state treasuries, which is expected to result in continuing downward pressure on reimbursement under traditional fee-for-service and episode-of-care payment methods. That pressure will accelerate the development of alternative value-based models by both governmental and private payors.

Increased coverage. One of the primary goals of the ACA was to expand coverage to millions of uninsured Americans. As the "shared responsibility" penalty for failure to purchase insurance under the individual mandate is relatively toothless, it is unclear how much of an impact that mandate will have on the amount of uncompensated care that institutional providers and individual practitioners will be required to deliver in coming years. The Court's Medicaid ruling may also blunt the Act's impact on reducing the rolls of the uninsured depending on how many States reject the expanded Medicaid coverage and associated federal funds. The development of state insurance exchanges and the various insurance reforms, particularly guaranteed issue and community rating, is hoped to slow and smooth out premium increases and bring the cost of coverage within more family and business budgets. Penalties on employers with 50 or more employees will expand coverage unless businesses elect to pay the penalties as a cheaper alternative to buying coverage.

More consolidation and integration. The value-based reimbursement systems needed to implement the

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expansion of coverage under the ACA cannot work in a fragmented, cottage-industry style national healthcare system. Sophisticated information technology capabilities for gathering, sharing and particularly analysis of data will be needed to track and improve quality and cost-effectiveness in real time on a large scale. This requires capital and integration, most easily achieved by integrated health systems but also possible under more loosely-knit networks of independent practitioners in ACOs. Small practices and community hospitals will struggle to keep up unless they join forces contractually or via merger with larger players who can provide access to the tools needed to manage costs and quality in a post fee-for-service world.

Tighter fraud rules are here to stay. The ACA added more teeth to the existing fraud and abuse provisions of the Medicare and Medicaid laws. These include an additional $350 million in federal enforcement funding over the next ten years; stepped-up oversight of providers and suppliers participating or enrolling in Medicare, Medicaid, and CHIP; increases in the federal sentencing guidelines for health care fraud offenses for crimes that involve more than $1,000,000 in losses; enhanced data-matching agreements among Federal agencies; increased surety bond requirements for enrollment; expansion of Recovery Audit Contractors (RACs); classification of violations of the Stark physician referral law and Anti-Kickback law as automatic False Claims Act violations subject to whistleblower suits; and mandatory repayment of overpayments within 60 days of identification.

Providers are employers, too. As employers, the impact on providers will depend on the number of workers they employ. Beginning in 2014, employers with more than 50 employees will be subject to penalties if they fail to provide certain minimum benefits. Companies with up to 25 FTE employees and with average annual wages of less than $50,000 may be eligible for tax subsidies toward the cost of premiums. Employers of all sizes will have additional coverage choices through the state insurance exchanges.

INDUSTRY REACTIONS

Provider advocates' reactions are generally positive but guarded. The American Hospital Association's President and CEO Rich Umbdenstock said "Today's historic decision lifts a heavy burden from millions of Americans who need access to health coverage." Jeremy Lazarus, M.D., President of the American Medical Association, praised the expanded coverage, the prohibition of coverage denials due to pre-existing conditions and lifetime caps on insurance, the expansion of dependent coverage through age 26, expanded research funding and coverage for prevention and wellness care and the preservation of the American system of both private and public insurers. Glen Stream, MD, MBI, President, American Academy of Family Physicians said "The Affordable Care Act provides a foundation for reforming our health care system, but much work still lies ahead including a permanent replacement for the Sustainable Growth Rate formula and meaningful medical liability reform."

The future of health reform now moves from the Supreme Court to the court of public opinion as both parties are expected to cast the November election as a referendum on the still highly-divisive legislation.

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Wearing Two Hats at Once: Employed Physicians and Medical Staff Rights

By William H. Maruca, Esq.

Hospitals and health systems now employ between 20 and 25 percent of all physicians, according to a recent American Hospital Association survey, representing a 34 percent increase over the past decade. Reasons for the trend vary — among them are hospitals' desire to legally lock in physicians' patient referrals; physicians' frustrations with decreasing reimbursement and payor headaches; the increasing cost and complexity of private practice; the evolution of larger, more fully integrated provider entities; and generational differences in attitudes about entrepreneurship and work-life balance. Employed physicians may gain a measure of financial security and lifestyle advantages, but the tradeoff is a reduction in autonomy. Employment relationships are generally defined by detailed contractual provisions, but employed physicians are also members of medical staffs where governance is defined by bylaws and determined by committees of peers. It is important for employed physicians to understand how those two roles interact and which system takes precedence, and to address these issues to the extent possible when negotiating the employment relationship.

Medical staff membership and clinical privileges are granted under hospitals' bylaws as required in Pennsylvania and most other states by hospital licensure requirements. Pennsylvania Department of Health regulations require a hospital's medical staff to be organized to provide for the election or appointment of its officers, and to establish the bylaws, rules and regulations of the medical staff. The medical staff must define in its bylaws the requirements for admission to staff membership and for the delineation and retention of clinical privileges. The bylaws must set forth qualifications for membership and clinical privileges and a system of due process, including fair hearings and appeal mechanisms for medical staff decisions. Due process protections are also required as a condition of the immunity from lawsuits provided under the federal Health Care Quality Improvement Act and are required for accreditation by the Joint Commission. The model is quasi-judicial and intended to be impartial and objective.

In contrast, an employer-employee relationship usually tilts more heavily in favor of the employer's rights, as set forth in written agreements when they are present (as is almost universally the case with hospital-employed physicians). Employment contracts may be terminable by one or both parties without cause, or may be only terminable for breach or upon the occurrence of specific events, with or without an opportunity to cure the alleged breach. One of those events is usually the loss or suspension of medical staff privileges.

Similarly, termination of employment frequently requires the employed physician to relinquish his or her staff membership and clinical privileges and forgo any hearing, appeal or other due process rights. This may be coupled with a restrictive covenant prohibiting the former employee from continuing to practice in the hospital's service area following termination, and may also prohibit the physician from reapplying for privileges for the duration of the noncompete.

Hospital administrators understandably prefer to avoid having to prove the reasons for a physician's termination in a court-like setting before a potentially unsympathetic "jury" of physician peers. This may be particularly applicable when the reason for the termination is based on allegations of "disruptive" behavior, which may be difficult to document. Disruptive physician disputes have increased in recent years, in part because the Joint Commission has adopted a zero-tolerance approach to such behavior by both physicians and administrators. Nevertheless, physicians should not routinely agree to surrender their due process rights upon becoming employed without determining whether any other protections may be preserved.

As a physician considers an offer of employment from a hospital or hospital affiliate, the contract should be carefully reviewed to consider not just what triggering events may cost the physician his or her job, but how, and by whom, the decision is to be made. Hospitals and health systems employ physicians through a variety of methods, including directly through the hospital itself, through a (usually nonprofit) subsidiary of the hospital or its holding company parent, or through a stand-alone practice entity owned and controlled nominally by a physician-insider of the health system (a so-called "friendly" or "captive" PC). These subsidiaries and affiliated entities may include employed physicians on their governing boards, but are not required to do so. Some health systems employ all their physicians through the same corporate entity while others set up or acquire separate entities for each specialty or even for individual physicians. The determination of exactly who is the "employer" and how that employer makes termination decisions is critical. It may be possible to negotiate terms under which a physician may not be terminated except with a majority or supermajority vote of the physician representatives on the governing board, or to develop other protections against arbitrary action by the administration. The success of such negotiations will be driven by traditional bargaining power considerations and the relative flexibility of the hospital. Smaller community hospitals are likely to be more willing to offer concessions to secure desired physician practices.

A hospital may not always want to remove a former employee from its staff. Given the frequently illogical economics of physician employment, a hospital may want to shed a physician's salary obligations to save money but still want to keep that physician as an independent member of the staff and retain his or her patient base. This cycle has occurred in prior waves of practice acquisition and divestiture and may happen again.

Note that termination or other reductions in clinical privileges for reasons related to clinical quality or professional conduct are reportable to the National Practitioner Data Bank, as are physician resignations or voluntary reductions during an investigation of such allegations. However, if under a physician's employment contract the physician is required to forfeit staff membership and privileges upon termination of employment, even if for cause, there may not be any reporting requirement. Data Bank reports can be formidable obstacles to future employment, licensure and

managed care contracting, so there are times when being "fired" by a hospital employer may be preferable to seeking your day in court in a medical staff hearing and losing your case. In some cases it may be possible to negotiate a mutually-agreed upon separation that avoids a Data Bank report as well as the blot on a physician's employment record associated with an involuntary termination.

If you are considering hospital employment, or if you are currently employed by a hospital or health system affiliate, it is important to understand your rights as an employee and a staff member, and how those rights may vary depending on which hat you are wearing and the terms of your employment.

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OIG Publishes Negative Advisory Opinion on Proposed Anesthesia Arrangements at Physician-Owned ASCs

By Victoria Heller Johnson, Esq.

The U.S. Department of Health and Human Services, Office of Inspector General (OIG) issued a negative advisory opinion, No. 12-06, on May 25, 2012, in connection with two proposed business arrangements involving an anesthesia practice and physician-owned ambulatory surgery centers (ASCs). The opinion expressed concerns over aspects of both arrangements and found that, if the requisite intent existed, either arrangement could constitute grounds for penalties and/or administrative sanctions under the federal Anti-Kickback Statute.

The requestor of the opinion (Requestor) was a physician-owned anesthesia services provider comprised of 31 physician members, 10 physician employees and three administrative employees. The Requestor provides anesthesia services on an exclusive basis at several physician-owned ASCs. The ASCs are operated by the physician-owners in accordance with the ASC Safe Harbor to the Anti-Kickback Statute [42 CFR 1001.952(r)]. Under the Requestor's existing arrangements with the ASCs, it billed separately for the professional fees associated with the anesthesia services provided at the ASCs.

Faced with increasing financial pressure from competitors, the Requestor proposed two different variations to its existing exclusive anesthesia services arrangement:

Pursuant to Arrangement A, the Requestor would remain the exclusive anesthesia provider at the ASCs and continue to bill separately for its professional services. However, it would begin paying the ASCs a per patient management fee for the following "management services":

- pre-operative nursing assessments;
- space for the Requestor's physicians, their personal effects and their documentation and records at the ASC; and
- assistance with transferring billing documentation to Requestor's billing office.

The management fee payable to the ASCs would be in addition to their facility fee reimbursement from Medicare and private payors; however, federal healthcare program patients would be excluded from the management fee calculation. The Requestor certified that the management fee would represent fair market value for the management services provided and would not take into account the volume or value of referrals or any other business generated between the parties.

Pursuant to Arrangement B, the physician-owners of the ASCs would themselves set up separate subsidiary companies (the Subsidiaries) to provide anesthesia services at the ASCs. The Subsidiaries would furnish and bill for the anesthesia services at the ASCs. In turn, the Subsidiaries would engage the Requestor (the anesthesia practice) as an independent contractor to essentially manage all of the day-to-day operations of the Subsidiaries. In return, the Requestor would receive a negotiated fee for these management services that would be paid out of the collections for anesthesia services received by the Subsidiaries, with the Subsidiaries retaining any profits.

The OIG analyzed each of the proposed Arrangements separately in light of the requirements of the Anti-Kickback Statute and found both of them to be problematic.

First, the OIG concluded that the management fee payable under Arrangement A was problematic because the payments that the ASCs received from Medicare and other

payors for facility fees were inclusive of the same services that the ASCs were now receiving a management fee for from the Requestor. So, in essence, the ASCs were double dipping – getting paid for the same services twice. The OIG concluded that the fact that federal program beneficiaries were excluded from the management fee was irrelevant because the additional monies paid to the ASCs by the Requestor could unduly influence the ASCs to select the Requestor as the exclusive provider of anesthesia services at the ASCs.

Second, the OIG found Arrangement B to be problematic for several reasons. First, the OIG found that the ASC Safe Harbor would not protect the arrangement since it only applies to surgical services, not anesthesia services. Next, neither the employment safe harbor nor the personal services and management contracts safe harbor to the Anti-Kickback Statute would protect the profits of the Subsidiaries payable to the physician owners under Arrangement B.

The OIG then concluded that Arrangement B was troublesome in that it possessed many of the characteristics of a suspect contractual joint venture as outlined in the Special Advisory Bulletin entitled "Contractual Joint Ventures" [68 Fed. Reg. 23,148 (April 30, 2003)]. Specifically, the arrangement was suspect where:

- the owners of the ACSs were expanding into a related line of business that was dependent on referrals from the ASCs;
- the owners' business risk in the venture was minimal because the owners controlled the stream of referrals;
- the owners were proposing to contract out to the Requestor virtually the entire operation of the Subsidiaries;
- the Requestor was an established provider of the same anesthesia services that the Subsidiaries would be providing, and would otherwise be a competitor of the Subsidiaries;
- the owners and the Requestor would be sharing in the economic benefit of the Subsidiaries; and
- the Requestor admitted it was under financial pressure to enter into the proposed Arrangement or risk losing the business of the ASCs.

The OIG concluded that Arrangement B was designed to permit the owners of the ASCs to do indirectly what they could not do directly – to receive compensation in the form of a portion of the Requestor's anesthesia services revenues in return for their referrals to the Requestor.

Accordingly, the OIG stated that both Arrangement A and Arrangement B could potentially generate prohibited remuneration under the Anti-Kickback Statute and that the OIG could potentially impose administrative sanctions against the parties if the requisite intent was present.

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Off-label Drug Promotion: The False Claims Act and Anti-Kickback Statute

By David Restaino, Esq.

Physicians sometimes prescribe a drug or medical device for a use that has not been approved by the Food and Drug Administration, a so-called "off label" use. A great deal of focus has been placed on pharmaceutical manufacturers' off-label promotion of drugs and the compliance issues confronting those manufacturers. Often absent from that discussion is any recognition of the compliance issues challenging the recipients of those promotional activities, specifically, the health care industry. Health care companies must be alert to the unique compliance questions facing them (e.g., preventing their employees from bowing to the pressure and accepting some form of remuneration in exchange for increasing the use of a particular drug — even when the drug may have been illicitly promoted for non-approved, off-label uses).

The laws that create compliance incentives

In some respects, compliance programs begin and end with the federal False Claims Act (FCA)[1] and Anti-Kickback Statute (AKS).[2] Stated differently, government enforcement of these statutes emphasizes the need for compliance both for companies and their owners, officers, and managers. The FCA makes it a violation to:

- knowingly present or cause to be presented a false or fraudulent claim for payment or approval;
- knowingly make or use a false record or statement material to a payment of a false or fraudulent claim; and/or
- conspire to defraud the government by getting a false or fraudulent claim paid or allowed.

The concept of a "knowing" violation is broadly interpreted. Importantly,

"relators" (i.e., whistleblowers) can bring a fraud action on behalf of the government. Similarly, the AKS makes it illegal to offer to pay to induce a person to purchase or order any item or service for which payment may be made under a federal health care program, or recommend purchasing or ordering such an item or service. Prosecutors do not need to prove that a defendant had actual knowledge of the AKS or a specific intent to violate the statute.

Violations of the FCA and the AKS can result in penalties, convictions, and exclusion from federal health care programs.

Massive corporate penalties—many exceeding $100 million—have garnered recent headlines. The government's use of exclusion from federal programs as a remedy would be a "career killer" for most individuals. This fact is highlighted by a recent example, in which three pharmaceutical executives personally paid over $30 million in combined penalties, yet challenged the imposition of a 12-year ban from federal health care programs.[3]

Policies and guidelines shape compliance efforts

Medical practitioners retain the ability to prescribe drugs for off-label uses. Nevertheless, health care compliance officers should also be aware of other policies and guidance that concern the interaction between pharmaceutical manufacturers, their sales representatives, and the health care industry.

The Accreditation Council for Continuing Medical Education (ACCME) has policies and guidelines designed to ensure independence of continuing medical education programs. These require the disclosure of program sponsorship and conflicts of interest to avoid improper preferential status being given to a particular drug or medical device.

Additionally, the Department of Health and Human Services (DHHS) Office of the Inspector General (OIG) guidance, titled Compliance Program for Pharmaceutical Manufacturers,[4] includes elements of an effective compliance program, (e.g., encouraging "hotline" reporting when sales representatives improperly promote off-label uses). Importantly, it also includes safe harbors that may shield the remuneration paid by manufacturers.

Regulatory safe harbors impact promotional efforts

In assessing the legality of pharmaceutical programs directed at the health care industry, savvy compliance personnel recognize that the financial incentives for manufacturers to promote off-label uses are such that there will always be tension in the "grey areas" of drug promotion. Accordingly, compliance personnel should stay abreast of the regulatory safe harbors which are, essentially, pronouncements that establish which promotional practices are acceptable.

Among other things, the safe harbors shield certain remuneration applicable to group purchasing organizations, discounts, personal services, management contracts, and a litany of other activities pertinent to the health care industry.[5] Even particular arrangements that do not fall within a safe harbor are not, in and of themselves, illegal; rather, they will be subject to greater government scrutiny.

Creating compliance assets

When approaching off-label issues and implementing compliance programs, several over-arching themes should be developed, including:

- enacting a compliance program, business code of conduct, and standard operating procedures;
- appointing a compliance officer and a compliance committee;
- imposing mandatory training;
- reviewing and overseeing conference presentations and the circulation of journal articles;
- enforcing compliance accountability via performance evaluations;
- establishing an internal disclosure program.

In the health care industry, particular focus should be paid to:

- preventing unearned compensation to pharmacists;
- ensuring that fair market value is paid for all drugs;
- avoiding situations where over-filled drug vials or "free" quantities are nevertheless billed to Medicare at full value;
- scrutinizing the methods for coding drug reimbursement; and
- ensuring that the exchange of off-label information is undertaken only for medical or scientific reasons.

Compliance officials should also pay special attention to social media which, by its very nature, encourages dialogue outside of normal channels. It also presents additional challenges for monitoring personnel, as well as the interaction with the public. Although the Food and Drug Administration (FDA) was intent on adopting guidelines,[6] it has yet to act to finalize any, leaving companies to guess the proper compliance approach for social media.

The next step is to seek out information and immediately deal with adverse results. In some respects, this should involve the use of audits to discover compliance issues, which also signals to staff that someone is watching (e.g., auditing contracts to

ensure fair market value has been paid or that volume discounts are not masquerading as "trials").

Audits, however, are not the only method to create a dynamic and responsive compliance system. There should be a process in place to implement—and test—the compliance plan to ensure its continuing viability. This is not an audit but, perhaps, it can be viewed as an audit of the compliance program itself, rather than the underlying substantive activities. Also, it is just as important to manage the "compliance assets" by choosing the appropriate systems to tackle priorities.

Simply put, consider auditing the auditors. Finally, all good compliance programs anticipate new issues. To the extent you can, plan ahead.

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1. 31 U.S.C. §§ 3729 to 3733.
2. 42 U.S.C. §§ 1320a-7b.
3. Friedman v. Sebelius, Docket No. 11-5028 (D.C. Cir.). Oral argument of the defendants' appeal was conducted on December 6, 2011, but an opinion had not yet been issued when this article went to press.
4. 68 Fed. Reg. 23731 (May 5, 2003).
5. See 42 C.F.R. § 1001.952.
6. 74 Fed. Reg. 48083 (September 21, 2009).

OFCCP Rescinds Medical Providers Directive

By Kenneth A. Rosenberg, Esq.

On April 25, 2012, the U.S. Department of Labor's (DOL) Office of Federal Contractor Compliance Programs (OFCCP) announced that it has rescinded Policy Directive 293, which provided guidance for determining whether a health care provider or insurer falls within the OFCCP's jurisdiction as a federal contractor or subcontractor. In particular, Directive No. 293 provided that healthcare entities that merely received reimbursement payments from TRICARE or otherwise participated in a TRICARE network were federal contractors or subcontractors and thus subject to its jurisdiction. The OFCCP maintained that such health care entities were required to comply with federal affirmative action rules and regulations such as preparing an Affirmative Action Plan and submitting to compliance evaluations and audits.

According to the DOL's Office of the Solicitor, the recent enactment of the National Defense Authorization Act (NDAA) and the pending case of *OFCCP v. Florida Hospital of Orlando*, ALJ Case No 2009-OFC-0002 (October 18, 2010) warranted the rescission of Directive 293. In sum, Section 715 of the NDAA states that a TRICARE managed care support contract that includes the requirement to establish, manage or maintain a network of providers may not be considered a contract for the performance of health care service or supplies for the purpose of determining whether such network providers are subcontractors under the Federal Acquisition Regulation or any other law. Based on the enactment of Section 715 of the NDAA, Florida Hospital of Orlando moved to dismiss an OFCCP complaint that sought to assert jurisdiction over the hospital based on its participation in TRICARE.

As a result of these developments, the OFCCP has announced that it will be sending out letters in the coming weeks to health care providers or insurers who have pending compliance evaluations to notify them if the agency is still asserting a basis for jurisdiction other than TRICARE. If a health care provider or insurer receives this notification, it will have 30 days, from the date of receipt of the letter, to submit the Affirmative Action Plan requested in the OFCCP's original scheduling letter.

Ultimately, this development should be good news for many health care providers and insurers as the OFCCP will no longer be seeking to assert jurisdiction over them merely based on their participation in or receipt of reimbursements from TRICARE. Hence, many healthcare entities and insurers will no longer be deemed federal contractors or subcontractors and thus will not be required to prepare Affirmative Action Plans, submit to compliance evaluations and audits or otherwise comply with federal affirmative action rules and regulations.

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