



THE ABA HEALTH LAW SECTION

THE HEALTH LAWYER

IN THIS ISSUE

Physicians Post-PPACA: Not Going Bust at the Healthcare Buffet	1
Disclosing and Refunding Overpayments in Healthcare Cases	16
Valuation of Professional Services Arrangements: An Alternative to the Traditional Physician Employment Model	27
Updates to 2011 Emerging Issues Conference Presentations	34

PHYSICIANS POST-PPACA: NOT GOING BUST AT THE HEALTHCARE BUFFET

David W Hilgers, Esq.
Brown McCarroll
Austin, TX

Sidney S. Welch, Esq.
Arnall Golden Gregory
Atlanta, GA

The passage of the Patient Protection and Accountable Care Act (“PPACA”)¹ has already had a substantial impact on American medicine. Whatever repeals, reformations, defundings, or modifications lie in the future for healthcare reform, the concepts and trends represented by this legislation and its progeny clearly will have an enormous impact on healthcare delivery and the entire healthcare industry. However, no sector of the healthcare industry will be as heavily impacted as the American physician. To risk being accused of hyperbole, PPACA is potentially the final event in a long series of occurrences which will fundamentally transform the structure of the American healthcare industry and the role of the physician in the same. The likelihood of this change has long been expected, but physicians have been amazingly resistant to the predictions. The pressures created by PPACA and the changes it represents may be impossible to overcome.

To understand the potential and probable impact of PPACA for

physicians, it is important to understand the backdrop against which it arrives.

Pre-PPACA Physician Environment

Declining Physician Reimbursement

Due to a number of factors, physician reimbursement declined by 25 percent from 1995 to 2008.² In the past year alone, physicians have anguished while waiting for Congress to force a delay to the sustainable growth rate (“SGR”), which repeatedly threatened to further reduce Medicare payments to physicians by at least 25 percent. Relief finally came in late 2010 for a one-year period and again in December 2011 for another two months,³ but these temporary fixes leave a specter of uncertainty hanging over physician practices.

This decline in reimbursement naturally has resulted in a corresponding decline in physicians’ compensation. According to the most recent data available, from 1995 to 2003 a physician’s net income adjusted for inflation declined seven percent for many specialties.⁴ This decline has been both consistent and exponentially increasing.





A Bridge Over Troubled Water

Not long ago, I had dinner with my friend Beth Schermer, who related her experiences in being recruited by then-Arizona governor Janet Napolitano to assist in bringing divergent forces together to establish a new four-year medical school in Phoenix.

The interested parties included the two major state universities, numerous hospitals and medical groups, research organizations, and foundations – all with their own vision, priorities and needs. Multiple obstacles were encountered en route to a resolution. To Beth the project was both challenging and exhilarating. It led her to rethink the role of leaders and lawyers in navigating conflict and bringing many parties to a single goal, and ultimately led to her refocusing her efforts from the traditional practice of law to business consulting.

My conversation with Beth has led me to rethink how I as a lawyer approach conflict resolution. As lawyers, we are usually engaged by individual clients to represent their interests in litigation or negotiations with other parties. Each side's objective is usually to maximize its self-interest, and we perceive our role to be serving as the client's instrumentality in achieving that goal. Our rules of professional responsibility are to a large extent predicated on this perceived role of the lawyer. Arbitration and mediation, as alternatives to litigation in the resolution of disputes, nonetheless operate in the same paradigm of the lawyer seeking to maximize his or her client's position.

While the traditional role works well for most of our efforts on behalf of clients, recent changes in the way healthcare is organized, paid for and delivered raise the question of whether new approaches to conflict resolution are needed. Today, the government, private insurers, and patient safety advocates, among others, are calling for a degree of collaboration among stakeholders not previously seen. All of us have first-hand experience with the enmity and suspicion that often characterize relationships among hospitals, physicians, payors and consumers. Yet, without effective collaboration, ideas such as accountable care organizations, care management agreements and gainsharing seem destined for failure.

Consider these examples:

- A patient and family aren't ready for discharge, have nowhere to go, and set up camp in the hospital.

continued on page 37



THE HEALTH LAWYER

THE ABA HEALTH LAW SECTION

The Health Lawyer (ISSN: 0736-3443) is published by the American Bar Association Health Law Section, 321 N. Clark Street, Chicago, IL 60654-7598. Address corrections should be sent to the American Bar Association, c/o Member Records.

Requests for permission to reproduce any material from *The Health Lawyer* should be addressed in writing to the editor.

The opinions expressed are those of the authors and shall not be construed to represent the policies or positions of the American Bar Association and the ABA Health Law Section.

Copyright © 2012 American Bar Association.

2011-2012 Officers and Council of the ABA Health Law Section are as follows:

- | | | |
|---|---|---|
| Chair
David H. Johnson
Bannerman & Johnson
Albuquerque, NM
505/837-1900
dhj@nmcounsel.com | Vice Chair
Kathleen Scully-Hayes
Social Security Administration
Baltimore, MD
866/613-3960 x11443
kathleen.scully-hayes@ssa.gov | Budget Officer
Daniel A. Cody
Reed Smith LLP
San Francisco, CA
415/659-5909
dcody@reedsmith.com |
| Chair-Elect
David L. Douglass
Shook Hardy & Bacon
Washington, DC
202/662-4861
ddouglass@shb.com | Secretary
Michael E. Clark
Duane Morris, LLP
Houston, TX
713/402-3905
meclark@duanemorris.com | Budget Officer-Elect
Alexandra Hien McCombs
Concentra
Addison, TX
972/364-8241
alexandria_mccombs@concentra.com |
| Immediate Past Chair
Linda A. Baumann
Arent Fox, LLC
Washington, DC
202/857-6239
baumann.linda@arentfox.com | | |

Section Delegates to the House of Delegates

- | | |
|---|---|
| Gregory L. Pemberton
Ice Miller
Indianapolis, IN
317/236-2313
gregory.pemberton@icemiller.com | J. A. (Tony) Patterson, Jr.
Northwest Healthcare Corporation
Kalispell, MT
406/751-4175
tpatterson@krmc.org |
|---|---|

Council

- | | | |
|--|---|--|
| Gregory E. Demske
U.S. DHHS/OIG
Washington, DC
202/205-0568
gregory.demske@oig.hhs.gov | Eugene M. Holmes
Proskauer Rose LLP
Washington, DC
202/416-5866
eholmes@proskauer.com | Charity Scott
Georgia State University
College of Law
Atlanta, GA
404/413-9183
cscott@gsu.edu |
| Robert W. Friz
PricewaterhouseCoopers LLP
Philadelphia, PA
267/330-6248
robert.w.friz@us.pwc.com | William W. Horton
Johnston Barton
Proctor & Rose, LLP
Birmingham, AL
205/458-9413
whorton@johnstonbarton.com | Robyn S. Shapiro
Drinker Biddle & Reath LLP
Milwaukee, WI
414/221-6056
robyn.shapiro@dbr.com |
| C. Joyce Hall
Watkins & Eager
Jackson, MS
601/965-1982
jhall@watkinseager.com | Priscilla Keith
Indiana University School of Law
Indianapolis, IN
317/274-1951
pdkeith@iupui.edu | Hilary H. Young
Joy & Young, LLP
Austin, TX
512/330-0228
hyoung@joyyounglaw.com |

Young Lawyer Division

Marc M. Meyer
Law Office of Marc Meyer PLLC
Magnolia, TX
281/259-7575
marc@marcmeylawfirm.com

Publication Co-Chair

Michael E. Clark
Duane Morris, LLP
Houston, TX
713/402-3905
meclark@duanemorris.com

Board of Governors Liaison

R. Kinnan Golemon
KG Strategies, LLC
Austin, TX
512/479-9707
kg@kgstrategies.com

Publication Co-Chair

Charles M. Key
Wyatt, Tarrant & Combs, LLP
Memphis, TN
Liaison to the Publications Committee
901/537-1133
ckey@wyattfirm.com

Section Director

Wanda Workman
American Bar Association
321 N. Clark Street
Chicago, IL 60654-7598
T: 312/988-5548 F: 312/988-5814
wanda.workman@americanbar.org

The Health Lawyer Editor

Marla Durben Hirsch
Potomac, Maryland
301/299-6155
mdhirsch@comcast.net

Physicians Post-PPACA: Not Going Bust at the Healthcare Buffet

continued from page 1

Perhaps the greatest factor contributing to declining physician reimbursement is the struggle to reduce the insupportable rate of healthcare inflation, by both private insurers and the government. The physician compensation component of these costs is perhaps the easiest cost factor to reduce because physicians are generally organized into small, independent practices that cannot jointly negotiate for higher fees due to American antitrust laws. In this battle, physicians have very little ability to negotiate higher rates from insurers because physicians have been slow to consolidate, whereas hospitals and insurers have consolidated quickly, enabling them to better negotiate to protect their interests. In many states, only one insurer dominates the market.⁵ In many towns, only one hospital operates. Consolidation in these markets gives both the hospitals and the insurance companies an enormous advantage over physicians, who have to negotiate as individual small practices, whereas the much larger insurance companies are able to exert irresistible leverage in negotiations to reduce the rates paid to doctors for their medical services. Meanwhile, the consolidated hospital systems have a negotiating advantage in their compensation discussions with insurers as well as with physicians for call pay and other physician compensation.

Another factor creating the decline in physicians' income is their reduced ability to benefit from ancillary services. As physicians' fees have decreased, they have looked to the revenues from ancillary services to supplement their compensation. However, the federal government has limited physicians' ability to utilize ancillary services to supplement their income through further narrowing the opportunities available to physicians under the federal Anti-Kickback ("AKS")⁶ and Stark laws.⁷ These diversification efforts are often viewed

by the government as efforts to overutilize ancillary services to increase physician revenue. In fact, the frequently used in-office exception to the Stark law, which allows a physician to refer a patient to the physician's office if it is for in-office MRI, CT, PET or other radiology services, has been modified by PPACA to require physicians to notify the patient of similar services offered by other providers in the area.⁸ Additionally, both Medicare and private payors have reduced the fees paid for ancillary services provided by doctors on an outpatient basis.⁹

In addition to diminishing compensation, physicians have been subject to continuing operating cost increases. Not only have rent, labor, and malpractice insurance costs continued to rise,¹⁰ but increased administrative costs demanded by insistent regulatory requirements have overwhelmed medical groups.¹¹ The physicians are caught in the squeeze between decreasing reimbursement and increasing costs with no clear solution in sight.

Regulatory Pressure

The regulatory pressures on physicians are overwhelming. Pressures to comply with false claims provisions, compliance plans, AKS and Stark regulations, The Health Insurance Portability and Accountability Act ("HIPAA"), the Occupational Safety and Health Act, the Controlled Substances Act and licensing requirements, coupled with potential recovery audit contractor ("RAC") audits and Medicaid fraud unit investigations and increased scrutiny from the Centers for Medicare & Medicaid Services ("CMS") as well as potential for prosecution by the U.S. attorneys offices all combine to exhaust the resources of even the largest healthcare providers. To smaller medical groups, the resources that must be dedicated to these regulatory demands are impossible to financially support.

Another factor discouraging physicians is the reality that even technical violations can support both civil and criminal prosecution that is both costly and frightening. For example, the failure to sign a written contract can, and has, resulted in a claim for refund of all Medicare dollars paid to the hospital as the result of referrals from the doctor that didn't sign the contract. Further, this is not an uncommon claim in the present compliance environment.

Culture Change

Another fundamental change in the physician's environment has been a change in the culture of American medicine. Very little room exists in modern American medicine for TV doctor Marcus Welby, whose idyllic practice never bothered with numbers issues like costs. Today's regulatory requirements and economic pressures demand a highly efficient business model for a physician practice. In the past, the physicians could give free care because they were generating revenue sufficient to subsidize that care. In today's world, that margin does not exist. Consequently, physicians are required to work long hours, see many patients, and spend substantial amounts of time on non-patient activities, such as medical teaching, administration and research.

Meanwhile, younger physicians graduating from medical school have a different view of their career than their seniors. Generally, these younger physicians are interested in shorter work hours, reduced administrative responsibilities, and fewer leadership requirements. They typically are more interested in working as physician-employees than in creating an independent practice with all its corresponding responsibilities.¹² These factors, plus a daunting number of actual and anticipated physician baby boomer retirements, create increasing pressure on physicians to find a new business model.¹³

continued on page 4

Physicians Post-PPACA: Not Going Bust at the Healthcare Buffet

continued from page 3

Lack of Capital

A number of physicians have and are making efforts to respond to the changing healthcare landscape in innovative and creative ways, implementing cost-cutting measures for their patients and implementing electronic health record (“EHR”) systems. However, in addition to the regulatory constraints, physicians are impeded significantly in these efforts by a lack of access to capital. Physician practices do not provide a structure to develop capital resources, since most of the profit is paid in compensation to their doctors.¹⁴ As a result, physicians are either abandoning these innovative efforts in frustration or having to partner with others to survive.¹⁵

Federal Policy Pressure

The final element in the pre-healthcare reform physician environment is the clear federal regulatory policy designed to encourage physician groups to move into integrated systems or larger physician groups. The examples of this policy are numerous: (i) the loopholes or exceptions that have been developed which allow hospital-owned groups to circumvent certain AKS and Stark requirements;¹⁶ (ii) the quality bonus programs developed by Medicare, which are from a practical standpoint only available to large physician organizations because only these large practices have the infrastructure to measure for these quality metrics and deliver them across a large patient population; (iii) the requirement to move to EHRs, which is an expense outside the realm of possibility for most small physician groups; (iv) the ACE Demonstration pilot program, which bundles physician-hospital payments;¹⁷ and (v) the push to Accountable Care Organizations (“ACOs”).¹⁸

As a consequence of many of these changes in the culture

and economics of physician practice, medical practices have already begun to change dramatically. Large integrated systems have begun to develop, and their preferred methodology for integration has been employment of physicians. The push toward physician hospital employment is a new trend. In the recent past, managed care organizations experienced increasing enrollment rates in the late 1980s and early 1990s and more physicians left private practice in favor of employment opportunities as hospitals tried to build larger integrated systems.¹⁹ However, as Health Maintenance Organization (“HMO”) enrollment slowed, the impetus for integrated care diminished. Additionally, the hospitals discovered that these physician groups were expensive and difficult to operate. Consequently, by the turn of the century, many of these hospital groups had been disbanded and the doctors returned to private practice.²⁰ By 2000, only slightly more than 7.5 percent of all physicians were employed by hospitals.²¹

This state of affairs has dramatically changed. In 2008, 13 percent of all physicians were employed by hospitals.²² A survey of residents in 2008 indicated that 22 percent expected to be employed by hospitals, as opposed to 2003, when only five percent had the same expectation. This expectation was corroborated by survey results from the Medical Group Management Association (“MGMA”), which reported that in 2009 more than half (65 percent) of established physicians were placed in hospital-owned practices and almost half (49 percent) of physicians hired out of residency or fellowship were placed within hospital-owned practices.²³ Some preliminary statistics from the last 12 months show that this trend has continued through 2011, with 74 percent of hospital leaders planning to hire even more doctors in the near future.²⁴ While many attribute PPACA and the threatened cuts

to Medicare as speeding up this trend, the race to physician employment actually began in 2009 with Medicare cuts in imaging. However, it is difficult to ignore the activities occurring right now between physicians and hospitals as they seek ever-more imaginative ways to integrate their structures.

As can be seen, the long-standing American physician business model was under great pressure from environmental factors before the passage of healthcare reform. With diminishing compensation, increasing regulatory pressures, changing physician culture, lack of access to capital, and federal policy pressures, the small independent practice that has dominated the healthcare delivery system was already on the ropes. However, PPACA has created significant cause to ask whether this business model can survive given the future course of healthcare.

PPACA Provisions Directly Impacting Physicians

Anti-Kickback Reforms

As mentioned earlier, the pre-PPACA environment for physicians reflected an ever-increasing regulatory scrutiny by the federal government and state governments for healthcare fraud. However, the statutes and regulations made some defenses available to doctors to contest fraud claims brought by the federal or state governments. PPACA effectively eliminated some of the government’s barriers to prosecuting physicians by clarifying previous rulings in circuit courts and precluding defenses typically used by defense attorneys to contest fraud claims.²⁵

One example is the change to the AKS’ requirement that the government prove a knowing and willful violation of the statute.²⁶ Prior to PPACA, circuit courts disagreed on the issue of whether a person had to have actual knowledge that he was

violating the AKS.²⁷ PPACA added the following language regarding scienter: “With respect to violation of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.”²⁸ This change clarifies that concern and reduces the burden of proof for the prosecution, since the prosecution does not have to prove a predominant intent to violate the AKS, but only that one motive of defendant was to generate referrals.

Changes to the Stark Laws

Disclosure of Imaging Ownership

Federal regulators and policymakers have long believed that allowing physicians to receive revenue from imaging owned by the physicians invites over-utilization of those services. Through various mechanisms, including the federal anti-markup provisions,²⁹ the elimination of shared ownership of imaging facilities,³⁰ and the elimination of the per-click payment structure,³¹ CMS has greatly reduced the ability of the physicians to own imaging facilities.

For example, as noted above, PPACA requires physicians referring patients for imaging services within their group practice to give their patients written notice that the patient may obtain this service outside the physician’s group practice.³² This provision applies to MRI, CT, and PT scans, as well as “any other radiology and imaging equipment that the Secretary determines appropriate.”³³ In addition to this notification, the physician is required to provide a written list of alternative suppliers in the area where the patient resides.³⁴ The number of patients that will change their mind and seek imaging elsewhere is likely to be de minimis, but the burden on physician practices and the opportunity for a prosecutable mistake or violation on the physician’s part are significant, although the final rule by CMS does ease some of the administrative burdens on physicians.³⁵ While this new rule can

adversely impact physicians’ ability to own and operate an imaging facility, many also believe that the trade-off in offering the patient the choice is important and outweighs the potential impact on physicians.

Self-Disclosure Protocol

Under Section 6409 of PPACA, the Department of Health and Human Services (“HHS”) was authorized and required to create a self-disclosure protocol that allows physicians to self-report Stark violations to the government.³⁶ This provision seemingly will allow CMS to compromise or waive Stark sanctions, which it had heretofore not had the ability to do. It was hoped that the regulations promulgated under this provision would give some greater definition as to what types of Stark violations would be subject to waiver or reduction in penalty. However, the recently promulgated regulations do little more than quote the language of the statute and are very unhelpful in determining how these self-disclosures may impact physicians.³⁷ In fact, to date only two cases have been settled by CMS under the new rules, with no guidance as to how the settlements were obtained and what, if any, further action was taken against the self-referring entities.³⁸

Physician Ownership of Hospital Prohibition

Probably the most important change to the Stark law contained within PPACA is the prohibition against physician ownership of hospitals.³⁹ From its inception, the Stark law had contained a provision that allowed physician ownership of hospitals under certain circumstances. In many states, this exception to the Stark law has resulted in a rapid growth of hospitals owned at least partially by physicians. Opponents of physician-owned hospitals argued that this growth of physician-owned hospitals resulted in higher utilization or “cherry-picking” of patients. Consequently, proposals were made

to eliminate cherry-picking or over-utilization.⁴⁰

However, PPACA opted for complete prohibition, subject to a grandfathering provision. The final result is that a physician-owned hospital holding a Medicare provider number prior to March 23, 2010 (the date of PPACA’s enactment) cannot expand the number of beds, procedure rooms, and operating rooms for which it was licensed on that date.⁴¹ PPACA grants a small exception for hospitals that were in construction and that did not have their Medicare provider number on March 23, 2010.⁴² Those hospitals were allowed to continue construction and operate as long as they completed their construction before December 31, 2010 and obtained their Medicare provider number before that date.⁴³ In addition, no physician-owned hospital may expand the percentage of ownership in the hospital after the date of enactment.⁴⁴

The consequence of this change will be the eventual elimination of any hospitals developed by physician owners. Those hospitals that presently have physician ownership will be able to continue for some unknown period of time. Their inability to expand will likely require many of them to divest their physician ownership or ultimately fail economically.⁴⁵

The irony of this change is that it eliminates one method for integrating physicians and hospitals. Another irony is the reality that much of the competition for existing hospital systems has been created by expansion of physician-owned hospitals.⁴⁶ The elimination of this competition combined with the continued concentration of the hospital industry will ensure that hospitals will not have as many competitive pressures to reduce their rates or perform services more efficiently.⁴⁷ The only pressure on hospitals to reduce rates and perform services efficiently will come from the payment methodology. These same

continued on page 6

Physicians Post-PPACA: Not Going Bust at the Healthcare Buffet

continued from page 5

payment methodologies if applied to physician-owned hospitals would generate the same incentives to provide more quality services at higher efficiency, without the anti-competitive impact.⁴⁸

False Claims Act

The False Claims Act (“FCA”)⁴⁹ has become the statute of choice for federal prosecutors in the enforcement of the AKS and Stark law. While the penalties and remedies in the FCA already give the prosecutor a substantial advantage, PPACA further strengthened the FCA in several ways:

1. PPACA affirmatively requires providers to report and return overpayments and to report in writing the reason the overpayment occurred.⁵⁰ No longer can physician practices arguably engage in a cost-benefit analysis of repayment and hope to “fly under the radar.” While the federal government has long held that overpayments must be refunded, PPACA dramatically increases the requirements for and consequences of overpayments.⁵¹ The new law creates an affirmative and express obligation to make repayment, and the failure to do so is now another violation of the FCA.⁵² A report of an overpayment must be made within 60 days after discovery of the overpayment.⁵³ Failure to do so is deemed to be a false claim.
2. PPACA amends the AKS to clarify that claims for services resulting from the kickback constitute a false claim.⁵⁴
3. PPACA expands the reach of the FCA to payments made in connection with any insurance plan issued under the new health benefit exchanges.⁵⁵ Therefore, the FCA will not apply just to Medicare or Medicaid, but to any private insurance plans issued under the exchanges. This is a substantial expansion of the types of payments subject to the FCA.
4. The *qui tam* provisions of the FCA were also expanded so that it is now

easier for whistleblowers to collect from these claims. First, the law changed the limitations of public disclosure. In the past, if facts used to demonstrate a violation of the FCA were already made in state proceedings or private litigation, they were not available for a relator to utilize in a whistleblower claim and the whistleblower would not be entitled to recovery. Under PPACA, revelations in a state proceeding or private litigation are no longer public disclosures that would disqualify a relator from recovering under a whistleblower claim.⁵⁶

The original source exception was broadened, as well. Prior to PPACA, the whistleblower had to have knowledge of the facts underlying the allegation that was “direct and independent...”⁵⁷ The language is now changed to say that knowledge that is “independent of and materially adds to the publicly disclosed allegations” is and will entitle the whistleblower to recover.⁵⁸

Other Provisions Strengthening Compliance Authority

In addition to the changes to the FCA, PPACA strengthened the government’s compliance resources in other ways:

1. PPACA expanded administrative penalties available to CMS. Now, Medicare and Medicaid payments to a provider can be suspended “pending an investigation of a credible allegation of fraud.”⁵⁹ Further, CMS can exclude any entity that knowingly makes or causes to be made a false statement or omission in an application agreement, bid, or contract to participate as a provider under a federal healthcare program.⁶⁰
2. PPACA authorized the Secretary of HHS to mandate providers to have a compliance program.⁶¹ These mandatory compliance programs

will apparently be rolled out to different categories of providers over the next several years. However, it is very likely that physicians will be included in these mandated compliance programs.

3. PPACA expanded the resources available to prosecute fraud and abuse.⁶² Three hundred million dollars was added to the funds available to prosecute fraud and abuse over the next 10 years. PPACA authorized increased provider scanning and enhanced oversight of providers. It expanded the use of RAC audits for Medicaid and Medicare Parts C and D. It also broadened HHS’ subpoena power to apply to cases involving allegations that a party is defrauding federal healthcare programs. Nor did healthcare reform ignore the criminal penalties for healthcare fraud. PPACA required that federal sentencing guidelines be amended to increase sentences for defendants convicted of federal healthcare offenses and added violations of the AKS to the category of offense.

These enhancements to the prosecution are considered by the government to be important tools needed to reduce fraud and abuse and, thus, reduce healthcare costs. That may very well be true, but the increased compliance costs they create adds exponentially to the costs of practicing medicine. These changes further increase the pressure on the small practice to seek protection from a larger organization that can afford the resources necessary to comply with the labyrinth of federal and state regulations.

PPACA Reforms Beneficial to Physicians

Although there are a number of healthcare PPACA provisions that could be viewed as detrimental to physicians, PPACA did provide certain

benefits to physicians, particularly in the area of reimbursement for primary care.

1. Primary care physicians will receive a 10 percent incentive payment for all Medicare charges.⁶³ This payment is inclusive for primary care practitioners, defined by Section 5501 as a physician with a specialty in family medicine, internal medicine, geriatrics, and pediatrics.
2. General surgeons performing major procedures in health professional shortage areas from 2011 to 2015 will receive a 10 percent incentive payment.⁶⁴
3. Psychotherapy services were subject to a five percent incentive payment through December 31, 2010.⁶⁵
4. PPACA authorizes the Secretary of HHS to establish geographic payment adjustments for physicians in 56 localities, which include 42 states, Puerto Rico, and the Virgin Islands.⁶⁶ These provisions allow the geographic practice cost index (“GPCI”) to be adjusted as follows: For 2010, the law reinstated a floor of 1.00 on the work GPCI that expired December 31, 2009. For 2010 and 2011, Medicare increased the practice expense GPCI in all payment locales that had a practice expense GPCI below the floor of 1.00 (Montana, North Dakota, South Dakota, Utah, and Wyoming). These changes had the effect of payment increases in a number of states.
5. The Medicare quality reporting incentive payments of one percent was paid in 2011 and 0.5 percent will be paid from 2012 to 2014 for voluntary participation in patient quality reporting.⁶⁷ Additionally, a 0.5 percent payment will be made to physicians who participate in a qualified maintenance of certification program.⁶⁸ However, the physician payment will be reduced 1.5 percent in 2015 for physicians who do not successfully participate in the patient quality reporting

program. In 2016, a two percent penalty may be assessed for failure to participate.

6. Medicaid payments for primary care physicians were raised to Medicare rates for 2013 and 2014.⁶⁹

Of course, one major potential benefit created by PPACA to physicians is the substantial expansion of insurance coverage to the large numbers of patients who presently do not have healthcare insurance. Some already estimate that between an aging population and overall population growth, U.S. physicians’ workload will increase by 29 percent from 2005 to 2025.⁷⁰ Theoretically, the further expansion of potential payments and payor sources by an increased number of insured patients should be a benefit to doctors.

However, in reality many physicians around the country are already fully occupied in providing patient care. They are not missing the patient volume, but they are being squeezed by reduced reimbursement for those patients and increased cost of care as described earlier. The increased demand for access to doctors may only bring more criticism on the doctors as they develop long delays for appointments or limit their practices. This is what occurred in Massachusetts when universal insurance was implemented.⁷¹

Indirect Implications of PPACA for the Physician Industry

One of the major new initiatives legislated in PPACA is payment methodology reforms and incentives to create new types of integrated delivery organizations, such as ACOs.⁷² Except for ACOs, the statute does not describe in detail what these organizations will look like. However, an examination of the various proposed structures leaves little doubt that these innovations will drive the healthcare industry in general and physicians in particular to significant integration.

Medicare Shared Savings Program

PPACA’s ACO program is called the “Medicare Shared Savings Program” or “MSSP”. Generally speaking, an ACO is an organization of physicians and other healthcare providers held accountable for the overall quality and cost of care delivered to a defined population of traditional fee-for-service Medicare beneficiaries, who are assigned by CMS to an ACO.⁷³ The theory behind the ACO concept is that coordination of care (and thus cost-savings) is difficult to achieve without integration among the providers that deliver patient care. Therefore, ACOs are incented, in the form of “shared savings” discussed herein, to manage care in a manner that results in cost savings.⁷⁴ The ACO also holds providers accountable for clinical outcomes by required clinical outcomes reporting and other performance measures.⁷⁵

While extremely similar to the players in the alphabet soup of managed care players in the 1990s – the independent physician associations (“IPA”s), the physician-hospital organizations (“PHO”s), and the HMO⁷⁶ – ACOs differ significantly in that the accountability rests with the providers, rather than the insurers; no health plan intermediary is required to contract with the provider organization; ACOs have great flexibility in their provider composition; and ACOs allow for payment under a fee-for-service arrangement.

The ACO Shared Savings concept gets heightened attention under PPACA. PPACA established an ACO program for Medicare, which is scheduled to begin in 2012.⁷⁷ While the MSSP applies only to Medicare, many anticipate that third party payors likely will follow this trend.⁷⁸ In fact, PPACA allows for preferential participation in the Medicare ACO program for organizations that have ACO arrangements with third party payors.⁷⁹

One of the other initiatives created by PPACA was legislative

continued on page 8

Physicians Post-PPACA: Not Going Bust at the Healthcare Buffet

continued from page 7

direction to the Secretary of HHS to create and begin operation of the Center for Medicare & Medicaid Innovation (“CMI”) no later than January 1, 2011.⁸⁰ PPACA charges CMI with testing innovative payment and service delivery models to reduce program expenditures under Medicare and Medicaid while preserving or enhancing the quality of care. In selecting such models, HHS must give preference to models that also improve the coordination, quality, and efficiency of healthcare services furnished to Medicare or Medicaid beneficiaries or beneficiaries of both programs. PPACA also gives HHS the authority to waive certain laws such as the AKS and Stark law while testing payment models.

National Pilot Program on Payment Bundling

PPACA calls for the Secretary to establish a pilot program for integrated care, using episodic payments centered around hospitalization.⁸¹ This pilot program will be available to entities comprised of providers of services and suppliers including a hospital, a physician group, a skilled nursing facility, and a home health agency. These entities will be required to submit an application to the Secretary of HHS to provide applicable services. The Secretary is authorized to develop various payment methods for these pilot programs.⁸² Those payment methods can include bundled payments and bids from entities for episodes of care.

Family Medical Homes

The federal government has participated in family medical home pilot projects for several years, as noted below. PPACA authorizes HHS to provide grants or contract directly with states to establish community-based interdisciplinary, interprofessional teams to support primary care practices.⁸³ These teams must agree to provide services to eligible individuals with chronic conditions.

PPACA sets out a number of requirements for a family medical home. Since these entities are not hospital centric, they require personal physicians to lead other health providers in caring for the patients. It is assumed that care will be coordinated through all of the providers using integrated healthcare technology, which some argue must be updated to meet the new demands.⁸⁴ Interestingly, it has a requirement that payments recognize the primary care value and should reflect both physician and non-physician value, including non-face-to-face visits in care management.

Presently, there are estimated 26 ongoing medical home pilots encompassing more than 14,000 physicians in over 4,500 practices, treating five million patients.⁸⁵ So far, the results have been mixed. Overall, not all physicians and other providers adapt quickly to this change in their practice. Further, many times patients do not perceive this change to be beneficial. In particular, the use of nurse practitioners and paraprofessionals often are perceived by the patients to be a restriction on their access to care. However, data does suggest that patient outcomes improve and costs become lower with use of a medical home, but it requires substantial investment in technologies and infrastructure to obtain this success.⁸⁶

Other Programs

PPACA is a cornucopia of innovative delivery models. These models include demonstration projects such as Integrated Hospitalization Care,⁸⁷ Medicaid Global Payment Project,⁸⁸ and the Pediatric Accountable Care Program.⁸⁹ CMI⁹⁰ has 20 models listed for testing, including the patient-centered medical home, payment and practice reform in primary care, and direct contracting with providers.⁹¹ PPACA provides six billion dollars of federal money to develop nonprofit,

member-run health insurance programs to compete with the existing programs. It authorizes payment changes to hospitals, which would require doctor participation to achieve. These changes include value-based purchasing, reductions in payments for hospital infections, and reductions in payments for hospital re-admissions.

Although these proposed programs may appear, at first, like a helter-skelter fashioning of a lab experiment with the American healthcare system as the guinea pig, most of these proposed programs involve integration among providers in some fashion, whether through legal entities or contractual relationships. These integration efforts will require the ability of participants to develop cross-professional and facility organization that will involve administration and technology. Moreover, most of these programs involve the use of electronic communications of health records among these participants.

These programs also involve reformed payment structures that eschew the fee-for-service model for other joint payments that must be shared by the various providers through some formulaic or other methodology. If these models expand and proliferate, the role of the physician in these models is critical. The current, fragmented physician structure of the industry will have a difficult time positioning to provide this type of integrated care because it cannot generate the necessary capital, nor provide the infrastructure, the leadership, or the operational administration to cope with these requirements without collaboration among themselves.

Options for Physician Roles after Healthcare Reform

Given the current environment and the implication of healthcare reform, what will be the role of the physician in the future? This question

is quite different from what *should* be the role of the physician in the future. The economic difficulties, combined with the policy imperatives embodied in PPACA, create a strong probability for a new reality in the immediate future. Physicians will have to decide whether and how they want to participate in the new delivery models. Some physicians may choose to retire. Others may practice in rural areas that may not be greatly impacted. However, most will be required to change their practices if they are to continue practicing. Physicians may consider the following options available to them:

Remain as Independent, Small Practitioners

As noted above, physicians in small practices are under extreme economic pressure. They are entrapped in a web of the following potentially debilitating circumstances:

1. A fragmented, unaffiliated professional group with no ability to gain market leverage;
2. Highly regulated reimbursement rates in an environment emphasizing cost reductions;
3. Ever increasing layers of regulation directed at reducing their ability to generate supplementary revenue;
4. A highly complex set of regulations demanding costly technology and infrastructure; and
5. A substantial number of impending retirements with young replacement lacking entrepreneurial incentives.

In the face of this harsh environment, it will be difficult for physicians to maintain the existing fragmented practice.

Concierge Medicine

An increasing number of physicians have turned to concierge medicine, also known as retainer or boutique medicine, to retain their individual practices. Physicians providing concierge medicine charge their

patients directly, usually on a flat fee basis, for basic primary care medical services. These direct payments from the patients can be used as the sole source of income for the physicians, who take no insurance, or they can be used as supplementary payments to those physicians who take insurance, in addition to the concierge payments.

This business model has several limitations. First, the model typically works best for people in good health, since specialty and hospital care are not covered. Second, this model is harder (though not impossible) to apply to the low-income population. Third, as payment methodologies change from fee-for-service to bundled payments, shared savings, and other payment structures, the fee-for-service model utilized by many concierge doctors as the basic underpinnings of their economic viability may not be available. For example, a concierge physician who takes commercial insurance on a fee-for-service basis but receives supplemental payments from the patients will, in many cases, lose the ability to obtain those fee-for-service payments because of provisions in the insurers' provider contracts prohibiting balance billing.⁹² Fourth, the government and private payors may push to preclude concierge medicine, which has been regarded with some disfavor as a model favoring the wealthy. Also, some payors won't contract with a physician offering concierge medicine since it's seen as violative of his or her contract. On the other hand, some medical home pilots for chronic patients look much like a concierge model with longer visits and closer attention from the doctor. If the healthcare system continues to integrate, concierge medicine's role is unclear, although it may become part of the options available.

Large Medical Groups

Another possible structure for physicians in this new reform world is the large physician-owned medical

group. These groups may be single-specialty or multi-specialty. If this group is large enough, it will be able to use its leverage in the market to partner with hospitals in the development of an integrated delivery system. Their ability to deliver large numbers of physicians to an integrated system in a coherent and organized fashion will make them an attractive partner for hospitals seeking to develop large delivery systems. Because of this value to the integrated delivery system, these larger medical groups should be able to negotiate better economic positions for them in the system as well as greater roles in the ownership and governance of these systems, although the regulatory limitations for this kind of partnership is unclear and depends largely on the Secretary of HHS and her action or inaction on the authority granted to her regarding waivers of the AKS and antitrust laws.⁹³

However, large medical groups are not without challenges. Over the last few decades, physicians have resisted self-governed integrated organizations. These opportunities include chances for dissension and disagreement between the personalities owning the group over compensation and control, particularly if the group is multi-specialty. To keep pace with the other players, the group will require access to capital. Physician organizations have been unable to develop internal capital and have no methods to obtain outside investor capital. Finally, the rapid integration of a fragmented medical community into a large medical group requires extraordinary leadership. Physicians have not been trained to provide that type of leadership, and natural-born physician leaders are too few to develop many of these organizations in a short period of time. As a result, either the concept of physician leadership in the healthcare market will need to be redefined based on new models of organization or potentially only those large medical groups already in existence will be able to pursue this option.⁹⁴

continued on page 10

Physicians Post-PPACA: Not Going Bust at the Healthcare Buffet

continued from page 9

Management or Service Line Companies

Another model for physicians involves using management or service line companies with adjunct medical groups.⁹⁵ Many large specialty groups today, particularly hospital-based physicians, have organized and compete against each other for hospital contracts. Many hospitals find it very simple to contract with a group that will do a turn-key job and provide all of the outsourced medical and related administrative services for the hospital on a contract basis, as opposed to developing its own hospital-based group. These groups may contract on a regional basis or even develop into a standard corporate structure without substantial physician ownership. Rather, they will be run much like their hospital clients, with limited physician input. These groups will need to be able to manage physicians and provide effective medical services, which historically they have failed to do.

Options for Rural Physicians

While rural physicians must overcome the difficulties inherent in being small independent practitioners, rural physicians may be strong players in their locale. Because of the rural hospitals' need for physicians, those physicians, if united, even outside a single medical group, can exert enormous pressure on a hospital. Consequently, rural physicians may be able to continue in small groups with the hospital as the only coalescing entity in the community. The hospital's role will be increasingly complicated as it receives payments in a bundled or short-shared savings form but has to pay physicians in a standard fee-for-service mode. While frustrating for hospital administrators, this scenario may be the only one in which they likely are able to retain their present business model of the independent practice. This model is not without antitrust, AKS, and

Stark concerns since it relies on payments by the hospital in order to maintain the physician's practice. However, the extreme need in these communities will require either policy changes or more lenient prosecution at some point.

Hospital Employees

By far, the quickest method of creating integrated delivery systems is the hospital employment of physicians. An increasing number of physicians are looking for employment from hospitals as a stop-gap measure against reduced compensation. Hospitals are comfortable with the employer-employee relationship and believe that they will be better able to position themselves in a changing marketplace and control physicians as employees rather than as partners or contracted physicians.⁹⁶ Additionally, physician employment reduces many of the complexities of the AKS and Stark laws.⁹⁷ Clearly, under Stark the compensation for the physicians would still have to be measured by fair market value. However, this model eliminates such complicating concerns as ancillary service income, stand-in-the-shoes restrictions, and physician ownership of facilities.

What the employment model does not do is eliminate a potential future fraud and abuse concern. Specifically, as reimbursement continues to decline for physicians, many hospital-employed physicians may not be profitable individually. It may cost more to hire them and to pay their expenses than the amount of revenue they generate in their practices. In effect, the hospital would have to subsidize the physician's practice. At least one federal prosecutor has taken the position that a payment to a doctor that would put the physician's medical practice in a losing posture is automatically a violation of the Stark law.⁹⁸ This conundrum may evaporate

as healthcare reform progresses and the Secretary grants waivers to the Stark law and AKS. However, in the interim, this problem is a real concern for rural hospitals in particular because the reimbursement for physicians in rural areas is largely low-paying Medicare and Medicaid. Therefore, in order to attract physicians to rural areas, hospitals often need to subsidize the physician practice. Stark and anti-kickback issues create obstacles to those subsidies when the doctor is unable to generate enough revenue to support his or her own salary. The question becomes "Why is the hospital paying the doctor more than he can earn?" One assumes that the hospital needs the doctor to refer to the hospital. The problem with this answer in a world with Stark and anti-kickback laws is obvious.

Employment will result in a transformation of the physician's practice. Physicians will clearly have less control over their office operations and clinical methods. On the other hand, they will no longer be saddled with the administrative and operational duties of running the practice. Essentially, the physician looks more like part of the labor force that must negotiate with its employer for compensation changes.

Employed physicians also face the significant question of what roles they play in governance of the hospital. Most of the highly respected integrated systems in the country have developed from physician-centric organizations, and physicians presently retain a substantial role in the governance of those delivery systems. However, hospital-centric organizations have not developed that type of physician participation and governance. Of course, they have their medical directors and public relations doctors. Nonetheless, the medical staffs have been the core of the physician leadership. In integrated delivery systems, many physicians are not

involved in the hospital at all but perform strictly outpatient roles. In hospital-employment situations, physicians will have a hard time negotiating meaningful leadership roles in the delivery systems unless the hospital administration is receptive. Perhaps changing payment methodologies will convince hospital administration that physicians have to take an important role. However, more likely, those changes may exacerbate tensions and hospital administrators will continue to operate their top-down organizational structures, expecting physicians to perform as employees.

Partnering with Health Insurers

Recently, several of the large health insurance companies have ventured into the acquisitions of providers. United Healthcare acquired Monarch, a large physician network in California. Humana acquired Concentra, a large provider of worker's compensation care nationally. Cigna has acquired a medical group in Phoenix and a large physician management organization, HealthSmart, in the South and Southeast. Meanwhile, Blue Cross Blue Shield in Pennsylvania and West Virginia has acquired a six-hospital system.

This new trend creates possible options for physicians. Obviously, insurers are at least experimenting with the idea that they can better control costs if they control the physician through employment or other mechanisms. Thus, a possible option is to partner with an insurance company through employment or other contractual means. In some cases, this may be a very positive option for physicians. However, it should be noted that in the 1970s and 1980s, Prudential was a major player in healthcare through its subsidiary, PruCare. PruCare had associated medical groups, which were exclusive to PruCare, in many of its markets. This ultimately was a failed model and should be studied to make sure that it does not occur again.

Insurance CO-OPs

One of the more obscure provisions in PPACA was the funding of so-called insurance CO-OPs, which enable communities to set up insurers locally. PPACA also provided substantial funding to allow these CO-OPs to organize. Presently, these seem to be developing in the Midwest as local communities struggle to find competitors in their insurance markets. Although these organizations cannot be controlled by providers, certainly physicians could take a major role in organization of these CO-OPs and provide services to the members of these organizations.⁹⁹

Caveats

Physician Shortages

A major unknown in this portrait of American medicine's future is the impact of the impending physician shortage. The United States is beginning to experience a dramatic shortage of physicians. Presently, the United States has 352,908 primary care physicians, and the Association of American Medical Colleges estimates that 45,000 more will be needed by 2020.¹⁰⁰ Recently, the Association of American Medical Colleges projected that nationwide physician shortages would rise to 62,900 doctors in five years and 91,500 by 2020.¹⁰¹

These shortages are not only in primary care. A national survey conducted by the National Association of Children's Hospitals and Related Institutions found that the top pediatric specialist shortages were in neurology, developmental-behavioral pediatrics, gastroenterology, general surgery, and pulmonology.¹⁰² Moreover, this shortage will be exacerbated by the increase in demand. To some degree this physician shortage may be moderated by the use of physician extenders. Also, some people argue that a reduction in specialists will be a good development as unnecessary procedures will be reduced. However,

with the increased demand and already existing shortage, doctors will be at a premium in many locations.

The impact of this shortage on the physician landscape after reform is hard to project. This shortage likely would increase the leverage of physicians in securing positions. However, the present regulatory scheme may create limitations on this economic pressure. Presently, compensation of physicians is limited to fair market value. The fair market value is determined by consultants who look at compensation for similar physicians in the same region. If that present compensation has been depressed because of regulatory limitations on reimbursement, no clear mechanism will allow higher compensation to be paid to a new physician than is already paid in the market. No doubt, the government and/or the valuation consultants will eventually articulate a methodology that will allow this increase, but it may be delayed. Further, this physician shortage likely will not change the overall trend toward hospital employment of physicians rather than partnership between hospitals and physicians, because many of the factors discussed earlier which lead to a resurgence of physician employment still remain. The physician shortage will most likely eventually result in stabilizing and, perhaps even increasing physician compensation, but it will probably not change the trend toward integration of the providers into large delivery systems.

Intractable Management Issues

One of the reasons that it has been so difficult to consolidate physicians is the difficulty of managing them. As early as 2003 studies have shown that lack of cooperation by physicians and lack of leadership rank among the most frequently cited barriers to forming large medical groups.¹⁰³ The large, integrated systems like Mayo Clinic, Permanente, and Geisinger are historical anomalies that developed in unique communities under unique circumstances.¹⁰⁴ The industry has

continued on page 12

Physicians Post-PPACA: Not Going Bust at the Healthcare Buffet

continued from page 11

already witnessed the debacle of physician management companies efforts to corral physicians into manageable organizations at the end of the century, as most of these companies are now defunct or out of the management business. Hospitals have also made a hash of managing physicians for the most part in the past.

Presently, it appears that hospitals and other non-physician organizations are rushing into ACOs and other integrated entities by trying to capture as many physicians as possible and making hurried decisions to implement the ACO without creating effective management.¹⁰⁵ Some physician-run organizations are being implemented successfully, but those examples are few and far between for the reasons cited above. Not much thought is going into how those organizations can best be organized to insure the loyalty and cooperation of the physicians. The pressures of change likely will not allow for any cautious contemplation of new organizational structures that will avoid the past problems. For example, should doctor leaders from the acquired groups be given major decision power over the groups? Should the members of the group be able to select their own leaders of the employed group? Does the existing hospital medical staff model have potential application to these medical groups? Should the management group administering the medical group be the boss of the medical group or vice versa? It will take years to develop a new workable model. As usual, the industry likely will try to fix this after the great consolidation slows down. Those entities trying to react to this consolidating imperative should direct some resources to sharply questioning the existing ideas on how to make these groups effective, efficient delivery systems.

The “Quality Conundrum”

Finally, one very important caveat is the push to new “quality” frontiers in

medicine. These initiatives range from safety guidelines to hospital infection control to medication error prevention to “quality” profiles and measures. While the country’s current healthcare system clearly needs to strive for improved quality, outcomes, and efficiencies, some of the new proposed measures seem geared to drive the industry toward protocol-driven medicine rather than striving for innovation and improvement.¹⁰⁶ Such “cookbook” medicine is controversial in medical circles and its contribution to quality is questioned by many.

Conclusion

After implementation of healthcare reform, it is difficult to imagine any significant survival of the present fragmented physician industry structure, except in rural areas. The most likely portrait of physician life in the United States 10 years from now will include some large integrated systems in which physicians play an important role as partners. However, the majority of physicians will be employees of these integrated systems without any particular governance role. It remains to be seen how much physicians will participate in those organizations and at what compensation level they will be paid. Likely they will have roles akin to the medical staff in present hospitals. They will be much less entrepreneurial and much more of an employed labor mindset. Organized medicine will have declined substantially, perhaps to be replaced by unions. Depending on how the regulatory scheme develops, concierge medicine may or may not be an important part of the delivery system.

If the delivery systems are able to accommodate this form of healthcare, it may flourish. However, if it is seen as ineffective at reducing costs and providing care, those systems will not survive. All in all, it is hard not to conclude that the age of the fiercely

independent, entrepreneurial physician will rapidly decline over the next five years. Whether this is a good or bad thing for the health of the United States is not clear, but it will have a substantial impact on how doctors see themselves and how patients see their doctors.



David W. Hilgers is a Partner at Brown McCarroll, L.L.P. and is a member of the firm’s Healthcare Law Section. He has practiced law for

more than thirty-five years. His primary focus is on healthcare, corporate, and administrative law. Mr. Hilgers represents healthcare providers, including physicians, dentists, health systems, managed care organizations, long-term care facilities, multi-specialty groups, hospitals, hospital districts, and community mental health and mental retardation centers. He can be reached at dhilgers@brownmccarroll.com.



Sidney S. Welch is a Partner with Arnall Golden Gregory LLP’s healthcare practice. Ms. Welch is recognized nationally for

representing physicians and physician practices in all legal aspects of their practices. This expertise includes healthcare regulatory, corporate, contractual, administrative and litigation matters.

Ms. Welch currently serves as Chair of the American Bar Association Health Law Section’s Physician Issues Interest Group and Vice Chair of the American Health Lawyers Physicians and Physicians Organization Group. Ms. Welch is a frequent speaker and author on healthcare matters, and has been recognized as one of the nation’s top ten physician attorneys by Nightingale News. She can be reached at Sidney.Welch@AGG.com.

Endnotes

- 1 Pub. L. No. 111-148 (2010).
- 2 Douglas O. Staiger, David I. Auerbach, & Peter I. Buerhaus, *Trends in the Work Hours of Physicians in the United States*, 303 J. AM. MED. ASS'N 747 (2010).
- 3 See Pub. L. No. 111-309 (2010); see Medicare pay cut averted; Congress OKs two-month patch, AMA Alert Dec. 23, 2011, www.ama-assn.org/ama/no-index/news/2011-12-23-ama-alert-page.
- 4 HA T. TU & PAUL B. GINSBURG, *Losing Ground: Physician Income 1995-2003*, 15 Center for Studying Health System Change Tracking Report 1 (2006), <http://hschange.org/CONTENT/851/851.pdf>; Staiger et al., *supra* note 2.
- 5 David W. Emmons, Jose R. Guadado & Carol K. Kane, *Competition in Health Insurance: A Comprehensive Study of U.S. Markets, 2010 Update*, American Medical Association Division of Economic and Health Policy Research (2010).
- 6 42 U.S.C. §1320(a)-7b. The Anti-Kickback Statute ("AKS") provides for criminal penalties for certain acts impacting Medicare and Medicaid reimbursable services. Of primary concern is the section of the AKS which prohibits the offer or receipt of certain remuneration in return for referrals for or recommending purchase of supplies and services reimbursable under government healthcare programs.
- 7 42 U.S.C. §1395nn, §411.350, §411.389. The Stark law, technically known as the Ethics in Patient Referral Act, restricts self-referral, or the practice of a physician referring a patient to a medical facility in which he/she has a financial interest, for Medicare and Medicaid patients.
- 8 Patient Protection and Affordable Care Act ("PPACA"), Pub. L. No. 111-148, sec. 6001, 124 Stat. 119 (2010). See also further discussion of this modification later in this article.
- 9 Paula Nelson, *MANAGED CARE CONTRACTING – ANCILLARY CONTRACTING*, Managed Care Resources, Inc. (1998).
- 10 Press Release, Med. Grp. Mgmt. Ass'n. Medical Group Practice Cost Increases Outpace Revenues (October 20, 2008), <http://www.mgma.com/press/default.aspx?id=22678>.
- 11 Steffie Woolhandler, Terry Campbell & David U. Himmelstein, *Costs of Health Care Administration in the United States and Canada*, N Engl J Med 2003;349:768-75 (2003). See also Congressional Budget Office Report, *Key Issues in Analyzing Major Health Insurance Proposals*, December 2008.
- 12 Bill Wooten, *Generational Differences*, Presentation to the Texas Medical Association (October 2008). <http://www.slideshare.net/bmwooten/generational-differences-texas-medical-association-10-3-2008>.
- 13 Darryl Fears, *Retirements by baby-boomer doctors, nurses could strain overhaul*, Washington Post (June 14, 2010). <http://www.washingtonpost.com/wp-dyn/content/article/2010/06/13/AR2010061304096.html>.
- 14 Keith D. Moore, et al. PROVIDING CAPITAL FOR PHYSICIAN GROUP PRACTICES: NEW OPPORTUNITIES FOR HOSPITALS – STATISTICAL DATA INCLUDED, Life & Health Library (Dec 1999).
- 15 *Id.* Many physician practices had trouble at the turn of the century because of poor nationwide financial conditions and dried up existing capital sources, forcing many practices to partner up or sell to large medical companies.
- 16 Hospitals can subsidize medical groups they own, but they cannot subsidize independent medical groups.
- 17 The Medicare Acute Care Episode Demonstration ("ACE") is a hospital-based demonstration set up by CMS that is designed to test the use of bundled payment for both hospital and physician services for a select set of inpatient services to improve the quality of care through Medicaid fee-for-service. See CMS Press Release January 6, 2009, <https://www.cms.gov/DemoProjectsEvalRpts/downloads/ACEPressRelease.pdf>.
- 18 Bernadette Broccoli, TOWARD ACCOUNTABLE CARE: HOW HEALTHCARE REFORM WILL SHAPE PROVIDER INTEGRATION. Strafford Webinar – "Physician-Hospital Clinic Integration: Navigating the Complexities" page 4 (July 21, 2011). <http://media.straffordpub.com/products/physician-hospital-clinic-integration-navigating-the-complexities-2011-07-20/reference-material.pdf>.
- 19 Sharon Bell Buchbinder, et al. *Estimates of Cost of Primary Care Physician Turnover*, Am. Journal of Managed Care, 1431-1432, November 1999.
- 20 Carol K. Kane, PHYSICIAN MARKET REPORT NO. 2004-2 3 (Am. Med. Ass'n ed., 2001), <http://www.ama-assn.org/resources/doc/health-policy/pmr-022004.pdf>. See also O'Malley, Ann S., et al., *Greenville & Spartanburg: Surging Hospital Employment of Physicians Poses Opportunities and Challenges*, Community Report No. 6, Center for Studying Health System Change, Washington, D.C. (February 2011).
- 21 *Id.*
- 22 American Hospital Association's Statistics, 2008.
- 23 Med. Grp. Mgmt. Ass'n, PHYSICIAN PLACEMENT STARTING SALARY SURVEY: 2010 REPORT BASED ON 2009 DATA, (MGMA ed., 2010).
- 24 Lena H. Sun, HOSPITALS COURTING PRIMARY-CARE DOCTORS, (Wash. Post June 19, 2011).
- 25 Until the passage of PPACA, circuit courts around the country had ruled on similar cases differently. In *Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995), the court held that defendants charged with violation of the AKS must have actual knowledge of the statute being violated and intent to violate it, in contrast to previous circuit court opinions to the contrary. See *U.S. v. Greber*, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). PPACA clarified this section to preclude any defense that the defendant did not have knowledge of the AKS.
- 26 The AKS prohibits individuals or entities from knowingly and willfully offering, paying, soliciting or receiving remuneration to induce referrals of items or services covered by Medicare, Medicaid or any other federally funded program (except the Federal Employees Health Benefits Program). 42 U.S.C. § 1320a-7b(b) (2006).
- 27 E.g., *Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995); Cf., *United States v. Starks*, 157 F.3d 833 (11th Cir. 1998). Prior to PPACA, a few circuit courts required a specific intent to violate the AKS.
- 28 Section 6402(f)(2) of PPACA (Pub. Law 111-148).
- 29 42 C.F.R. § 414.50 (2008).
- 30 73 Fed. Reg. 48434 (Aug. 19, 2008).
- 31 *Id.*
- 32 PPACA, Pub. L. No. 111-148, sec. 6001, 124 Stat. 119 (2010).
- 33 *Id.*
- 34 On November 2, 2010, CMS posted its final rule implementing this section of PPACA. In it, some of the administrative burdens on physicians were softened, but much of the section remained intact. CMS requires that the disclosure be made for all MRI, CT and PET services, but declined to expand the requirement to other imaging services. Physicians must give notice to the patient of at least five "suppliers", which is reduced from the initial requirement of 10. "Suppliers" includes all competing physicians in the area, but does not include providers of imaging services such as hospitals. Further, to help ease the burden somewhat, CMS is requiring that physicians include only suppliers within 25 miles of the physician's office, since the physician cannot possibly create an individualized notice for each patient regardless of where they live. CMS also clarified, however, that notice must be given to the patient each time the service is needed, and not only on the initial visit, although the requirement that the physician get the patient's signature and keep the signed notice for documentation has been removed. Finally, CMS will not make an exception to this requirement for emergency or one-time bases, nor will CMS provide standard disclosure language. See Centers for Medicaid & Medicare Services, Final Rule, 75 Fed. Reg. 73443 (November 29, 2010).
- 35 *Id.*
- 36 PPACA, Pub. L. No. 111-148, sec. 6409, 124 Stat. 119 (2010). See also Ethics in Patient Referral Act (commonly referred to as the "Stark Act") 42 U.S.C. § 1395nn.
- 37 For more information on the regulations, see CMS Self-Disclosure Protocols: https://www.cms.gov/PhysicianSelfReferral/98_Self_Referral_Disclosure_Protocol.asp#TopOfPage.
- 38 *Id.*
- 39 See *supra* note 32 at sec. 6001.
- 40 Following two separate moratoria, one in 2003 enacted by Congress and again by CMS in 2005, the Medicare Payment Advisory Commission ("MedPAC") and CMS launched investigations into specialty physician-owned hospitals which were excluded from Stark liability based on the "whole hospital" exception. The subsequent reports and testimony to Congress paved the way for the changes outlined in Section 6001 of PPACA. See MedPAC, "Report to the Congress: Physician-Owned Specialty Hospitals" and Michael Leavitt, "Study of Physician-owned Specialty Hospitals Required in Section 507(c)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003," Health and Human Services (2005).

continued on page 14

Physicians Post-PPACA: Not Going Bust at the Healthcare Buffet

continued from page 13

- 41 See *supra* note 32 at sec. 6001.
- 42 *Id.*
- 43 *Id.*
- 44 *Id.*
- 45 Tim Eaton, HEALTH LAW REFORM TARGETS PHYSICIAN-OWNED HOSPITALS (Austin Am. Statesman, May 29, 2010).
- 46 Spencer Harris & Brad Zarin. PHYSICIAN OWNED HOSPITALS. (Tex. Pub. Policy Found. August 2011).
- 47 *Id.* at 5. While hospitals and physicians will be measured and scrutinized based on their performance with the passage of PPACA, community hospitals may not have a competitive market to drive prices when physician-owned hospitals are gone.
- 48 *Id.*
- 49 31 U.S.C. §§ 3729–3733.
- 50 See *supra* note 32 at sec. 6402(d).
- 51 Mark Gallant, Salvatore Rotella, Jr., and Melanie Martin, PROVIDERS BEWARE: HEALTH CARE REFORMS MAKE FAILING TO PROMPTLY REFUND OVERPAYMENTS – INCLUDING THOSE ATTRIBUTABLE TO IDENTIFIED STARK VIOLATIONS – POTENTIAL FALSE CLAIMS ACT VIOLATIONS, Cozen O’Conner Health Law Alert (April 26, 2010). <http://www.cozen.com/admin/files/publications/health042610.pdf>.
- 52 See *supra* note 32 at sec. 6402.
- 53 *Id.*
- 54 *Id.* at sec. 6402.
- 55 *Id.* at sec. 1313.
- 56 *Id.* at sec. 10104.
- 57 31 U.S.C. § 3730(4)(A) & (B).
- 58 See *supra* note 32 at sec. 10104. Some believe that this change will have a significant impact on *qui tam* complaints because it may open the door for whistleblowers to rely on secondhand or indirect information when making an allegation, as long as allegations add new information to what is already available in the public domain. See McDermott Will & Emery, HEALTH CARE REFORM: LEGISLATION EXPANDS FALSE CLAIMS ACT, WHISTLEBLOWER CASES EXPECTED TO INCREASE, (March 31, 2010) http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object_id/a3520977-8f8a-4b5b-a83d-26ada4315a1d.cfm.
- 59 See *supra* note 32 at sec. 6402.
- 60 *Id.* at sec. 6408.
- 61 *Id.* at sec. 6401.
- 62 *Id.* at sec. 6402.
- 63 *Id.* at sec. 5501.
- 64 See *supra* note 32 at sec. 5501.
- 65 *Id.* at sec. 3107.
- 66 *Id.* at sec. 3102.
- 67 *Id.* at sec. 3002.
- 68 Effective January 2011, any physician who meets specified requirements may have their “Physician Quality Reporting System” quality percent for that year increased by 0.5%. Requirements include submitting quality measures data for a 12 month reporting period and completing a certification program for a year. See Centers for Medicaid & Medicare Services, PHYSICIAN QUALITY REPORTING SYSTEM MAINTENANCE OF CERTIFICATION PROGRAM INCENTIVE GUIDANCE, https://www.cms.gov/pqrs/downloads/MOC_Guidance_Final_1_2_3.pdf.
- 69 See *supra* note 32 at sec. 1202.
- 70 Robert B. Doherty, THE CERTITUDES AND UNCERTAINTIES OF HEALTH CARE REFORM, *Annals of Internal Medicine* (April 8, 2010).
- 71 “Physician Shortage in Massachusetts Continues to Squeeze Primary Care,” Henry Tanya Albert, AMEDNEWS.com, October 12, 2011; “Physician Workforce Study,” Massachusetts Medical Society, September, 2011; “Mass. Health Care Reform Reveals Doctor Shortage, National Public Radio, <http://www.npr.org/templates/story/story.php?storyId=97620520>, 21/1/08.
- 72 The initiatives in PPACA to create integrated healthcare organizations are likely to survive even if the Supreme Court declares parts of the statute unconstitutional. See Abelson, Harris and Pens, “Whatever Court Rules, Major Changes in Health Care Likely to Last.” *New York Times*, 11/14/2011.
- 73 *Id.* at sec. 3022.
- 74 *Infra* at 2.
- 75 See generally Elliott S. Fisher, Mark B. McClellan, John Bertko, Steven M. Lieberman, Julie J. Lee, Julie L. Lewis, & Jonathan S. Skinner, *Fostering Accountable Health Care: Moving Forward in Medicare*, 28 HEALTH AFFAIRS w219, w219–31 (2009), <http://www.dartmouth.edu/~jskinner/documents/FisherESFostering.pdf>.
- 76 These three players formed a large part of the managed care framework throughout the 1990’s. HMOs are health insurance groups that provide a range of coverages. IPAs are groups of individually practicing physicians who often contract with one or more HMOs to care for patients on a flat fee basis. Patients are restricted to the network of IPA physicians in order to receive coverage. PHOs are corporations formed by one or more hospitals and its medical staff that contract with HMOs to provide medical services in the managed care market. See Assistant Secretary for Planning and Evaluation, THE BASICS OF MANAGED CARE, U.S. Department of Health and Human Services (1994). <http://aspe.hhs.gov/Progsys/Forum/basics.htm>.
- 77 PPACA, Pub. L. No. 111-148, sec. 3022 (2010).
- 78 In November 2010, Humana joined with Norton Healthcare to form one of the nation’s first commercial ACOs as a pilot program to test the efficiency of the new model. See Chris Anderson, HUMANA, NORTON HEALTHCARE LAUNCH LATEST PAYER-PROVIDER ACO, *Healthcare Finance News* (November 30, 2010).
- 79 PPACA, Pub. L. No. 111-148 (2010).
- 80 *Id.*
- 81 PPACA, Pub. L. No. 111-148, sec. 3023 (2010).
- 82 See *supra* note 32 at sec. 3023.
- 83 *Id.* at sec. 3502.
- 84 Christine Sinsky, THE PATIENT-CENTERED MEDICAL HOME NEIGHBOR: A PRIMARY CARE PHYSICIAN’S VIEW, *Annals of Internal Medicine*, Vol. 154, No. 1, 61-62 (Jan. 4, 2011).
- 85 <http://www.mainequalitycounts.org/major-programs/patient-centered-medical-home/35/168-pcmh-summary.html>.
- 86 *Maximizing Family Medicine Practice Post PPACA*, California Academy of Family Physicians (November 21, 2010), <http://www.familydocs.org/advocacy/health-care-reform/maximizing-fm-post-ppaca.php>.
- 87 PPACA sec. 2704. This demonstration establishes a bundled payment demonstration project under Medicaid in up to eight states beginning in January 2012.
- 88 *Id.* at sec. 2705. This project requires the Secretary of HHS to coordinate with CMI to develop a payment system for up to five participating states which would have the states pay large safety net hospital systems or networks under a global capitated payment model.
- 89 *Id.* at sec. 2706. This project requires the Secretary of HHS to establish a five-year Pediatric ACO demonstration which states can apply to participate in.
- 90 CMI was created in CMS to test innovative payment and delivery system models that can deliver quality care at lower cost levels. CMI is authorized to develop new methods to deliver healthcare and test them through pilot projects. Such flexibility to develop innovative systems had not been available to CMS before PPACA.
- 91 *Id.* at sec. 3021.
- 92 James Doherty & Samantha Freed, LEGAL IMPLICATIONS OF CONCIERGE MEDICAL PRACTICE FOR HEALTH PLAN PROVIDERS AND ENROLLEES, http://www.msba.org/sec_comm/sections/health/docs/Legal%20Implications%20of%20Concierge%20Medical%20Practicefinal.pdf.
- 93 See *supra* note 32 at sec. 3022(f).
- 94 F.J. Crosson, Allan Weiland and Robert Berenson, PHYSICIAN LEADERSHIP “GROUP RESPONSIBILITY” AS KEY TO ACCOUNTABILITY IN MEDICINE, *The Permanente Journal*, Vol. 8 No. 3 (Summer 2004).
- 95 Under this model, a management company is typically set up that is jointly owned by a hospital and independent physician members of the staff. The physicians in this arrangement retain their independence (they are not employed by the hospital) and allow hospitals to provide medical services without establishing a hospital owned medical practice. The management company will usually manage one or more service lines that are offered by the hospital. For example, a management company could be set up to manage the surgical services or the cath lab. See Marshall Burack, PHYSICIAN-HOSPITAL MANAGEMENT ARRANGEMENTS, *Akerman Senterfitt* (Sept. 26, 2011).

- ⁹⁶ Physician employment has been cyclical in the past 20 years based on the regulatory environment. As discussed above, the 1990s saw a rapid increase in physician employment followed by a period of sparse HMO enrollment which led to many physicians opening independent practices. The recent Medicare cuts in imaging in 2009, combined with a new generation of physicians with priorities centered around a balanced work life and a nationwide recession which has depressed incomes, physician employment by hospitals has starkly risen over the past two years.
- ⁹⁷ 42 C.F.R. § 1001.952(i) (2011); 42 C.F.R. § 357(c) (2011).
- ⁹⁸ This logic becomes particularly onerous in rural hospital communities. There, the patient mix is strictly Medicaid and some Medicare, combined with self-pay.
- ⁹⁹ See also, Robin Fisk and Leah Stewart, *CO-OPs: A Little Known Provision of the Health Reform Law, The Health Lawyer*, Volume 24 No. 1, (October 2011). 21- 25.
- ¹⁰⁰ Suzanne Sataline & Shirley S. Wang, *Medical Schools Can't Keep Up*, THE WALL STREET JOURNAL Digital Network, April 12, 2010, <http://online.wsj.com/article/SB1000142405702304506904575180331528424238.html>.
- ¹⁰¹ Carolyn Krupa, *Physician Shortage Projected to Soar More than 91,000 in a Decade*, AMEDNews.com, October 11, 2010 at <http://www.ama-assn.org/amednews/2010/10/11/prsb1011.htm>.
- ¹⁰² Press Release, Children's Hospital of Wisconsin, National Shortage of Pediatric Subspecialists Poses Challenge to Children's Access to Care (1/13/2010), at <http://www.chw.org/display/ppf/docid/28018/islisting/yes/thispage/1/newsnavid/45450/router.asp>.
- ¹⁰³ Lawrence Casalino, et al. BENEFITS OF AND BARRIERS TO LARGE MEDICAL GROUP PRACTICE IN THE UNITED STATES, Arch Intern. Med. Vol. 163, 1958-1964 (Sept. 2003).
- ¹⁰⁴ These major systems were all founded by doctors in the early to mid-20th century by doctors. As they grew, they acquired hospitals and became nonprofit integrated systems over many years. It is difficult to replicate the environment which allowed this to develop and it certainly cannot be done in a short period of time.
- ¹⁰⁵ Jenny Gold, ACCOUNTABLE CARE ORGANIZATIONS, EXPLAINED, www.NPR.org (Jan 18, 2011). <http://www.npr.org/2011/04/01/132937232/accountable-care-organizations-explained>.
- ¹⁰⁶ Jason Fodeman. THE NEW HEALTH LAW: BAD FOR DOCTORS, AWFUL FOR PATIENTS, Galen Institute (April 2011).

The Editorial Board provides expertise in specialized areas covered by the Section. Individual Board members were appointed by the Interest Group Chairs and Editor Marla Durben Hirsch. If you are interested in submitting an article to *The Health Lawyer*, you may contact one of the Editorial Board members or Ms. Hirsch. With the establishment of the Editorial Board, the Section strengthens its commitment to provide the highest quality analysis of topics in a timely manner.

Marla Durben Hirsch
Potomac, Maryland
301/299-6155
mdhirsch@comcast.net

Lisa L. Dahm
South Texas College of Law
Houston, TX
eHealth, Privacy & Security
Editorial Board Chair
713/646-1873
ldahm@stcl.edu

Howard D. Bye-Torre
Stoel Rives LLP
Seattle, WA
Employee Benefits & Executive
Compensation
206/386-7631
hdbye@stoel.com

Michael A. Clark
Sidley Austin Brown & Wood
Chicago, IL
Tax & Accounting
312/853-2173
mclark@sidley.com

Marcelo N. Corpuz III
Walgreens Health Services
Deerfield, IL
Business and Transactions
847/964-8228
marcelo.corpuz@walgreens.com

Jason W. Hancock
Hospital Corporation
of America
Brentwood, TN
Health Care Facility Operations
615/372-5480
jason.hancock@hcahealthcare.com

Sherine B. Hargrove
US DHHS/OGC
Office of the General Counsel
Rockville, MD
Young Lawyer Division
301/443-2211
sherine.hargrove@hhs.gov

**serving in her private capacity, not as a representative of OGC or HHS, and no endorsement by them should be implied.*

Bruce F. Howell
Bryan Cave
Dallas, TX
Medical Research, Biotechnology & Clinical Ethical Issues
214/721-8047
bruce.howell@bryancave.com

Charles M. Key
Wyatt, Tarrant & Combs, LLP
Memphis, TN
Liaison to the Publications Committee
901/537-1133
ckey@wyattfirm.com

Rakel M. Meir
Tufts Health Plan
Watertown, MA
Managed Care and Insurance
617/923-5841
Rakel_Meir@tufts-health.com

Monica P. Navarro
Thomas M. Cooley Law School
Auburn Hills, MI
Physician Issues
248/751-7800
navarrom@cooley.edu

C. Elizabeth O'Keeffe
University of Mississippi Medical Center
Jackson, MS
Public Health & Policy
601/815-5297
cokeeffe@umc.edu

Leonard M. Rosenberg
Garfunkel, Wild & Travis, PC
Great Neck, NY
Healthcare Litigation & Risk Management
516/393-2260
lrosenberg@gwtlaw.com

Felicia Y. Sze
Hooper, Lundy & Bookman, P.C.
San Francisco, CA
Payment & Reimbursement
415/875-8503
fsze@health-law.com

Andrew B. Wachler
Wachler & Associates
Royal Oak, MI
Healthcare Fraud & Compliance
248/544-0888
awachler@wachler.com

The articles published in *The Health Lawyer* reflect the opinions of the authors.
We welcome articles with differing points of view.

DISCLOSING AND REFUNDING OVERPAYMENTS IN HEALTHCARE CASES

Steven J. Chananie, Esq.
Leonard M. Rosenberg, Esq.
Nora A. Colangelo
(Compliance Paralegal)
Garfunkel Wild, P.C.
Great Neck, NY

Bruce Howell, Esq.
Bryan Cave LLP
Dallas, TX

Healthcare providers have long been advised (and sometimes required) by federal and state authorities to self-disclose any overpayments received from governmental healthcare programs. Historically, disclosure obligations have not always been clear, especially if the overpayment resulted from a healthcare provider's unintentional act or lack of actual knowledge of improper billing or referral practices. Recent federal legislation, however, has clarified that even a provider who does not act with actual knowledge in failing to refund overpayments may nevertheless face substantial liability. Moreover, such legislation has also imposed a specific 60-day time limit for reporting and refunding identified overpayments received from the Medicare and Medicaid Programs.

Even with the new legislation, however, there are still many factors to consider – and some still unresolved issues that must be navigated – in deciding when and how to pursue a self-disclosure. This article will provide an overview of: (1) the scope and nature of the legal obligation to disclose and refund overpayments, especially as clarified under the recent federal legislation and as provided in long-standing guidance from federal agencies; and (2) the options and processes for disclosing overpayments to government agencies.

The Legal Obligation To Disclose And Refund

The Social Security Act imposes criminal penalties on providers who knowingly keep overpayments received from federal healthcare programs.¹ The government has relied on such penalty provisions to support the premise that, when a healthcare provider has knowledge of an overpayment, there is an affirmative legal obligation to refund the money to the government. In fact, the Office of the Inspector General in the Department of Health and Human Services (“OIG”) has cited to this provision in the Social Security Act and stated that the failure to repay overpayments within a reasonable period of time could be interpreted as an intentional attempt to conceal the overpayment from the government, thereby establishing an independent basis for a criminal violation under this statute.²

Congress clarified the scope of the obligation to refund in 2009 in the Fraud Enforcement and Recovery Act (“FERA”),³ and then again in 2010, as part of the Healthcare reform legislation under the Patient Protection and Affordable Care Act (“PPACA”).⁴ FERA and PPACA, among other things, amended two other federal statutes – the civil False Claims Act (“FCA”)⁵ and the Civil Monetary Penalties Law (“CMPL”)⁶ – to expand the scope of the obligation to refund and impose potentially severe monetary penalties for any violation of that obligation.

The Amendments to the FCA under FERA

Prior to the 2009 enactment of FERA, the FCA provided for the imposition of treble damages⁷ and monetary penalties on a person who, among other acts, “knowingly makes,

uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government.”⁸ The Department of Justice (“DOJ”) has regularly argued that this provision created “reverse” false claims liability that covered the knowing retention of payments from federal programs when the person had no right to them.⁹

In FERA, Congress resolved any possible controversy over this “reverse” false claims theory by making explicit in the FCA statutory language two provisions: first, FCA liability arises when a person “knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government” (emphasis added);¹⁰ and second, an “obligation” to pay includes “an established duty, whether or not fixed, arising . . . from the retention of any overpayment.”¹¹ These two changes were intended, according to the Congressional history, to clarify that the retention of overpayments are actionable under the FCA. Indeed, the Senate Report accompanying FERA specifies that it was a DOJ recommendation that Congress make it a violation of the FCA “once an overpayment is knowingly and improperly retained, without notice to the Government about the overpayment.”¹² Accordingly, as the Senate Report stresses, “any knowing and improper retention” of an overpayment would be actionable, if the overpayment is retained “beyond the final submission of payment as required by statute or regulation.”¹³

These FERA amendments are far reaching, given that under the FCA, the terms “knowing” and “knowingly” are defined very broadly. Specifically, these terms include not only having

“actual knowledge,” but also acting in “deliberate ignorance” or in “reckless disregard of the truth or falsity” of information in a claim or record. Moreover, the statute expressly provides that “no proof of specific intent to defraud is required.”¹⁴ As there is an expectation that providers will stay current with all Medicare requirements,¹⁵ these lower thresholds traditionally have been proven if, for instance, Medicare disseminated specific information updating how to document and code a particular service and a provider of that service did not incorporate that updated information into its documentation and coding practices and consequently submitted false claims. Therefore, even if a healthcare provider does not act with actual knowledge in retaining an overpayment, but receives and retains an overpayment from a federal healthcare program (which includes Medicare and Medicaid) through “deliberate ignorance” or in “reckless disregard,” that provider may still be subject to FCA liability. In practical terms, this means that providers have an obligation to monitor payments received from federal healthcare programs and have reasonable processes in place to identify overpayments and credit balances.¹⁶

The Requirement to Disclose and Refund Within 60 Days under PPACA

With the enactment of PPACA, Congress expanded its clarification of the FCA and established, for the first time, a time limit for healthcare providers to disclose and return overpayments. This time limit, however, is not triggered until the overpayment is “identified” and thus, presumably the provider has actual knowledge of its existence.

Specifically, under PPACA any Medicare or Medicaid funds received or retained to which a healthcare provider is not entitled must be both reported and refunded within 60 days from the date the overpayment is “identified,” or by the date any corresponding cost

report is due (if applicable) to the appropriate agency (e.g., Medicare or Medicaid contractor or state oversight agency). Moreover, the report must include a written explanation of the reason why the overpayment occurred.¹⁷ This provision went into effect immediately upon enactment on March 23, 2010. PPACA broadly defines “overpayment” to mean “any funds that a person receives or retains under” Medicare or Medicaid to which the person, “after applicable reconciliation, is not entitled.”¹⁸ It is not yet clear what “applicable reconciliation” may mean, although, at the very least, it likely includes various types of reimbursement reconciliation processes by Medicare or Medicaid as is often required by statute or regulations for cost reports and rate setting processes.¹⁹

Failure to report and refund within 60 days, as required by this new provision, will result in liability under the FCA and the overpayments being treated as false claims.²⁰ In addition to linking potential penalties under the FCA to the retention of overpayments, PPACA also amended the CMPL to allow treble damages and additional administrative fines to be imposed on persons who have knowledge about an overpayment and fail to make a timely report and refund.²¹ In short, even if an identified overpayment did not initially arise from a violation of the FCA, the CMPL or any other law, the act of failing to report and refund the overpayment within 60 days may, by itself, independently give rise to liability. As a result, healthcare providers who discover they have been overpaid by Medicare or Medicaid should act to report and refund such funds within 60 days.

Unresolved Issues Concerning the 60 Day Requirement

This new 60 day requirement presents a number of potential problems.

First, many overpayments can be difficult to quantify and it can take – in some cases – far longer than 60 days to do so. Such difficulties may arise, for

instance, when a possible overpayment is discovered that involves numerous services and bills, each of which must be examined to determine whether there was, in fact, an overpayment or the extent of the overpayment. Such cases may require the review of substantial numbers of medical charts and billing records, the hiring of an outside consultant, or conducting a review of a statistically valid random sample and then performing an extrapolation. In such cases, it may be physically impossible to complete, or unreasonable to expect completion of, the review and quantification of the overpayment within the mandated 60 day time period.

Although the provider in such cases could certainly provide a preliminary report to the appropriate governmental agency, it would not be able to actually refund the overpayment in many cases until after the amount had been quantified. The PPACA provision, however, requires *both* the disclosure of the overpayment *and* the actual refund to occur within the 60 days. Notably, the Centers for Medicare & Medicaid Services (“CMS”) appears to have already acknowledged this issue, even though regulations interpreting PPACA have not yet been issued.²² As will be discussed below, when CMS promulgated its self-disclosure protocol for overpayments that arise under the federal Stark Law, CMS expressly provided that the overpayments would not have to be refunded within 60 days under PPACA, but only after the parties had resolved the issue through the CMS self-disclosure process.²³

Second, until implementing regulations are adopted, it is not clear what exactly constitutes the identification of an overpayment so as to start the 60-day clock. Does it start once the healthcare provider first has *any* actual knowledge that an overpayment has been received? This might occur, for instance, when a patient advises that he or she has been billed for services not provided

continued on page 18

Disclosing and Refunding Overpayments in Healthcare Cases

continued from page 17

or when a question is raised through the provider's compliance program about possible overpayments. In such cases, however, it may not be clear until a much more extensive review is conducted whether the allegation involves an actual overpayment or, if it does, whether the potential overpayment involves only an isolated case or is the result of a more systemic billing error. Does the clock start running after the provider receives the first report, after it confirms that there is at least some overpayment, or after it determines the true size and scope of the issue? With such high stakes involved, a conservative interpretation of when an overpayment is "identified" may be advisable until guidance is provided by the federal government.²⁴

Third, until the implementing regulations are enacted, it is also unclear whether there is a dollar threshold that must be reached before the 60 day requirement is triggered, along with its requirement to not only refund, but also to submit a written report to the appropriate governmental entity. Many healthcare providers routinely identify small overpayments and automatically refund them as part of their regular business practices (such as through electronic bill adjustments). Such routine refunds are usually made without a written disclosure and explanation, as is now required under PPACA. It is unclear whether such routine refunds must now be made with a written disclosure and explanation. Such a requirement would arguably serve no useful public policy, as it would likely make routine refunds of small amounts much more complicated and time consuming.

In New York, the Medicaid Inspector General has interpreted the PPACA provision to require a written disclosure to the state only when the amount of the overpayment is, in the aggregate, in excess of \$5,000; routine overpayments for amounts less than

this may be refunded pursuant to the normal electronic adjustments.²⁵ While this interpretation is perhaps reasonable, it is a temporary stop-gap until the federal government issues its own interpretive regulations.

Overpayments and The Federal Anti-Referral Laws

Overpayments can result not only from errors in how services are billed, but also from violations of the federal anti-referral laws, which include the Anti-Kickback Statute ("AKS")²⁶ and the Ethics in Patient Referrals Act (the so-called "Stark Law").²⁷ Under these laws, it can be illegal in some circumstances for one healthcare provider to refer patients to or order services from another provider, if there is remuneration provided in exchange for the referrals (under the AKS) or there are certain financial relationships between the providers that do not meet a specified exception (under the Stark Law). If prohibited referrals are made under these laws, then bills may not be submitted to Medicare and/or other federal healthcare programs for the referred services; and, if bills are nevertheless submitted, any resulting payments will be considered overpayments and may also result in FCA liability.

The federal government has long argued that bills submitted to Medicare or Medicaid for services referred in violation of the AKS are false or fraudulent under the FCA. A number of federal courts upheld this argument, reasoning that bills submitted to Medicare in particular contained express or implied certifications that the services were provided in compliance with all federal laws and regulations, including the AKS. As a result, if the services were in fact obtained in violation of the AKS, the certification was thereby false, making the bill false and actionable under the FCA.²⁸

Under PPACA, Congress expressly endorsed the holdings of

these federal cases by amending the AKS to expressly provide that, "in addition to the penalties provided" under the AKS itself, "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of" the FCA.²⁹ Under the AKS itself, however, a violation is established only when, as a factual matter, there is proof beyond a reasonable doubt (the AKS itself is a criminal statute) that something of value ("remuneration") was provided with an intent to induce the referral or ordering of items or services reimbursed by federal healthcare programs (primarily Medicare and Medicaid).³⁰ While the FCA is a civil statute with a lower burden of proof, some of the prior federal cases held that a violation of the AKS did not have to be proven beyond a reasonable doubt in an FCA case, but only by a preponderance of the evidence as required under the lower FCA civil burden of proof.³¹

As for the Stark Law and its implementing regulations, they have, since their inception, expressly provided that bills could not be submitted to Medicare for services that result from prohibited referrals. If such bills are submitted, then any resulting Medicare payments had to be refunded.³² In addition, if a provider knows or should have known that it was submitting claims in violation of the Stark Law, then the provider would also be subject to possible civil monetary penalties of \$15,000 for each prohibited service claimed.³³ Notably, the Stark Law also expressly provides that such monetary penalties apply when a provider knows or should know that a refund was otherwise required. Finally, a few federal courts have held, as with AKS cases, that claims submitted to Medicare in violation of the Stark Law can also be false claims actionable under the FCA.³⁴

In short, the obligation to disclose and refund is not limited to only

improper or erroneous billing that results from a failure to provide, code for, or bill for a service in compliance with all applicable laws, regulations or rules. Rather, payment for a service that is otherwise properly rendered, coded and billed in all regards may still have to be refunded if the service was the result of a referral that was made in violation of either the AKS or the Stark Law.

Overpayments and Potential Criminal Liability

Overpayments can and do result not only from improper billing and referral practices, but also from acts of fraud that constitute crimes under various federal or state healthcare penal statutes. Moreover, some of these statutes potentially make it a crime to knowingly retain overpayments from not only federal healthcare programs, such as Medicare or Medicaid,³⁵ but from non-governmental payors as well. In some cases, the federal government has relied on such criminal statutes to pursue healthcare providers for knowingly retaining overpayments.

A settlement agreement announced by the U.S. Attorney in the Eastern District of Tennessee with a large group of cardiologists illustrates this point. The underlying case was brought as a civil *qui tam* suit under the FCA against the physicians. The relators were two employees of the group. After the U.S. Attorney became involved, however, the case expanded into a federal criminal investigation with allegations that the group had failed to refund credit balances due not only to government healthcare programs, but to patients and private insurers as well. According to federal prosecutors, this failure continued for many years, even after the group's board of directors became aware of the practice. The government alleged that the group had a policy to retain overpayments and to issue refunds only if the health insurance plan at issue specifically requested a refund. As a result, the U.S. Attorney's Office brought criminal charges,

alleging that the group had committed the crimes of "Health Care Fraud" and "Theft or Embezzlement in Connection with Health Care" as a result of having retained the overpayments.³⁶

The crime of Health Care Fraud³⁷ occurs when a person knowingly and willfully executes, or attempts to execute, a scheme or artifice to, among other things, "defraud" any "health care benefit program," which is defined broadly as including not only federal healthcare programs, but private insurance plans, as well.³⁸ In the case of the Tennessee cardiologists, the U.S. Attorney's Office viewed the group's purposeful failure to disclose known overpayments to the third party payors as a criminal intent to "defraud," thereby constituting the crime of Health Care Fraud.³⁹ Similarly, the U.S. Attorney's Office interpreted the crime of Theft or Embezzlement in Connection with Health Care⁴⁰ as also including the knowing retention of an overpayment. This crime prohibits, among other things, the knowing and willful conversion to one's own use, without authority, any funds or credits received from a healthcare benefit program in connection with the delivery of or payment for healthcare items or services.⁴¹

The physician group denied wrongdoing, cooperated in the investigation and was granted a pretrial diversion pertaining to the criminal charges. The eventual settlement agreement with the Justice Department resolved both the criminal allegations (for approximately \$1.2 million), as well as the civil FCA action (for approximately \$1.7 million).⁴²

Making A Disclosure And Refund

Given the steep potential civil and criminal liabilities for failing to disclose and refund overpayments, and in light of the new federal legislation, healthcare providers must carefully consider when, to whom, and how they should

make disclosures and refunds. Refunds can be made, for instance, directly to a Medicare Administrative Contractor ("MAC"); through a self-disclosure to the OIG or to an appropriate state or federal agency (including the DOJ or a U.S. Attorney's Office);⁴³ or through routine electronic billing adjustments. Further, the distinction between a simple refund and a formal disclosure is not always clear.

To the MAC

As a threshold matter, if a Medicare overpayment is identified, if the amount is relatively small, and if it appears to have been the result of an inadvertent billing error, a direct refund to the provider's MAC may be appropriate.⁴⁴ As already mentioned above, however, there is no guidance as of yet as to whether there is any threshold amount below which a direct refund without a formal self-disclosure is not required. Similarly, there is not yet guidance as to how extensive the "explanation" of the overpayment must be. For instance, it is not clear whether it is sufficient to process a refund and simply indicate "billing error" as the reason for the overpayment.

Prior to PPACA, with its 60 day requirement, CMS established protocols in Medicare program manuals for its contractors to identify, process, track, and report unsolicited, voluntary refunds received from healthcare providers and other entities.⁴⁵ CMS has also developed a standard refund form that MACs may make available for use by healthcare providers in making voluntary Medicare refunds.⁴⁶ The form requires the provider to specify the reason for the overpayment by indicating one of several "reason codes" listed on the form itself.⁴⁷ Without interpretive regulations from CMS under PPACA, it is possible to argue that simply completing the refund form and indicating the appropriate reason code is sufficient to satisfy PPACA's mandate to disclose, explain and refund. If so, then using the refund form may be sufficient in most, if not

continued on page 20

Disclosing and Refunding Overpayments in Healthcare Cases

continued from page 19

all, cases to satisfy PPACA's requirements. Otherwise, and to the extent that there is doubt in this regard, a provider can follow a more conservative approach and submit the form to the MAC with a more extensive explanatory cover letter.

MACs are required to advise providers annually that acceptance of a voluntary refund does not in any way limit CMS or any other federal agency from pursuing any appropriate criminal, civil or administrative remedy that may arise or relate to the underlying claims submission.⁴⁸ Thus, simply paying back the money owed will not forestall a fraud investigation. If a MAC concludes that an overpayment raises concerns about the integrity of the provider, CMS has instructed its contractors to refer the matter to the OIG.⁴⁹ CMS also instructs its contractors to handle refund checks conditionally. As a result, if a provider endorses a refund check as "paid in full" or with similar language that would indicate the provider has discharged its debt obligation, the MACs are instructed to send an immediate rebuttal letter by certified mail indicating that the matter is being researched, and that the amount of payment may be insufficient to fully extinguish the debt.⁵⁰

The OIG Self-Disclosure Protocol

If a healthcare provider determines that an overpayment from Medicare or Medicaid was the result of something more than a routine or inadvertent billing error, then the provider also has the option of using the OIG's Self Disclosure Protocol (the "OIG Protocol") to disclose, explain and refund the overpayment.⁵¹

The OIG promulgated the OIG Protocol in 1998, long before FERA and PPACA were enacted, and it sets forth a lengthy submission and review process that, in many cases, can take much longer than PPACA's mandated

60 day period before a refund is actually made. If a provider follows the Protocol in good faith, however, it arguably would be inappropriate and inequitable for the OIG to recommend an FCA action to the DOJ solely on the basis that the provider did not submit a refund check within the 60 day period, because the provider was cooperating with the OIG under the OIG Protocol. Indeed, the OIG even specifies in the OIG Protocol itself that participating providers should not make any refunds without the OIG's prior consent and that the OIG itself will not accept payments until its inquiry is completed.⁵²

The OIG Protocol is premised on the OIG's belief that healthcare providers must be willing to "police themselves, correct underlying problems and work with the government to resolve these matters."⁵³ There is no legal requirement that a healthcare provider utilize the OIG Protocol. Although the OIG has stated that providers have a "legal duty to ensure the integrity of their dealings" with federal healthcare programs, the decision to follow its "suggested" protocol rests exclusively with the provider.⁵⁴

The OIG specifies that its Protocol is *not* an appropriate vehicle for reporting simple overpayments that do not involve violations of any laws. Rather, these types of common errors should be brought directly to the attention of the MAC that processes the providers' claims, as discussed above. The OIG Protocol should only be followed when the provider has performed an initial assessment and reasonably believes that some practice potentially violates federal criminal, civil or administrative law.⁵⁵ Of course, most overpayments – even if the result of an inadvertent mistake – often still involve a violation of Medicare or Medicaid reimbursement regulations or rules, at the very least. Thus, it is not always fully clear when to use the OIG Protocol.

The benefits and risks associated with using the OIG Protocol must be carefully weighed. Potential benefits include: (i) the possibility of minimizing the potential cost and disruption of a full-scale OIG investigation; (ii) the opportunity to negotiate a fair settlement that avoids more serious consequences, including treble damages and substantial penalties that might otherwise have resulted; and (iii) the opportunity to avoid a criminal prosecution or being excluded from participation in federal healthcare programs.

Conversely, the risks associated with disclosure can be substantial. In response to a disclosure, for instance, the OIG provides no commitment as to how a disclosure will be resolved or what concrete benefits the disclosing provider will achieve by disclosing. If the provider discloses pursuant to the OIG Protocol, the OIG avers only that it will give data derived from the disclosure substantial weight in determining any program overpayments and in recommendations to the DOJ for resolution of the provider's FCA or other liability. Moreover, the OIG will not be bound by any findings made by the disclosing provider's audit or investigation, and may conclude that the matter warrants referral to the DOJ for further investigation and possible criminal prosecution.⁵⁶ Finally, if the OIG uncovers new issues during its review and verification of the provider's disclosure, the OIG can treat those issues separately, and any potential benefit that might otherwise accrue to the disclosed matter will generally not apply to a newly uncovered issue.

Even if a healthcare provider decides not to use the OIG Protocol, for whatever reason, any overpayment must still be disclosed, explained and refunded within 60 days of identification to an appropriate state or federal agency. At the very least, this will require a disclosure to the appropriate MAC or state Medicaid agency.

The CMS Stark Protocol

In two Open Letters to the health-care community, issued by the OIG in 2006 and 2009, the OIG discussed application of its Protocol to violations of the AKS and Stark Law. In the 2006 Letter,⁵⁷ the OIG stated that violations of both of these laws could be disclosed pursuant to the OIG Protocol.⁵⁸ In the 2009 Letter,⁵⁹ the OIG retreated from this position and limited the types of cases it would accept under the OIG Protocol, especially under the Stark Law.

Specifically, for AKS-related disclosures made after March 24, 2009, the OIG required a minimum \$50,000 settlement to resolve the matter. Although the OIG stated that it would continue to accept disclosures that involve “colorable violations of the AKS, whether or not it also involves colorable violations” of the Stark Law, the OIG went on to stress that it would no longer accept disclosures that involved only potential liability under the Stark Law.

Congress filled the void left by the OIG’s decision not to entertain disclosures of Stark Law violations under its Protocol when it enacted PPACA. The legislation mandated that the Secretary of the Department of Health and Human Services (“HHS”), in cooperation with the OIG, establish a new and separate disclosure protocol to enable providers to disclose actual and potential Stark Law violations. It also authorized HHS to reduce amounts owed due to Stark Law violations, based on consideration of, among other factors, the timeliness of the self-disclosure.⁶⁰

In response to this Congressional mandate, CMS released its voluntary Self-Referral Disclosure Protocol on September 23, 2010 (“CMS Protocol”).⁶¹ At the outset, it is important to note that the CMS Protocol expressly addresses the problematic PPACA requirement that a refund must be made within 60 days of the identification of an overpayment. Implicitly recognizing the complexity of many

Stark Law issues and the fact that it will likely take substantial time to resolve a Stark Law disclosure, the CMS Protocol provides that, once the disclosing provider receives confirmation that its electronic disclosure has been received, CMS will suspend the provider’s obligation to actually refund any potential overpayment until either a settlement is reached, the provider withdraws from the CMS Protocol, or CMS itself removes the provider from the disclosure process. CMS also stresses that the CMS Protocol should not be utilized for potential or actual Stark Law violations that also implicate the OIG’s administrative authority to impose civil monetary penalties for violations of the AKS.⁶² In such cases, CMS advises providers to not disclose under the CMS Protocol, but to use the OIG’s Protocol only.⁶³

Similar to the review process pertaining to the OIG’s Protocol, once CMS accepts a provider’s disclosure under the CMS Protocol, CMS expects the provider to act in good faith and work diligently to resolve the issue. Likewise, CMS makes no promises as to how it will resolve a disclosure or whether it will accept the disclosing provider’s analysis. Instead, CMS stresses that a particular matter may warrant referral to the DOJ for possible criminal prosecution or resolution of potential FCA liability or to the OIG for resolution of potential liability under the CMPL.

The CMS Protocol sets forth a relatively straightforward process. The provider must electronically submit a written disclosure to CMS (with a copy by regular mail) that includes, among other items, a description of the violation, including how it was discovered; measures taken to prevent future abuses; a full legal analysis explaining which elements of the applicable Stark exceptions were met and not met; and a financial analysis, including the methodology used to calculate the amounts due.

CMS will then verify the disclosure details and will make individual determinations of whether any reduction in the amount due is warranted based on the facts and circumstances presented. CMS has no obligation, however, to reduce any amounts due and owing, but may consider: (1) the nature and extent of the improper or illegal practice; (2) the timeliness of the self-disclosure; (3) the cooperation in providing additional information related to the disclosure; (4) the litigation risk associated with the matter disclosed; and (5) the financial position of the disclosing party.

While serving similar purposes, the CMS and OIG Protocols have several differences in how they are structured. The CMS Protocol, for instance, is silent as to whether the provider can request that DOJ participate in settlement negotiations. Both Protocols do state, however, that the agency may disclose the matter to law enforcement if warranted. The process in each Protocol, moreover, is slightly different. By way of example, and unlike the OIG Protocol, the CMS Protocol specifies as noted above that disclosures must be electronic; that a “complete legal analysis” of the application of the Stark Law to the matter must be provided, including descriptions of any applicable exception and why the elements of the exception are not met; and that a financial analysis must be submitted with the initial disclosure that includes the full amount itemized by year that is actually or potentially due based under the applicable Stark “look-back period” (i.e., the period of non-compliance).

In addition, the risks associated with making a disclosure under the CMS Protocol must be carefully evaluated. In this regard, CMS has virtually no public track record for settling cases under its CMS Protocol despite having set up a “Self-Referral Disclosure Protocol Settlements” page on its website.⁶⁴ It is thus not clear what kind of positions CMS might take in a particular case and how it might evaluate a disclosing provider’s

continued on page 22

Disclosing and Refunding Overpayments in Healthcare Cases

continued from page 21

potential liability. This uncertainty is of particular concern given that a Stark violation can result in the disallowance of Medicare payments for an entire referral stream of cases. The OIG, by contrast, has a substantial and public track record that can be reviewed in deciding whether to use the OIG's Protocol.⁶⁵

Deciding When and How To Make a Disclosure

Deciding when and how to make a voluntary self-disclosure can be complicated and is not without risk. Consultation with experienced healthcare counsel, especially in complex disclosure cases, should be considered. While a detailed discussion of the various considerations that should be considered is beyond the scope of this article, there are a few basic guidelines that can be helpful in evaluating potential voluntary disclosures.

As a threshold matter, it is important to confirm that there has, in fact, been an overpayment from a third party payor. While this may seem obvious, it is not always easy to determine in all cases.

First, identify the exact error or deficiency that appears to be involved. It may, for instance, be inadequate documentation of a medical service, incorrect coding, or some error in the manner in which a service was delivered or billed.

Next, analyze whether the error or deficiency was one that actually resulted in violation of a third party payor rule or regulation that governs reimbursement. In many instances, it will be clear that there was an overpayment that must be refunded, as when there is a double payment, a payment for a service that is not separately reimbursable, or a payment in an amount greater than that provided for the service rendered. In other instances, however, it is not as clear that the deficiency affects reimbursement, such as

when the rule or regulation that is violated is not an express condition of reimbursement under the applicable rules, and the underlying otherwise reimbursable service was clearly provided. In these instances, a more detailed legal analysis will be required, and this analysis may vary to some degree based on which third party payors are involved.

If it is determined that there is an overpayment that must be refunded, the next step is to determine whether the underlying error was an isolated one or part of a larger pattern (and thus requiring a retrospective review). A review of the error must be done to determine its underlying cause. Was the error, for instance, an isolated and inadvertent data entry mistake, the result of a billing software glitch, or the result of a coding employee's misunderstanding of the applicable coding rules? The answers to these types of questions may require focused internal inquiry that includes interviews of staff, review of systems, and some type of sampling and review of records. If the error appears to be part of a larger pattern, it is important to determine its scope: was it isolated, for instance, to only one computer program, one coder or one provider location? The scope of any retrospective review and refund needs to be tailored to the identified scope of the problem.

It is also important to identify *when* the larger pattern began. When, for instance, was the computer system reprogrammed with the error, or when was the new coder who misapplied the rules employed? This analysis is crucial to determine how far back a retrospective review and refund must go. In addition to a cut-off date based on the facts, it is also necessary to analyze the applicable statute of limitations, the allowed audit period for the applicable governmental agency, or the look back provisions under the applicable third party payor contract.

After identifying the time period to be covered by the retrospective review, the size of the potential universe of claims involved must be determined. If the total number of claims to be refunded can be readily identified – through running a computer program, for instance – then it may be possible to calculate an exact refund for each claim. If, on the other hand, the universe of claims is exceedingly large, and the claims to be refunded can be identified only by reviewing the records of each case, then it may be necessary to review a statistically valid random sample from the universe, and to calculate a refund based on extrapolation of the resulting identified error rate.

Once the amount of the refund is calculated for each payor, then it must be determined to whom the disclosure and refund must be made, taking into account the discussion and overview provided in the rest of this article. If a governmental payor is involved, and the 60 day time limit under PPACA applies, then it is important to conclude the review and make the disclosure and refund within that 60 day period. If, however, it is not possible to calculate the amount to be refunded within the 60 days, then it is advisable, at the very least, to make a disclosure in writing to the appropriate government agency, explaining the issues involved, the status of the review, and when the amount to be refunded will be calculated.

The provider needs to carefully evaluate the underlying reasons for the overpayments and determine to which agency it is best to make the disclosure. If a simple inadvertent overpayment is involved, for instance, a disclosure and refund to the MAC may be all that is required. On the other hand, if the underlying reasons involve potential malfeasance by provider staff, then it may be advisable to consider following the OIG or CMS Protocol.

As a final note, whatever disclosure avenue is chosen, it is imperative that healthcare providers fully document their efforts to comply with the new reporting/refunding requirements and how any issue was investigated and, if substantiated, reported and refunded within the new time limit.

Conclusion

Historically, there has been under the Social Security Act, and arguably under the FCA, an obligation to refund any overpayments knowingly received from a federally funded healthcare program. Under the recent federal laws discussed above, however, that obligation has been reaffirmed, clarified and subjected to more stringent – and express – requirements, including the sometimes onerous 60 day time limit. Under these laws, it is also imperative that healthcare providers keep up-to-date with Medicare and Medicaid program rules and demonstrate their good-faith compliance, in the first instance, with program requirements. Then, when potential overpayments are identified, the provider must move decisively and quickly to quantify the amount and make a timely disclosure and refund.



Steven J. Chananie is a Partner/Director at Garfunkel Wild, P.C. and the head of the firm's Compliance and White Collar

Defense Practice Group, which advises clients on compliance matters, assists them in implementing or modifying their compliance programs, and defends clients in criminal, civil and regulatory government actions.

In his practice, Mr. Chananie has represented numerous healthcare providers, helping them to set up comprehensive compliance programs and advising them on regulatory and fraud and abuse issues. Compliance clients include hospitals, faculty practice plans,

laboratories (both independent and hospital-based), physician practices, nursing homes, and home health agencies. He has also defended numerous of these clients against civil and criminal government actions and investigations, including False Claims Act cases, threatened Anti-Kickback prosecutions, and various state and federal audits.

Mr. Chananie has lectured nationwide on compliance, regulatory, defense and related issues. He can be reached at schananie@garfunkelwild.com.



Leonard M. Rosenberg is a Partner and Chair of the Litigation and Arbitration practice group at Garfunkel Wild, P.C. Mr.

Rosenberg is Co-Chair of the firm's Appellate Practice Group and a member of the firm's Healthcare practice group.

Mr. Rosenberg represents and counsels clients in federal and state court civil and administrative trials, arbitrations, hearings, and mediations. His practice includes litigation of a wide variety of commercial and business issues, including technology contract disputes and judicial review of agency and other administrative determinations. Mr. Rosenberg also has a broad employment law practice, defending clients against all types of employment claims.

In addition, Mr. Rosenberg's healthcare practice includes over 20 years of experience representing hospitals in medical staff credentialing and peer review matters, including intra-hospital hearings and appeals, proceedings before the New York State Public Health Council, and litigation arising from the peer review process. Mr. Rosenberg counsels and represents physicians in professional conduct proceedings before the New York State Department of Health, Office of Professional Medical Conduct.

Mr. Rosenberg also has substantial experience in defending healthcare providers against defamation and other claims arising from their legal duty to report suspected cases of child abuse.

Mr. Rosenberg is the editor of "In The New York State Courts," a summary of

recent court decisions in healthcare law. The column is a regular feature of the Health Law Journal published by the Health Law Section of the New York State Bar Association. He is also Vice Chair of the Editorial Board of *The Health Lawyer*. Prior to joining the firm, Mr. Rosenberg served as an Assistant District Attorney in Kings County, New York. He can be reached at lrosenberg@gwtlaw.com.



Nora A. Colangelo has been the Compliance Paralegal at Garfunkel Wild, P.C. since 2000. Ms. Colangelo assists attorneys in the

healthcare, compliance and white collar defense and environmental practice groups. She aides clients in implementing fraud and abuse compliance programs; and researches a wide array of compliance, regulatory and business matters. Ms. Colangelo also develops compliance training materials for clients and educational programs for professional associations and has co-authored numerous articles on compliance and related issues. Prior to joining Garfunkel Wild, Ms. Colangelo served as the Principal Administrative Assistant of the Legal Affairs Division of the Queens County, NY District Attorney's Office. She can be reached at ncolangelo@garfunkelwild.com.



Bruce F. Howell, J.D., M.S., is a board certified health lawyer (Texas State Board of Legal Specialization) and Counsel to the law firm of Bryan

Cave, LLP. Mr. Howell is a founder and past chairman of the Health Law Section of the Dallas Bar Association, immediate past Chair of the Health Law Section of the Texas State Bar, past Chair of the American Bar Association Interest Group on Medical Research, Biotechnology and Clinical Ethics, and Vice Chair of the American Bar Association *Health Lawyer* Editorial Board. He was a member of the Board of Directors of Southwest Transplant Alliance (organ transplant organization), the French-American Chamber of Commerce, and the

continued on page 24

Disclosing and Refunding Overpayments in Healthcare Cases

continued from page 23

University of North Texas Health Science Center Institutional Review Board. He is also admitted as a Fellow of the Dallas Bar Foundation. He is a frequent writer and speaker on physician, clinical, genetic and ethical issues, and has been voted a Texas Super Lawyer and one of the “Best Lawyers in America” for the past five years. He can be reached at bruce.howell@bryancave.com.

Endnotes

- ¹ Social Security Act § 1128B (42 U.S.C. 1320a-7b[a][3]) authorizes criminal penalties when a person or entity has knowledge of the occurrence of any event affecting the initial or continued right to a benefit or payment from a federal healthcare program, and conceals or fails to disclose that event with a fraudulent intent to secure the benefit or payment, either in a greater amount or quantity than is due, or when no such benefit or payment is authorized. The maximum penalties for violating this criminal statute is a fine of up to \$25,000, or imprisonment for up to five years, or both. *Id.* Some states have similar provisions. In New York, for instance, it is an “unacceptable practice” under the State Medicaid Program to have knowledge of any event affecting the right to payment of any person and to conceal or fail to disclose the event with the intention that a payment be made when not authorized or in a greater amount than due. 18 N.Y.C.R.R. § 515.2 (b)(3).
- ² Although this particular guidance from the OIG was contained in its Compliance Program Guidance for Hospitals (63 Federal Register 8987, 8998 [February 23, 1998]), the OIG’s point arguably applies to other healthcare entities and individual providers, as well.
- ³ Public Law No. 111-21, § 4.
- ⁴ Public Law No. 111-148, § 6402.
- ⁵ 31 U.S.C. § 3729 *et seq.*
- ⁶ 42 U.S.C § 1320a-7a.
- ⁷ The FCA already contains an incentive for self-disclosure by allowing courts to reduce the mandatory treble damages to “not less than 2 times the amount of damages which the government sustains” if the court finds that: (i) the person committing the FCA violation furnished all information known to that person to government investigators within 30 days after the date the information became known to that person; (ii) the disclosing person cooperated fully with the government investigation; (iii) a criminal prosecution, civil action or administrative action had not commenced prior to the disclosure; and (iv) the disclosing person had no actual knowledge of a governmental investigation into the violation. 31 U.S.C. §3729(a)(2).
- ⁸ Former 31 U.S.C. §3729 at (a)(7) (2000).
- ⁹ Senate Report 111-10, Part III, § 4 (E); see, e.g., *U.S. v. Bourseau*, 531 F.3d 1159 (9th Cir. 2008); *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235 (3rd Cir. 2004); also see DOJ Press Release, dated February 18, 2011 announcing \$9.1 million false claims settlement with Catholic Healthcare West resolving allegations that included a failure on the part of three hospitals in its system to return overpayments received due to Medicare processing errors when the erroneous payments were discovered. <http://www.justice.gov/usao/cae/news/docs/2011/02-18-11CHWPressRelease.html>. In *United States v. Yale University School of Medicine*, 3:97CV02023 (D. Conn.) (as reported in the FY 1998 DOJ Health Care Fraud Report [<http://www.justice.gov/criminal/fraud/documents/reports/1998/healthcare.pdf>], the U.S. intervened in a *qui tam* action and obtained a \$1.2 million FCA recovery based on the government’s allegation that the school improperly handled a significant amount of credit balances.
- ¹⁰ 31 U.S.C. §3729(a)(1)(G).
- ¹¹ *Id.* at (b)(3).
- ¹² Senate Report 111-10, Part III, § 4 (E). available at [http://thomas.loc.gov/cgi-bin/cpquery/R?cp111:FLD010:@1\(sr010\)](http://thomas.loc.gov/cgi-bin/cpquery/R?cp111:FLD010:@1(sr010)). Alternatively, access to the Senate Report can be obtained through a link found by searching for the “Fraud Enforcement and Recovery Act” on <http://Thomas.gov>.
- ¹³ *Id.*
- ¹⁴ 31 U.S.C. §3729 (b)(1).
- ¹⁵ See *Heckler v. Community Health Services of Crawford County, Inc., et.al.* 467 U.S. 51(1984); 42 CFR § 411.406(e) (providers are expected to be knowledgeable regarding Medicare coverage of services through receipt of CMS notices, including manual issuances, bulletins, or other written guides or directives and Federal Register publications); *In the Case of Stevens v. CMS* (DAB CR1511 2006) (rejecting petitioner’s claim that she was not aware of new licensing requirements and holding as “well-settled” that, as a participant in the Medicare program, she had a duty to familiarize herself with the legal requirements for reimbursement).
- ¹⁶ Thus far, there is a split in the few courts that have addressed whether the FERA reverse false claims act provision is retroactive. See *Bahrani v. ConAgra*, 624 F.3d 1275 (10th Cir. 2010) (newly revised § 3729(a)(1)(G) was not made retroactive by Congress); *Stone v. Omnicare*, 2011 WL 2669659 (N.D. II July 7, 2011) (claims regarding unlawful retention of overpayment under federal programs in 2000-2005 dismissed as FERA amendments are not retroactive); *U.S. ex rel. Sanders v. Allison Engine Co., Inc.*, 667 F.Supp.2d 747 (S.D. Ohio, 2009) (retroactive application of amendments to FCA set forth in FERA violated the *Ex Post Facto* Clause); but see *U.S. ex rel Huey v. Summit HealthCare* (2011 WL 814898 (D. Arizona March 3, 2011) (allowing FCA claim based, *inter alia*, on 3729(a) (1) (g) to survive motion to dismiss where improper retention of overpayments spanned from 2007 to 2009). Of course, even if FERA is not retroactive, providers still have, at the very least, an affirmative obligation to return any overpayments knowingly received.
- ¹⁷ Public Law No: 111-148, § 6402; see 42 U.S.C. § 1320a-7k(d).
- ¹⁸ 42 U.S.C. § 1320a-7k(d)(4)(B).
- ¹⁹ Notably, under FERA, what is considered “the final submission of payment” for purposes of determining when an overpayment has occurred includes the relevant statutory or regulatory periods designated for the “reconciliation of cost reports.” Given that such reconciliation can take a substantial period of time, any overpayment amount may not be fixed until that reconciliation is finished. Senate Report 111-10, Part III, § 4 (E).
- ²⁰ 42 U.S.C. § 1320a-7k(d)(3).
- ²¹ Public Law No: 111-148, § 6402 (adding new subsection a(10) to 42 U.S.C § 1320a-7a).
- ²² Although government agencies commonly promulgate regulations that correspond to the statutes for which they have implementation or oversight responsibility, not every statute has corresponding regulations. In this instance, the OIG has not proposed any rule making activity in this area and the Department of Health and Human Services’ latest regulatory agenda (76 FR 40052, published July 7, 2011) does not contain any reference to such rules being under development.
- ²³ This approach by CMS is similar to the historical approach announced on March 12, 2009 by former New York State Medicaid Inspector General, James Sheehan, in self-disclosure guidance for Medicaid providers for purposes of Medicaid refunds. In that guidance, the Office of the Medicaid Inspector General (“OMIG”) states that while “repayment is encouraged/accepted as early in the [self-disclosure] process as possible, . . . the OMIG will not accept money as full and final payment for self-disclosures prior to finalizing the audit/investigatory process.” http://www.omig.state.ny.us/data/images/stories/self_disclosure/omig_provider_self_disclosure_guidance.pdf. Subsequently, in a webinar presented on September 14, 2010, OMIG explained that refunds should not be made until OMIG completes its verification process. <http://www.omig.ny.gov/data/content/view/204/294/>.
- ²⁴ In New York, the Medicaid Inspector General has taken a narrow view of when an overpayment is identified under PPACA, defining “identification” to include when (i) an employee or contractor identifies an overpayment in a hotline call or email; (ii) a patient advises that service was not received; (iii) a recovery audit contractor (“RAC”) advises that a dual eligible Medicare overpayment has been found; (iv) OMIG informs the provider regarding claims submitted for deceased patients; (v) learning that an employee or ordering physician is unlicensed or excluded from participating in federal healthcare programs; (vi) a *qui tam* action is filed or a government agency brings a lawsuit; or (vii) the filing of an indictment or other instrument alleging criminal charges. Thus, former

- Medicaid Inspector General James Sheehan has defined “overpayment” as the “fact of the overpayment” and “not the amount of the overpayment.” See OMIG Webinar #2: Mandatory Reporting of Government Overpayments Under the Obama Health Program (presented July 14, 2010), available at <http://www.omig.ny.gov/data/content/view/204/294/>.
- 25 New York State OMIG Compliance Webinar #2 (presented July 14, 2010) – Questions and Answers, available at: <http://www.omig.ny.gov/data/content/view/209/294>.
- 26 42 U.S.C. § 1320a-7b(b).
- 27 42 U.S.C. § 1395nn.
- 28 See, e.g., *U.S. ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13 (1st Cir. 2009); *U.S. ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88 (3rd Cir. 2009); *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir. 2004); *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899 (5th Cir. 1997).
- 29 Public Law 111-148, Section 6402; 42 U.S.C. §1320a-7b(g).
- 30 It is the government’s burden to prove every element of the charged offense beyond a reasonable doubt. *U.S. v. Medina*, 485 F.3d 1291 (11th Cir. 2007), citing *Christoffel v. United States*, 338 U.S. 84, 89 (1949); See e.g. *U.S. v. Jackson*, 220 Fed.Appx. 317 (5th Cir. 2007) (evidence that defendant wrote the particular checks in issue as payment for referrals of Medicare or Medicaid patients allowed jury to conclude defendant guilty beyond a reasonable doubt; *U.S. v. McClatchey*, 217 F.3d 823 (10th Cir. 2000) (reversing district court’s grant of acquittal upon finding that the evidence presented would have permitted any reasonable jury to find beyond a reasonable doubt that hospital executive knowingly, voluntarily, and purposefully entered into an agreement with the specific intent to offer or pay remuneration to induce two physicians to refer Medicaid patients to the hospital).
- 31 See *Sedima, SPRL v. Imrex Co., Inc.*, 473 U.S. 479, 491 (1985) (a RICO prosecution in which the Court held “in a number of settings, conduct that can be punished as criminal only upon proof beyond a reasonable doubt will support civil sanctions under a preponderance standard”); *U.S. v. Rogan*, 459 F.Supp.2d 692, 716, n12 (N.D. Illinois 2006) (a False Claims Act case in which the trial court applied the *Sedima* holding, stating that, “the criminality of predicate offenses in any underlying civil statute . . . does not mandate application of a higher burden of proof in a civil case”).
- 32 42 U.S.C. §1395nn (g).
- 33 *Id.* at (h).
- 34 See *U.S. ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88 (3rd Cir. 2009); *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235 (3rd Cir. 2004); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir.1997).
- 35 Although Medicaid Programs are administered by the states, they are jointly funded by the states and the federal government. 42 C.F.R. 430.0.
- 36 “ETHC Agrees to Pay \$2.9 Million,” Cox, Brian, Farragut Press (January 11, 2007). “Doctors Group to Pay \$2.9 Million in Penalties,” Satterfield, Jamie, The Knoxville News-Sentinel (January 5, 2007); 2007 WLNR 240256.
- 37 18 U.S.C. § 1347.
- 38 As a result of the breadth of this crime, it has been used by federal prosecutors to prosecute not only frauds committed against the Medicare and Medicaid programs, but frauds against private insurance plans, including, for instance, a state no-fault automobile insurance program (*U.S. v. Lucien*, 347 F.3d 45 [2nd Cir. 2003]), and the submission of false invoices to a nonprofit health maintenance organization (*U.S. v. Baldwin*, 277 F.Supp.2d 67 [D.C. District 2003]).
- 39 PPACA significantly amended the Health Care Fraud statute, potentially making it easier for prosecutors to prove a case by lowering the intent threshold. Specifically, a person need not have actual knowledge of the statute or specific intent to commit a violation of it in order to be proven guilty. See Public Law 11-148, Section 10606.
- 40 18 U.S.C. § 669.
- 41 Other federal criminal statutes that the federal government potentially could use to establish a legal duty to disclose an overpayment, and to prosecute the fraudulent retention of such, might also include: Embezzlement of Public Money or Property, which makes it a felony to “knowingly convert” a thing of value of the United States or any department or agency to another person’s use (18 U.S.C. § 641); and False Statements Relating to Health Care Matters, which makes it a felony for a healthcare provider to knowingly and willfully conceal or cover up a material fact by any trick, scheme, or device or to make materially false, fictitious or fraudulent statements or representations in connection with the delivery of healthcare (18 U.S.C § 1035).
- 42 2007 WLNR 240256.
- 43 Whether to disclose or not to the DOJ or a specific US Attorney’s Office is beyond the scope of this article and requires a careful analysis of the severity and cause of the overpayment (e.g., was it the result of criminal behavior or intentional fraud) and the potential advantages to being transparent at an early stage with the federal prosecutorial authorities. The US Attorney’s Manual, for instance, provides guidance to US Attorneys regarding how they should evaluate potential prosecutions of corporate entities, including giving credit (e.g., reduced sanctions) due to voluntary disclosure or choosing alternatives to criminal prosecutions (e.g., civil or regulatory actions).
- 44 Refunding state Medicaid funds can be accomplished by following state-specific rules or by using the OIG’s self-disclosure Protocol (discussed below). As states implement additional Medicaid integrity measures, they too are devising formal systems for providers to self-disclose overpayments. For instance, Georgia, New Jersey, New York, Pennsylvania, and Texas all have issued guidance and protocols for providers to report overpayments received from their respective Medicaid Programs:
- GA: http://www.georgia.gov/00/channel_title/0,2094,31446711_118367597,00.html;
- NJ: <http://www.state.nj.us/njomig/disclosure/>;
- NY: <http://www.omig.ny.gov/data/content/blogsection/25/208/>;
- PA:<http://www.dpw.state.pa.us/learnaboutdpw/fraudandabuse/medicalassistanceproviderselfauditprotocol/index.htm>;
- TX: https://oig.hhsc.state.tx.us/providerselfreporting/self_reporting.aspx.
- 45 Medicare Financial Management Manual (Publication 100-06), Ch. 5, §410.
- 46 *Id.* at §411.1.
- 47 A provider must indicate on the refund form information necessary for the proper identification and processing of the refund, including the patient name, Medicare claim number, reason code for claim adjustment, and cost report year (if applicable). The standard form also asks whether the refund is being submitted by an individual or entity that is subject to a Corporate Integrity Agreement (“CIA”) with the OIG, or is a participant in the OIG self-disclosure Protocol.
- 48 Medicare Financial Management Manual (Publication 100-06), Ch. 5, §410.10.
- 49 Medicare Program Integrity Manual, Pub. 100-08, Chapter 4, §4.18.1.
- 50 Medicare Financial Management Manual, Pub. 100-06, Chapter 5, § 410.5.
- 51 The Protocol has several required steps. The provider must conduct an internal investigation and self-assessment, including a calculation of any overpayments, and prepare a written submission to the OIG; The provider should also document the circumstances under which the disclosed matter was discovered and the measures taken to address the problem and prevent future abuses. In reviewing the disclosure, the OIG will verify the provider’s calculation of federal healthcare program losses, and strongly recommends that the assessment follow its guidelines. The breadth of the OIG’s review is dependent on the “quality and thoroughness of the internal investigative and self assessment reports.” 63 Federal Register 58399, 58403 (October 30, 1998).
- 52 63 Fed. Reg. at 58403.
- 53 *Id.* at 58399.
- 54 *Id.* at 58400.
- 55 The OIG also specifies, however, that providers who uncover an “ongoing fraud scheme” should not use the OIG Protocol, but instead should directly contact the OIG immediately. 63 Federal Register at 58400. The OIG has indicated in its compliance program guidance documents that some violations may be so serious that they warrant immediate notification to governmental authorities, prior to, or simultaneous with, commencing an internal investigation. For example, the OIG believes a provider should immediately report misconduct that: (i) is a clear violation of administrative, civil, or criminal laws; (ii) has a significant adverse effect on the quality of care provided to federal health-care program beneficiaries; or (iii) indicates evidence of a systemic failure to comply with applicable laws or an existing corporate integrity agreement, regardless of the financial impact on

continued on page 26

Disclosing and Refunding Overpayments in Healthcare Cases

continued from page 25

- federal healthcare programs. See, e.g., 63 Federal Register 8987, 8998, n. 58 (February 23, 1998).
- ⁵⁶ In deciding whether to bring charges against an organization, the DOJ's "Principals of Federal Prosecution of Business Organizations" instructs U.S. attorneys to consider, among other things, whether the organization made a voluntary and timely disclosure. U.S. Attorney's Manual 9-28-700.
- ⁵⁷ An Open Letter to Health Care Providers, April 24, 2006 (available on the OIG's website at <http://oig.hhs.gov/fraud/selfdisclosure.asp>).
- ⁵⁸ In particular, the OIG stated that its Protocol would be acceptable for reporting impermissible financial arrangements involving an benefit knowingly conferred by one health-care provider upon another referring provider (e.g., an arrangement under which a physician pays a hospital below market value for leasing office space). The OIG also expressed a willingness to settle such self-disclosed matters at the "lower end" of a continuum based on the number and dollar value of improper claims.
- ⁵⁹ An Open Letter to Health Care Providers, March 24, 2009 (available on the OIG's website at <http://oig.hhs.gov/fraud/selfdisclosure.asp>).
- ⁶⁰ Public Law No. 111-148, Section 6409.
- ⁶¹ Available on CMS's website at: http://www.cms.gov/PhysicianSelfReferral/65_Self_Referral_Disclosure_Protocol.asp#To.
- ⁶² Under the CMPL, the OIG has administrative authority to impose monetary penalties for violations of the AKS. 42 U.S.C. §1320a-7a(a)(7).
- ⁶³ If, however, a provider is operating under a CIA or Certification of Compliance Agreement ("CCA") with the OIG, then the CMS Protocol specifies that the disclosure under the CMS Protocol should be copied to the provider's OIG monitor assigned under the CIA or CCA.
- ⁶⁴ See <https://www.cms.gov/PhysicianSelfReferral/DPS/list.asp#TopOfPage>. The website advises that only "select" resolved self-disclosures will be listed and that the list will be updated on a quarterly basis, but there are currently only two settlements posted, despite reports indicating that CMS officials acknowledged receiving 109 self-disclosure cases as of September 2011. (Veiled Disclosures: Providers Eager to Know Extent Of CMS' Leniency for Stark Law Violators, Modern Healthcare, September 26, 2011). The first settlement posted, however, was initially announced to the public in a press release issued by Saints Medical Center in Lowell, Mass. That settlement involved a "one-time payment to CMS of \$579,000." The press release indicates that amount was "less than the reserve . . . set aside . . . to address this issue." Unnamed sources in a related news story say that the alleged Stark violation involved night coverage, stipends, and medical directorships
- and that the liability could have been as high as \$14 million. AIS Health, *Report on Medicare Compliance* (citing the Lowell Sun), Feb. 21, 2011. The second settlement listed, dated November 11, 2011, announces the settlement of "several violations" of the physician self-referral statute disclosed by an unnamed critical access hospital located in Mississippi that involved the failure to satisfy the requirements of the personal services arrangements exception for arrangements with certain hospital and emergency room physicians. The violations disclosed were settled for \$130,000.
- ⁶⁵ The OIG reports to Congress on a semi-annual basis regarding all of its accomplishments. In the Fall 2011 report (posted at <http://oig.hhs.gov/reports-and-publications/semiannual/index.asp> on November 22, 2011 for the period covering April 1, 2011 to September 30, 2011), the OIG reported that self-disclosure cases overall resulted in \$8.4 million in receivables. For the prior period, the OIG reported \$20 million in self-disclosure receivables. The types of issues self-disclosed included a substantial number of CMPL cases involving excluded persons; a few involving claims with misused provider identification numbers; and a few claims involving services not provided as claimed. Also, from 2010 to present, OIG posted 15 instances of self-disclosures involving AKS and/or Stark violations.

NOTES AND ERRATA

Our December 2011 issue (Vol. 24, No. 2, p16) included an article by A. Brian Albritton, entitled "Can They Do That? Government Threats to 'Come Down and Look Around' to Force Settlement in *Qui Tam* Cases." He may be reached at brian.albritton@phelps.com. Mr. Albritton blogs on the subject of the False Claims Act and *Qui Tam* actions at www.falseclaimsactlaw.blogspot.com.

In "Another Round of Contractors: The Medicaid RAC Final Rule" (December 2011, Vol. 24, No. 2, p20), the photographs of authors Jessica Lange and Jennifer Colagiovanni were accidentally transposed. *The Health Lawyer* regrets the error.

VALUATION OF PROFESSIONAL SERVICES ARRANGEMENTS: AN ALTERNATIVE TO THE TRADITIONAL PHYSICIAN EMPLOYMENT MODEL

Scott M. Safriet, MBA, AVA
Albert “Chip” Hutzler, JD, MBA, AVA
HealthCare Appraisers, Inc.
Delray Beach, FL

As the hospital/physician landscape continues to evolve, both parties are continually looking for ways to improve their alignment opportunities. The goals of such improved alignment are often focused on better clinical outcomes and improved financial integration.

One area that is gaining increased traction is the professional services arrangement (“PSA”), with a particular emphasis on implementing the PSA model in lieu of a traditional employment arrangement. Sometimes referred to as a “foundation model” or a “synthetic employment arrangement,” the PSA allows the target physicians to maintain their autonomy as a free standing group practice, receiving compensation from the hospital in exchange for providing clinical services, but without the day-to-day obligations of running a business.

From the hospital’s perspective, the model allows for a significant degree of flexibility in aligning with a group while avoiding physician concerns over loss of autonomy or inability to easily “unwind” the arrangement should the relationship not work out as planned. In a typical PSA model, the hospital will employ all non-physician staff of the group, and will contract with the group practice to provide professional, clinical services to its patients. In exchange, the group receives a set rate of compensation, typically paid on a “per unit” basis, often calculated to include employment taxes, benefits and certain other retained practice expenses.

This article discusses this emerging compensation arrangement, with a

particular emphasis on the rationale of the structure, determination of the appropriate “per unit” compensation rate, and varying issues that can affect the fair market value¹ (“FMV”) compensation in such arrangements.

Rationale for The PSA Model

With the possible exception of television stars, it seems that no one in business re-invents themselves more than physicians and hospitals. In response to ever changing regulations,² whether actually implemented or simply proposed, these two parties are continually exploring new ways to relate with one another, offset changes in reimbursement structures and address the payors’ (and patients’) demands for ever improving clinical outcomes.

Existing against the backdrop of these environmental dynamics is an issue of lifestyle. Physicians are simply placing less and less emphasis on the days of old (e.g., maintaining weekend office hours, taking many days of call coverage each month, etc.), and focusing on spending more time with family, while educating themselves on technological practice advancements. Enter the PSA: a contractual vehicle that is gaining in popularity in response to this market imperative to integrate for quality and efficiency improvement, while addressing some physicians’ aversion to making the leap to full-employment.

Structured properly, the PSA is a potential financial and operational win/win. The hospital gets to leverage its infrastructure, payor contracts and provider-based status (for billing of ancillaries), while the physicians receive FMV compensation for clinical services (and can distribute such compensation within their practice group as they see fit, subject to certain

constraints), a market based allowance for benefits and malpractice insurance, plus the opportunity to contract with the hospital for staffing and/or management services integral to the effective operation of the service line.

There are three main reasons why the PSA model is on the rise: (i) the decline of the independent physician model due to decreasing or uncertain reimbursement trends, increasing risk for physicians, and lifestyle considerations; (ii) the emergence of integrated health strategies, accountable care organizations (“ACOs”), and shared savings programs, including the Medicare Shared Savings Program (“MSSP”) with the intent of collaborative efforts improving outcomes and reducing costs; and (iii) the offer of a viable alternative to the employment model, which cannot be used in many states and has drawbacks such as the relative lack of physician autonomy.

While the PSA model may not be desirable or even possible in all states, the corporate practice of medicine restrictions in some states may “completely bar” the employment model, making the PSA model the only viable alternative to independent practice. Many states do have exceptions for hospital-physician arrangements or some other legal vehicle (such as the foundation model in California) that allows for a similar type of PSA model relationship to be utilized.

Productivity Metrics and The Various Valuation Approaches

The typical underpinning of the PSA model is that in lieu of a traditional employment arrangement, the physician (or group, as applicable) maintains its group practice entity. The

continued on page 28

Valuation of Professional Services Arrangements

continued from page 27

physician enters into an arrangement under which a hospital purchases the tangible assets and/or leases certain non-clinical staff from the physician, and then provides compensation to the physician in exchange for the provision of clinical services. Whereas a traditional employment arrangement has the ability to include a variety of compensation approaches, the PSA is typically based upon personally performed productivity, largely to avoid any possible concern over the physicians having an ownership interest in the entity performing the designated health services (“DHS”) under the Stark law.³ The most commonly used (and likely most supportable) metric is the use of work relative value units (“wRVUs”), as not only do they directly relate to the work effort of the physician, but as appropriate, also allow the hospital to “gross-up” the rate to include taxes and benefits as well as retained practice expenses (*i.e.*, malpractice insurance, CME costs, etc.).⁴

The development of the applicable wRVU rate necessitates careful evaluation of FMV, and is the main area where hospitals have tended (to their potential detriment) to *overestimate* the use of a single methodology (*e.g.*, simply relying on median rates from the benchmark compensation surveys, or only relying on an internally calculated market approach, and ignoring the results of a cost or income approach).⁵

By way of background, nearly all transactions between hospitals and referring physicians implicate the Stark Law.⁶ Therefore, they are required to fit into an applicable Stark law exception, otherwise they are prohibited.⁷ The potential penalties for failing to meet the Stark law requirements include repayment of all tainted claims and punitive payments, as well as possible loss of Medicare eligibility. The exceptions to the Stark Law which are applicable to PSA model arrangements all require the compensation under

compliant transactions to be *consistent with FMV* (as do exceptions related to employment arrangements), and importantly, the Stark law defines FMV differently from traditional notions of the term in other settings (most importantly, the IRS definition), thereby affecting the valuation approaches that can be utilized to value a particular arrangement.⁸ Nevertheless, valuers generally consider the same three approaches that are applied to assets when valuing service arrangements under the Stark FMV standard. The major approaches to value include the Cost, Income and Market Approaches, and their application to PSA model arrangements will be described in greater detail below.⁹

In many respects, the valuation of PSAs is analogous to valuation of employment arrangements, since both models share many common characteristics. Many of the same approaches and techniques are utilized, with the major difference being that the physicians maintain their own practice entity and direct responsibility for certain costs (*e.g.*, taxes, benefits, etc.) requiring appropriate adjustment in the analysis.

The determination of FMV with regard to the wRVU rate will often require the valuator to undertake multiple approaches, as there could be anomalies in the underlying data that negates (or mitigates) reliance on one approach over another. For example, sole reliance on a Market Approach may not take into consideration the high percentage of poor payors in the area and/or the atypical cost structure of the target physician’s practice. On the other hand, an Income Approach may yield over-inflated indications of value if the valuation firm overlooks the need to incorporate an “owner’s return” in the calculations. Furthermore, the Income Approach may not be able to be performed at all if the

target physician practice is unable to provide usable financial information.

With regard to a Market Approach, while in many ways it is the most straightforward (and relied upon) methodology in the context of making an FMV determination of a PSA, it is not without its drawbacks, the biggest of which is its singular dependence on making a comparison to available survey data.

Essentially, a Market Approach involves a process under which a target physician’s performance is compared against available benchmark data. Unfortunately, data from otherwise reliable sources can be “misused” in a variety of ways, and in the context of a PSA or employment agreement analysis, there is potential for (i) over-emphasis on regional compensation differences; (ii) “cherry picking” from among different surveys or survey tables; (iii) failure to consider ownership/ancillary profits that may be inherent in 90th percentile compensation reported by market survey data;¹⁰ and (iv) assuming that there is always correlation between the reported data for compensation and productivity. As such, it is prudent to review and analyze multiple metrics of productivity, including wRVUs, professional collections, median compensation per wRVU, etc. Through the use of a “percentile matching technique,” the valuator will match up each productivity variable with the corresponding expected level of compensation. Since each variable has certain characteristics that may yield unintended results, the valuator will make a “weighting” determination, primarily based on the unique facts of the arrangement as well as the validity of the data.

The general correlation of reported compensation and productivity is well documented in Medical Group Management Association (“MGMA”) and other physician compensation surveys,

though the degree and strength of correlation varies depending on physician specialty and circumstances. This is an inherently logical and fair result. However, while compensation and productivity are often correlated, parties are often surprised to learn that **compensation is inversely correlated with reported productivity ratios**. This result suggests that the correlation between compensation and productivity data is simply not linear (*i.e.*, when compensation is plotted against productivity on a graph, the result is a curve shaped relationship – meaning that as productivity increases, compensation still increases, but not as rapidly at higher levels as it increases at lower productivity levels). This counter-intuitive result is where substantial confusion lies, and risks the possibility of a significant valuation error.

In contrast to the Market Approach, the consideration and use of the Cost and Income Approaches can serve to offset and mitigate the limitations of the Market Approach. While sufficient data is not always available to allow the use of all three approaches, particularly with the valuation of PSAs and employment arrangements, the use of multiple approaches allows the valuator to consider the totality of marketplace considerations in appraising a service arrangement. Furthermore, the Cost and Income Approaches allow a view into the local marketplace, as the valuator can incorporate into the analysis a full array of economic factors that may be affecting compensation of the target physician.

Under the Cost Approach, a valuator endeavors to understand the historical compensation levels of the target physician in order to make a determination about the FMV of a proposed compensation arrangement. However, the relevance of a physician's historical compensation depends on the degree of "comparability" between the physician's practice and the proposed employment arrangement. Historical compensation can be considered as an

indication of the FMV for the services provided by a physician as long as the service arrangement and corresponding compensation meet certain criteria. These criteria include the following:

- The physician and the entity contracting with the physician for services did not have a referral relationship that resulted in a non-arm's-length compensation for purposes of establishing FMV under applicable healthcare regulations.¹¹
- The services provided historically are substantially similar to those services that will be provided under the proposed service arrangement.
- The services are provided in an operational and/or clinical setting that is comparable to the setting under the proposed arrangement.

To undertake the analysis, the valuator will obtain "historical" practice financials for the target physician, and then make a series of normalizing adjustments to allow for an effective comparison. The adjustments to historical compensation include those that make the historical service arrangement comparable to the proposed arrangement in terms of the scope of services provided, the benefits paid in addition to cash compensation, and certain normalized operating costs associated with the provision of the services. The adjustments for normalized benefits and operating costs are made so as to place the key economics of the arrangement on a comparable basis with those expected in the marketplace.¹²

Similar to the Cost Approach, the Income Approach also requires certain financial data, but instead of normalizing historical information, the valuator will request a practice pro-forma statement of operations to be developed by the hospital.¹³ The Income Approach can be used to forecast the "distributable earnings" available for physician compensation in a practice. From this amount, the valuator would make a deduction from the distributable earnings for an estimate of market-level

benefits for the physicians. In addition, recognizing that there is a carrying cost to the deployment of required assets required to operate a practice, the valuator would also make a deduction from distributable earnings to account for an appropriate "owner's return on invested capital" in order to arrive at the guideline level of compensation for physician services. The valuation concept behind this approach is that a forecast of the distributable earnings reflects the future value of the physician services provided to the practice. The forecast, however, should be prepared consistent with the conceptual framework of FMV, which entails the assumption that the practice will be operated by a hypothetical, typical employer entity.

Once all applicable approaches are completed, the valuator must synthesize the results to arrive at the applicable indication of FMV compensation. In performing this synthesis, the valuator should consider whether one or more approaches yielded values that do not appropriately reflect the intent of the agreement, and each approach is assessed in terms of its relative strengths and limitations. For example, the valuator may believe that the Cost Approach, reflective solely of past expense structure and physician earnings, may not be reflective of future expenses and reimbursement levels (and thus future compensation) under a proposed arrangement. Alternatively, the valuator may ascertain that the pro-forma developed by the hospital may appear to include unreasonable assumptions. Regardless, the valuator will typically identify one or more of the approaches as yielding relevant values, and will determine the appropriate "weighting" to apply to each in order to calculate the applicable level of FMV compensation. This resulting compensation range is then converted into the proposed compensation structure to allow for a meaningful comparison.

continued on page 30

Potential Problems with the Valuation Process

Potential Misuse of Survey Data

In reviewing salary survey data (e.g., MGMA¹⁴), it is important to note that while such surveys are heavily relied upon, they are not always the definitive snapshot of physician compensation in the marketplace. The widely used reference compensation surveys from MGMA, AMGA,¹⁵ and other associations and organizations are based on voluntary participation by the respondents, without the use of any statistical sampling methods or means of validating the responses. As such, without a careful review and application of the data, the user may not realize that selecting reference values from different tables could lead to problems (e.g., selecting national wRVU levels but regional compensation), or may fail to recognize that ownership and/or ancillary profits may be inherent in the higher percentiles of reported compensation. Following are four of the more commonly observed misconceptions and/or misuses of the compensation surveys:¹⁶

1. *Misconception: Surveys Present Compensation Only for Physician Clinical Services*

As instructed by the survey questionnaires, it is intended that *total cash compensation* from all sources, including clinical services, ancillaries (and technical revenues), medical directorships, on-call coverage, other service arrangements and owner compensation, be reported. Therefore, it can be rather easy to create a compensation “stacking” issue if one assumes that the survey data relates only to clinical services. A “stacking” issue refers to a situation where several different elements of compensation are separately evaluated and compared to total compensation survey data and deemed to be consistent with FMV on an

individual basis. However, when such elements are “stacked” together in a comprehensive employment arrangement, the results far exceed survey data for total compensation. As such, the appropriate method is to also compare aggregate compensation to total compensation survey information to ensure that aggregate compensation is consistent with FMV. Stacking is discussed in greater detail below.

2. *Misconception: Productivity Ratios Should Correlate with Actual Productivity (i.e. Compensation per wRVU Should be Higher if a Physician Generates More wRVUs)*

In fact, the MGMA survey has clearly stated since 2009 that, in its reported survey data, there is an “inverse” relationship between productivity and the compensation per wRVU rate.¹⁷ As such, the highest wRVU producers have the lowest comp/wRVU rate. This result is somewhat counterintuitive, and leads to substantial confusion and valuation risk.

3. *Misconception: The Median Compensation per wRVU Always Represents FMV*

This assumption defies statistical validity, as by the very definition of the term “median,” 50 percent of the respondents make *less* (and perhaps far less) than this amount. As such, while it may sound conservative, simply defaulting to the median compensation/wRVU value as an indication of FMV may lead to an overcompensation bias in the arrangement. Thus, while 50 percent of respondents do make more than the median compensation per wRVU rate, 50 percent make less, and thus, determination of the appropriate rate requires analysis of specific circumstances and substantial care to ensure the rate properly accounts for the inverse relationship between productivity ratios and productivity itself (see misconception #2 above).

4. *Misconception: Surveys Reflect the Current State of the Physician Marketplace*

The major compensation surveys are published annually, and reflect the marketplace of the prior year. Thus, they are likely not reflective of any known reimbursement or marketplace changes that are impending or which have occurred since the data was gathered. Compensation from year to year is variable and volatility is due to several factors, including geographic location, cost of living, economic conditions, and most importantly, changes in reimbursement patterns and medical advancements. Furthermore, the surveys only reflect the outcomes for those that responded, an inherent bias in and of itself.

The wRVU Model: Common Mistakes

As with most aspects of a transaction, the “devil is in the details,” and the proper calculation and treatment of wRVU’s is no exception, especially in the PSA, as the compensation is almost always exclusively based on physician productivity. By way of additional background, the wRVU is one of three components that make up the “total” RVUs used by Medicare (and many other payors) in the adjudication of physician claims. Unfortunately, if not careful when compiling the historical productivity information for a physician or group practice, a possible mistake is to inadvertently report *total* RVU’s (i.e., to also include relative values for practice expense and malpractice risk) and not simply work relative values (i.e., those solely related to the work effort of the physician). As such, a physician’s expected productivity may be significantly overstated, and thus, in any applications of the market approach which attempt to appropriately match compensation with productivity, the resulting indications of FMV compensation will be commensurately overstated.

A second area that can result in an overstatement of wRVUs results from the failure to consider CPT coding modifiers.¹⁸ As an example, a physician reporting a CPT code for a surgical procedure could have been an *assistant at surgery* which carries a reduced wRVU rate than for the primary surgeon. Similarly, when a surgeon performs multiple procedures on the same patient, the appropriate modifier must be used, as all follow-on procedures to the primary surgical event are subject to a reduction in value.

Other less common issues that lend themselves to possible errors in calculation are as follows:

Use of Midlevel Providers

Midlevel providers refer to non-physicians who provide medical care, such as nurse practitioners, physician assistants, imaging technologists, and other similar providers. This is always a tricky aspect of a PSA analysis, as the valuator needs to be careful to address where the midlevel provider resides in the equation (*e.g.*, if the physician is leasing the midlevel to the hospital, which is the most common practice, the benefit of any work performed, whether “incident to” (which refers to office-based services provided by the midlevel under the physician’s supervision which are typically reimbursed at full physician rates) or at the “midlevel provider rate” (typically services performed by midlevels in a hospital setting, where “incident to” billing is not allowed under Medicare rules, and which are reimbursed at about 80 percent of the physician rate) would accrue to the hospital). However, if the midlevel remains the financial responsibility of the physician (for example, as reflected on the practice financials in a PSA arrangement), then it would be appropriate to have the legitimate “incident to” wRVUs count toward the physician’s productivity.

Use of Blended Rate for Multiple Specialties

It is becoming increasingly common for hospitals to contemplate

entering into PSA’s with multi-specialty physician practices (*e.g.*, a cardiology practice that includes general cardiology, interventional cardiology and electrophysiology). Furthermore, for ease of administration, the hospital may want to pay the same compensation rate per wRVU regardless of the subspecialty. In this scenario, it is important not only to (i) calculate an applicable rate per wRVU for each subspecialty, but (ii) also obtain historical information relative to the percentage mix of wRVUs for each subspecialty, such that the applicable “weighted average” rate can be calculated. Lastly, it is also paramount to run a series of sensitivity analyses at varying levels of potential total wRVUs to ensure that the blended number still yields FMV results, regardless of the level of productivity.

One final area that deserves comment relates to the inclusion of applicable taxes and benefits in the wRVU rate (*i.e.*, the aforementioned “gross-up”). Up until several years ago, it was fairly common practice for valuation firms to simply acknowledge a hospital’s statement to the effect that “benefits provided will be consistent with similarly situated employees.” More recently, many in the valuation community have opened their eyes to the fact that physician benefit plans are becoming more and more robust. In certain situations, a very robust benefits plan, significantly higher than what comparable physicians receive, may be a source of a material increase in economic benefit to the physicians, and such excess benefits would generally need to be regarded as additional compensation in the FMV analysis.

On a related note, since the *reasonable* benefits and taxes are typically included in the “grossed-up” wRVU value, it is important to consider whether an increase in the physicians’ wRVU productivity will result in an overpayment for benefits and taxes since these expenses are mostly fixed (*i.e.*, once the FICA limit has been reached). This is commonly handled by placing a dollar cap on overall benefits.

Evaluating Possible Compensation Stacking Issues

While the underlying compensation methodology for the employment or PSA Model may be commercially reasonable and produce results that are consistent with FMV, a hospital’s desire to involve the same physician in a variety of additional compensated arrangements may result in an overall compensation arrangement that quickly becomes problematic. Since most PSAs are established on a pure productivity basis, most of the typical “stacking” culprits may be mitigated.

For example, a common accompanying arrangement is a medical directorship. Since these are most often compensated on the basis of worked and documented hours, there is *usually* not a large concern about overcompensation in the overall arrangement, since time devoted to these administrative duties may result in the generation of fewer wRVUs. However, what may appear to be a subtle change to the fact pattern (*e.g.*, the physician is paid a flat annual amount for medical director services in exchange for providing a “minimum” number of hours) can result in a situation where the total compensation may exceed FMV. In this scenario, without an effective time tracking mechanism in place, there is a possibility that the physician does not provide the required minimum number of medical director hours.

So, beware the notion that, by calling elements of compensation by different names, one can continue to “stack” the compensation higher. Essentially, all sources of compensation (including benefits, as discussed earlier) should be considered in the aggregate to establish compliance with FMV. Following are some other types of compensation arrangements that can lead to a problematic stacking issue:

- Sign-on bonus
- Quality bonus
- Call pay
- Service line management arrangement¹⁹

continued on page 32

Valuation of Professional Services Arrangements

continued from page 31

- Productivity bonus
- Tail insurance.²⁰

Conclusion

With careful planning and execution, a PSA may be an ideal vehicle to allow a hospital and physicians to better align their clinical goals and objectives. When properly structured, the PSA can mitigate physicians' aversion to traditional employment and the accompanying loss of autonomy. However, as with employment arrangements, PSAs must also comply with the FMV standard. The PSA must be commercially reasonable and consistent with FMV, both with respect to its individual components and when considered in the aggregate.



Scott M. Safriet, MBA, AVA, is a Partner and owner of HealthCare Appraisers. He has almost 20 years of broad healthcare

experience, the last six of which have been spent exclusively on a healthcare valuation focus. Mr. Safriet is able to leverage his broad healthcare background in leading engagements on a wide variety of compensation arrangements, and is a frequent speaker and author on healthcare valuation topics. He may be reached at (561) 330-3488 or via e-mail at ssafriet@hcfmv.com.



Albert ("Chip") D. Hutzler, JD, MBA, AVA, is a Partner at HealthCare Appraisers with more than ten years of experience as a

financial analyst and nearly 20 years of experience as an attorney, including positions in healthcare law, private equity investment banking, strategic business development and business affairs. He focuses on fair market value analysis of hospital arrangements with physicians

for clients nationwide, including on-call arrangements, medical directorships, employment arrangements and physician recruitment arrangements. Mr. Hutzler is a member of the ABA's Health Law Section and a frequent speaker and author on healthcare valuation topics. He may be reached at (561) 330-3488 or via e-mail at chutzler@hcfmv.com.

Endnotes

- ¹ As used herein, the term "fair market value" is as defined in 42 CFR §411.351.
- ² Examples of regulations that impact hospital-physician relationships include without limitation: (1) the Physician Self-Referral Prohibition, more commonly known as the "Stark" Law (42 USC §1395nn); (2) the Federal Anti-Kickback Statute (42 USC §1320a-7b(b)); (3) the False Claims Act (31 USC §§ 3729-3733); (4) the Civil Monetary Penalties Law (42 USC §1320a-7a); (5) the Emergency Medical Treatment and Active Labor Act or "EMTALA" (42 USC §1395dd); (6) the Medicare Shared Savings Programs or "MSSP" provisions of the 2010 Patient Protection and Affordable Care Act ("PPACA") (Section 3022 of PPACA and associated regulations); (7) IRS Private Benefit and Private Inurement guidance (See for example, Treas. Reg. 53.4958 et seq.); (8) the Sustainable Growth Rate (42 USC §1848(f)); (9) Joint Commission accreditation standards and requirements; (10) Medicare Conditions of Participation (42 CFR §482 et seq.); and (11) various state regulations, including what are sometimes referred to as baby kickback laws (see for example, Fla. Stat. § 409.920(2)(e)) and laws prohibiting the "corporate practice of medicine," (or "CPOM" laws), which refer to bans on non-physician ownership of medical practices (see for example, CA Business and Professions Code 2400 and 2052 which, when considered together, represent the CPOM ban in California).
- ³ "DHS" or "designated health services," as defined in the Stark law at 42 USC §1395nn(h)(6). The Stark Law prohibits all financial relationships (unless an exception exists) between a physician and healthcare entities to which the physician refers patients for DHS. DHS is a list of specific services set forth in the law, including imaging, therapy and other treatments, drug administration, and most importantly, all inpatient and outpatient hospital services. Thus, all physician-hospital arrangements implicate the Stark Law if the physician refers any patients to the hospital. The list of DHS is found at 42 § CFR 411.351.
- ⁴ Relative value units ("RVUs") are based on the Resource Based Relative Value Scale ("RBRVS") system established by the Centers for Medicare & Medicaid Services ("CMS") in the Medicare Physician Fee Schedule. The RBRVS system allocates units to specific medical procedures, which are identified by The American Medical Association's current procedure terminology codes ("CPT" codes) or the "Healthcare Common Procedure Coding

System" (known as "HCPCS" procedure codes), based on the general premise that certain physician services are worth more than others, whereby a standard hourly rate of compensation would fail to allow for such relative differences. CMS expends significant effort developing the RVU levels for each type of patient encounter, and they are applied consistently across all physicians. Work RVUs or "wRVUs" refer to the portion of an encounter which represents the physician's professional effort (vs. practice expense RVUs and malpractice RVUs, which relate to the other costs incurred to provide the service).

- ⁵ The MGMA *Physician Compensation and Production Survey* is widely regarded as the one of the best sources of information regarding physician compensation and productivity. Since 2009, the MGMA survey has warned users that the "compensation per wRVU" data reported by the surveys can be misleading. This is discussed in detail later in this article, and can be summarized as follows: there is a tendency for readers to assume that physicians with the highest productivity (i.e., the highest reported wRVUs) must have the highest reported compensation per wRVU rate, but it turns out that the opposite is true. While compensation and productivity are loosely correlated (i.e., as productivity increases, compensation also increases), the effective compensation per wRVU rate actually *decreases* as productivity increases. The reasons for this are not entirely clear, but are likely due to guaranteed compensation floors for certain physicians and the incremental costs incurred by physicians to enable them to produce the highest levels of wRVUs.
- ⁶ See note 3 above for further explanation of why physician-hospital relationships implicate the Stark law (i.e., because all hospital inpatient and outpatient services are considered DHS).
- ⁷ Many transactions that implicate the Stark Law may also implicate the Anti-Kickback Statute (where violations depend on the intent of the parties) or the IRS Private Inurement guidance (for non-profit entities). However, arrangements which are consistent with the narrow Stark definition of FMV are likely also consistent with similar notions of FMV under the Anti-Kickback guidance, as well as the broader FMV standard under the IRS guidance. Analysis tends to focus on the Stark FMV standard for several reasons, namely: (i) the Stark FMV standard is narrower than the IRS FMV standard; (ii) the Stark Law is a strict liability statute (i.e., parties can violate it without realizing they have done so); and (iii) it is absolutely mandatory that arrangements implicating the Stark Law fit into an applicable exception to comply with the statute (many of which have an FMV requirement).
- ⁸ CMS commentary explains that "...the definition of 'fair market value' in the statute and regulation is qualified in ways that do not necessarily comport with the usage of the term in standard valuation techniques and methodologies. For example, the methodology must exclude valuations where the parties to the transactions are at arm's length but in a position to refer to one another." (Stark II Phase II - 69 FR 16107, March 26, 2004).

- ⁹ The three traditional approaches to valuation were set forth by the IRS in Revenue Ruling 59-60 and are further defined in the International Glossary of Business Valuation Terms; they will be described further below.
- ¹⁰ Compensation data in the MGMA and other available surveys represents “total cash compensation” from all sources, which for those reporting physicians who have an ownership interest in their practice, would include ownership distributions (based on profits of the practice, including ancillary profits). It is likely that many, if not all, of the highest reported compensation values in the surveys (*i.e.*, values at the 90th percentile or above) represent some ownership compensation, which makes inherent sense, since non-owner physicians take less business risk. However, under the Stark In-Office Ancillary Services exception, certain non-owner physicians who are “members of the group” under the Stark Law may also be able to share in ancillary profits, which would be included in their reported compensation as well. However, if ancillary services are hospital provided (billed as a hospital service), physicians who are employed directly by a hospital or part of a PSA with that hospital would not be able to share in that revenue under the Stark law. Thus, survey data contains both types of physicians, requiring careful analysis when making comparisons between owner physicians and hospital affiliated physicians.
- ¹¹ See, for example, the Stark Law (42 CFR §411.350 – 411.389) and federal Anti-Kickback Law (42 USC §1320a-7b(b)).
- ¹² The Cost Approach is defined as “a general way of determining a value indication of an individual asset by quantifying the amount of money required to replace the future service capability of that asset,” from the International Glossary of Business Valuation Terms, which is based on the definition adopted by the IRS in Revenue Ruling 59-60. The Cost Approach is based on the Principle of Substitution; *i.e.*, the premise that a prudent individual will pay no more for a property than he/she would pay to acquire a substitute property with the same utility.
- ¹³ The Income Approach is defined as “a general way of determining a value indication of a business, business ownership interest, security, or intangible asset using one or more methods that convert anticipated economic benefits into a present single amount,” from the International Glossary of Business Valuation Terms, which is based on the definition adopted by the IRS in Revenue Ruling 59-60.
- ¹⁴ Medical Group Management Association’s *Physician Compensation and Production Survey*.
- ¹⁵ American Medical Group Association’s *Medical Group Compensation and Financial Survey*.
- ¹⁶ Surveys are frequently utilized by valuation professionals as one technique. However the Stark regulations do not require independent valuations for all transactions, and therefore, hospital executives, physicians and other individuals involved in completing transactions often make their own determinations of value, and may also use survey data (which is widely available) with significantly less understanding of the surveys.
- ¹⁷ See Medical Group Management Association’s *Physician Compensation and Production Survey, 2011 Report Based on 2010 Data*, page 12.
- ¹⁸ A CPT coding modifier is a two digit code used to supplement information or adjust the description to provide extra details concerning a procedure or service provided by a physician. Many modifiers are intended to appropriately reduce the wRVUs associated with a particular situation, as described further in the text that follows. Modifiers are required in certain circumstances by the Medicare Program Conditions of Participation. Failing to account for modifiers that appropriately reduce wRVUs would result in overstatement of wRVUs.
- ¹⁹ Service line management arrangements are utilized by hospitals to engage one group of physicians, usually in a single specialty, to provide coordinated and comprehensive management of a particular service line (*e.g.*, cardiology, neurology), in lieu of engaging multiple separate medical directors to provide the same services in a less coordinated fashion.
- ²⁰ Tail Insurance refers to the malpractice insurance to cover claims made after a physician leaves a particular position or practice. Malpractice insurance is typically sold on a “claims made” basis (meaning the coverage period covers claims made in the period, versus an “occurrence-based” policy which would cover incidents occurring during the period). Because claims may be made by former patients long after a physician leaves a practice, tail insurance is purchased to cover any claims until the applicable statute of limitations on making claims is exhausted.

ABA HEALTH LAW SECTION INTEREST GROUPS

Free Member Benefit: Get the latest info on your specialty(ies)!

Please enroll me in the following Interest Groups (Section Members may join up to three Interest Groups):

- | | |
|---|---|
| <input type="checkbox"/> Business & Transactions | <input type="checkbox"/> Managed Care & Insurance |
| <input type="checkbox"/> eHealth, Privacy & Security | <input type="checkbox"/> Medical Research, Technology & Clinical Ethical Issues |
| <input type="checkbox"/> Employee Benefits & Executive Compensation | <input type="checkbox"/> Payment & Reimbursement |
| <input type="checkbox"/> Healthcare Facilities Operations | <input type="checkbox"/> Physician Issues |
| <input type="checkbox"/> Healthcare Fraud & Compliance | <input type="checkbox"/> Public Health & Policy |
| <input type="checkbox"/> Healthcare Litigation & Risk Management | <input type="checkbox"/> Tax & Accounting |

Name: _____

ABA No. _____

Affiliation: _____

Address: _____

City/State/Zip: _____

Phone: _____ Fax: _____

E-Mail: _____

QUESTIONS? Call:
Wanda Workman, Section Director
 at 312/988-5548

Return to:
Simeon Carson
Health Law Section
American Bar Association
 321 N. Clark Street
 Chicago, IL 60654-7598

The Editorial Board of *The Health Lawyer* is pleased to provide these updates of presentations made at the Annual Emerging Issues in Healthcare Law Conference, held in New Orleans, February 2011. This is an additional benefit provided to Section members to keep you apprised of new developments in healthcare law. We hope that you find these updates useful.

Update to: Physician Ownership of Hospitals: Identifying and Dealing with the Restrictions, Options and Risks Following the Enactment of PPACA and Recent Litigation¹

Tracy Powell, Esq.
Sherrard & Roe
Nashville, TN

With the enactment of the Patient Protection and Affordable Care Act (“PPACA”) on March 23, 2010, significant changes were made to the Stark Law exception known as the “Whole Hospital Exception.” Section 6001 of PPACA not only limited the ownership of physicians in hospitals to the level as of March 23, 2010, the provisions of PPACA also significantly curtailed the expansion (in terms of number of beds, procedure rooms, etc.) of those physician-owned hospitals meeting the so-called “grandfathered status.”

At the 2011 EMI conference, our presentation addressed the changes and open questions arising from the changes. There were a number of provisions under PPACA whereby Congress had directed that CMS publish regulations or provide further clarification. Since the February EMI presentation, CMS published a proposed rule on July 18, 2011 as part of the calendar year 2012 OPSS and ASC payment rates. After the publication of the proposed rule, a comment period followed and the final rule was published on November 1, 2011.²

The final rule addressed the provisions under PPACA related to the expansion of the so-called “grandfathered” facilities (hospitals that had physician ownership prior to March 31, 2010, and also had in place a Medicare provider agreement no later than December 31, 2010). Under the provisions of PPACA, the grandfathered physician-owned hospitals were severely limited in their ability to expand by the addition of new operating rooms, procedure rooms, and beds. The final rule gave further clarification to those requirements; however, the final rule did not offer any unexpected relief to physician-owned hospitals. In order to qualify for an exception to the prohibition on expansion, physician-owned hospitals must meet certain inpatient admission, bed capacity, and bed occupancy criteria, or must qualify as a “high Medicaid facility” based on an analysis of a number of different data points.

In addition to the publication of the final rule described in the preceding paragraph, there is continuing litigation with regard to the constitutionality of PPACA. The United States Supreme Court announced on Monday, November 14, 2011, that it will review the decision of the 11th Circuit in litigation³ brought by 26 states challenging the constitutionality of PPACA, *Florida, et. al., v. U.S. Department of Health and Human Services*, Nos. 11-11021 & 11-11067.⁴ Oral arguments will be heard in March 2012, and some observers believe a decision may be issued prior to the November 2012 elections.

Further, the Physicians Hospital Association (“PHA”), a trade and advocacy group comprised of physician-owned hospitals and which advocates for physician ownership of hospitals, has filed its own litigation challenging the constitutionality of Section 6001 of PPACA.⁵ This action was filed in the Eastern District of Texas; summary judgment was granted to the government in February of 2011, and the case is now on appeal to the Fifth Circuit. In discussions with officials of the PHA, there is a belief that further action of the appeal will be delayed until the Supreme Court acts on the broader litigation referenced in the prior paragraph.

Legislation has been introduced in the House of Representatives to repeal provisions of Section 6001; H.R. 1159 was sponsored by Representative Doc Hastings of Washington. Other legislation (HR 1186) has been introduced that would repeal provisions of 6001 and 6002; this was introduced by Representative Samuel Johnson of Texas. None of the introduced legislation has made any significant progress as of this date.

Endnotes

- ¹ Originally presented by Kathy Poppitt, Esq., moderator, Cox Smith, Austin, Texas, Jennifer L. Rangel, Esq., panelist, Locke Lord, Austin, Texas, and Tracy A. Powell, Esq., panelist, Sherrard & Roe, PLC, Nashville, Tennessee.
- ² http://www.ofr.gov/%28X%281%29S%281vhcbbedrqvx4ykkoh2gdpps%29%29/OFRUpload/OFRData/2011-28612_PL.pdf.
- ³ <http://www.supremecourt.gov/orders/courtorders/111411zor.pdf>.
- ⁴ <http://www.ca11.uscourts.gov/opinions/ops/201111021.pdf>.
- ⁵ *Physicians Hospitals of America and Texas Spine & Joint Hospital, Ltd., v. Sebelius*, 781 F. Supp. 2d. 828 Feb. 18, 2011.

Update to: The Digital Revolution in Healthcare

Arthur E. Peabody, Jr., Esq.
Lead Medicare Counsel
BlueCross BlueShield Association
Washington, DC

Introduction

Technology is transforming the delivery of healthcare in the nation and across the world. Electronic health records (“EHRs”) and health information exchanges (“HIEs”) are at the center of a sea change in the way individual health information is created, managed and shared. The Health Information Technology for Economic and Clinical Health (“HITECH”) Act was enacted on February 17, 2009 as part of the American Reinvestment and Recovery Act (“ARRA”). The HITECH Act amended the Public Health Service Act (“PHSA”) to improve healthcare quality, safety, and efficiency through the promotion of health information technology (“HIT”) and the electronic exchange of health information. Section 3004 of the PHSA, as added by the HITECH Act, authorizes the Secretary of Health and Human Services (“HHS”) to adopt standards, implementation specifications, and certification criteria to enhance the interoperability, functionality, utility, and security of HIT. Section 3004(b)(1) of the PHSA more specifically directs the Secretary to adopt a set of standards, implementation specifications, and certification criteria. Title IV of Division B of ARRA amends Titles XVIII and XIX of the Social Security Act by establishing incentive payments to eligible providers to promote the adoption of meaningful use of interoperable HIT and qualified EHRs. The incentive payments are part of a larger scheme to “accelerate the adoption of HIT and utilization of qualified electronic medical records.” See, 75 FR 36157 (June 24, 2010); 75 FR 44314 (July 28, 2010).

This update addresses the status of relevant regulatory implementation of activities designed to implement the HITECH Act, associated programs, new HIT proposed regulations, and issues relating to healthcare technology arising since the ABA Health Law Section’s Emerging Issues Conference in February 2011 in New Orleans.

Standards and Certification

On January 13, 2010, HHS issued an interim final rule and, subsequently, on July 28, 2010, the Secretary adopted a final rule setting forth the initial standards, implementation specifications, and certification criteria for EHRs and EHR modules. 75 FR 2014, 75 FR 44590. EHR software is tested and certified according to adopted certification criteria to ensure they can properly implement adopted

standards and implementation specifications. Certification provides assurance that the EHRs can meet the requirements of meaningful use.

The Office of the National Coordinator for HIT (“ONC”) has been operating under a “temporary program,” 75 FR 121 (June 24, 2010), and will transition to a “permanent program” in July, 2012, 76 FR 1262 (January 7, 2011), a delay of six months from the initial regulatory date set for implementation. 76 FR 68192 (November 3, 2011). One accreditation organization (ONC-Approved Accreditor or “ONC-AA”) will be approved through a competitive process to accredit certification bodies. The ONC-AA will be selected every three years through a competitive process. Under this program an entity will certify other entities to certify EHR programs and modules. Presently, five organizations have been selected as ONC-Authorized Testing and Certification Bodies (“ATCBs”). Pursuant to the permanent program a designated organization will replace ONC as the body certifying organizations or ATCBs to evaluate EHR programs. Use of certified EHR technology is a core requirement for healthcare providers to become “meaningful users” and eligible for payment under the Medicare and Medicaid EHR incentive programs.

Meaningful Use

Pursuant to 75 FR 44314 (July 28, 2010), incentive payments are being made to Medicare and Medicaid eligible providers for adoption and implementation of Stage 1 of “meaningful use” of EHRs that meet the initial regulatory requirements. Payments began in May 2011. Utilizing an incremental approach, meaningful use will be implemented in three stages. Payments through the three stages are designed to provide incentives of the adoption of EHRs by eligible providers. The U.S. market for EHR systems is expected to reach \$8.3 billion by 2016, growing at an annual rate of more than 12 percent.

The Director of ONC has recommended a delay in implementation of Stage 2 for one year. The delay is designed to ensure that healthcare providers attesting to compliance with Stage 1 in 2011 have adequate time to prepare for Stage 2 which had been scheduled for 2013. The HIT Policy Committee made recommendations to the ONC on the requirements of Stage 2 on June 16, 2011. The last day for eligible hospitals to attest to compliance with Stage 1 requirements for 2011 was November 30, 2011. The last day for eligible professionals to do so is February 29, 2012.

Requirements for Medicaid providers, where incentive payments are larger than for Medicare providers, have been modified or made less stringent. The Medicare and Medicaid Extenders Act eliminates the need for Medicaid providers to demonstrate EHR acquisition costs as a prerequisite for collecting meaningful use payments. Eligible providers need only document and attest that they have adopted and

continued on page 36

Update to: The Digital Revolution in Healthcare

continued from page 35

implemented meaningful use EHR technology to collect the maximum Medicaid incentives, e.g., \$21,250 for an eligible physician. Nonetheless, as of January 2012 not all states had active Medicaid meaningful use programs, limiting incentive payment disbursements through Medicaid.

Statistics regarding the implementation of meaningful use vary widely. According to ONC, 74 percent of hospitals have responded to surveys saying they are planning on investing in HIE services based on the adoption of EHRs and participation in the meaningful use incentive program. Other surveys report that over 40 percent of physicians intend to apply for meaningful use in 2011 or 2012.

Health Disclosures/Logging and Auditing

On May 31, 2011 HHS/OCR issued a notice of proposed rulemaking pursuant to the HITECH Act extending the requirement that covered entities and their business associates are responsible for the PHI contained in a designated record set by affording patients the right to obtain a consolidated access report identifying who has viewed their electronic health data. 76 FR 31426 (May 31, 2011). The proposed regulation has been widely criticized as going beyond the scope of HIPAA's and the HITECH Act's requirements, affording little benefit to patients, and requiring substantial additional expenditures in technology in light of the agency's alleged mistaken view that covered entities and their business associates already generate comprehensive audit trails. Some detractors charge that the reports would permit patients to "target" individuals who have accessed their protected health information ("PHI"). Advocates suggest that the increasing electronic exchange of PHI contemplated by a national HIE where information is exchanged on multiple occasions with some frequency justifies whatever additional steps may be necessary to ensure that patients know who has accessed their PHI.

Metadata

On December 8, 2010, the President's Council of Advisors on Science and Technology ("PCAST") issued a report recommending the development and use of a universal exchange language – the use of metadata – to promote data exchange and increase the security and privacy of PHI. The language would separate data into units that have metadata

tags which describe the permissible uses of the data. For example, a tag might initially serve to protect privacy by specifying the kind of information contained in the message and its sensitivity – limiting what individuals can do with the data after accessing it. As the concept is developed the tag might limit access to the information itself.

On December 10, 2010, HHS issued a Request for Information seeking public comment and recommendations on the PCAST report. In addition, in January 2011 ONC requested the HIT Policy Committee to analyze the report. In April 2011, the HIT Policy Committee filed its report recommending incremental steps to pursue the goals and objectives of the PCAST report.

Thereafter, on August 9, 2011 HHS issued an Advance Notice of Proposed Rulemaking setting forth proposed regulatory standards and specific questions for public comments regarding the metadata standards being considered in three categories, i.e., patient identity, privacy and governance, the initial elements of what the agency described as an incremental approach. 76 FR 48770, 48773. The standards are technical in nature. For example, the agency suggests that it is considering proposing that metadata be expressed according to the requirements "in the HL7 CDA R2 header" in XML format, ostensibly a means of providing wide coverage across data elements utilizing a single standard.

Implementation of metadata standards could serve to advance the privacy interests of patients, enable patients to sort their healthcare data more easily, and enhance the functionality and interoperability of HIEs.

HIEs

ONC's efforts to develop HIEs continue through a variety of means, including grants and demonstration projects. Fifty-six states and territories have received \$548 million to build out HIE capacities at the state level with a requirement that at least one third of their budget be allocated to interstate exchange. Various reports indicate that sustainable and mature HIEs are being developed across the nation. For example, an August 2011 report released by the National eHealth Collaborative describes 12 model programs, all of which are characterized as having developed strong business models that will sustain the exchanges financially. HIEs continue to hold out the promise of improving care and reducing costs.

Update to: The Affordable Care Act: We Had the Audacity... Now What? Regulating the Regulated: What Carriers Can Expect From PPACA

Monica L. Piñon, Esq.
Texas Department of Insurance
Austin, TX

A carrier's medical loss ratio ("MLR") represents the percentage of premium dollar received that is used on direct care, instead of on administrative costs. Beginning January 1, 2011, carriers offering small group or individual coverage must meet an 80 percent MLR

and large group coverage providers must maintain an 85 percent MLR.

Some states may already require carriers to comply with existing MLRs in rules and statutes. To date 17 states have publicly requested a waiver or deferment from compliance with PPACA's MLR standards, up from 10 as of EMI 2011. So far eight states have had determinations issued. The following states have had their waiver/deferment approved: Georgia, Iowa, Kentucky, Maine, New Hampshire, and Nevada. Delaware and North Dakota's requests have been disapproved. The other states' applications are either being reviewed for completeness or under consideration.

Chair's Corner

continued from page 2

- Negotiations for a new clinical network affiliation break down when the hospital and a physician group can't reach agreement over governance and money.
- Health system management is at loggerheads on implementing a new patient partnership program.

Our traditional advocacy skills may not be adequate tools for resolving conflicts in an environment where sustained collaborative relationships are critical. I believe that as attorneys we must learn to address the conflicts that inevitably arise in ways that allow our clients to continue to work together toward common, beneficial ends.

Our clients are experiencing large-scale change – in the delivery of healthcare, in reimbursement systems, in new quality and outcome measures – and with change comes conflict. As

counsel, we have a rare opportunity and responsibility to help our clients navigate through this new territory. But that navigation takes some new skills.

To address this need, members of the Section have developed a four-hour workshop to be held Wednesday afternoon, February 22, 2012 as part of our annual Emerging Issues in Healthcare Conference.

This interactive session, entitled *Leading Through Change: The Role of Attorneys in Supporting and Guiding System Change through Strategic Management of Conflict*, invites participants to engage in active dialogue with experts and one another to identify new skills and best practices to successfully address conflict while leading clients and stakeholders through uncertainty and change. The workshop leaders are four attorneys with extensive experience in assisting clients in addressing

conflict: Charity Scott, Beth Schermer, Debra Gerardi and Dale Hetzler. Their backgrounds include academic law, private practice, organizational consulting and in-house counsel.

Participants will have the opportunity to take an individual conflict styles assessment to identify personal ways of responding to conflict and to understand how others respond, as well. In addition to the dialogue, the session will include take-away strategies, resources and practical tools for early identification of potential conflict situations and for engaging clients, third parties and opposing counsel effectively in conflict-laden situations.

I hope that you can join me in participating in this important workshop. You and your clients will be glad you did.

David



HLS Co-sponsors 2012 Cancer Rights Conferences

The ABA Health Law Section, in collaboration with the Section's Breast Cancer Task Force, once again is co-sponsoring the Cancer Legal Resource Center's 2012 Cancer Rights Conferences. These one-day conferences provide participants with comprehensive information about the most common cancer-related legal issues. They will be attended by patients, survivors, caregivers, health-care providers, advocates, and business and community leaders. Other sponsors include the Disability Rights Legal Center, Loyola Law School Los Angeles, LIVESTRONG, Genentech, and the University of Michigan Comprehensive Cancer Center. Registration to all conferences is complimentary.

The four conferences will be:

- May 29, 2012, Boston, MA
- September 7, 2012, Chicago, IL
- October 5, 2012, Fresno, CA
- October 19, 2012, Houston, TX

For more information, or to register for any of the four Cancer Rights Conferences, please visit cancerrightsconference.org. For more information about the ABA Breast Cancer Task Force, please visit www.americanbar.org/groups/health_law/breast_cancer_task_force.html.

Health Law Section Announces Winner of the 10th Annual Writing Competition

The Health Law Section is pleased to announce the winner of the 10th Annual Law Student Writing Competition. Selected from 25 entries, **Jennifer Siegel**, a student at the University of Maryland School of Law, Baltimore, Maryland, won first place for her excellent paper, *Advancing Ethical Research Practices in the Military*. This article will be published in a future issue of *The Health Lawyer*. In addition, Ms. Siegel will receive a \$500 honorarium and complimentary attendance to the upcoming Emerging Issues conference in San Diego, CA.

The Section would also like to congratulate our runners up, **Jada J. Fehn**, a student at Hamline University School of Law, Saint Paul, MN for *The Assault on Bad Food: Tobacco-Style Litigation as an Element of the Comprehensive Scheme to Fight Obesity*; **Chelsea Homer**, a student at the University of Detroit Mercy School of Law, Detroit, MI for *The Incentive*

Conundrum: How the Stark Law has affected Physicians' Use and Referral of Ancillary Services, and **Rebecca J. Kopps**, a student at Northern Illinois University – College of Law, DeKalb, IL for *Dead on Arrival: The Health Insurance Industry's Bleak Prognosis due to Unconstitutional Ratemaking in the Patient Protection and Affordable Care Act*. These papers are also slated to be published in *The Health Lawyer*.

Questions or requests for more information can be made by contacting Simeon Carson at simeon.carson@americanbar.org.

HLS Comments on ACO Medicare Shared Savings Program

The Health Law Section submitted comments on the Interim Final Rule issued jointly by the Centers for Medicare & Medicaid Services ("CMS") and the Department of Health and Human Services' Office of Inspector General ("OIG") establishing waivers of the application of the Physician Self-Referral Law (also known as the Stark law), the federal Anti-Kickback Statute, and certain civil monetary penalties law provisions to specified arrangements involving accountable care organizations ("ACOs") as authorized by Section 1899(f) of the Social Security Act as necessary to implement the Medicare Shared Savings Program (the "MSSP"). The comments were prepared by the Section's ACO Task Force, then approved by the Section's Council and submitted to CMS on December 28, 2011.

A special thank you to all of our volunteer members. Contributors to these comments were **Claire Turcotte, Stephanie Willis, Catherine Greaves, John Steiner, Barry Liss, Christina Torossian, Matt Jenkins, Carol Bowen, David Crapo, Kelvin Ziegler** and **Amy Fehn**, who chaired the Task Force's working group on these comments. In addition, **William W. Horton**, Co-Chair of the Section's Health Law and Policy Review Coordination Committee, served as reviewer of the Task Force's work and participated in the preparation of the final comments.

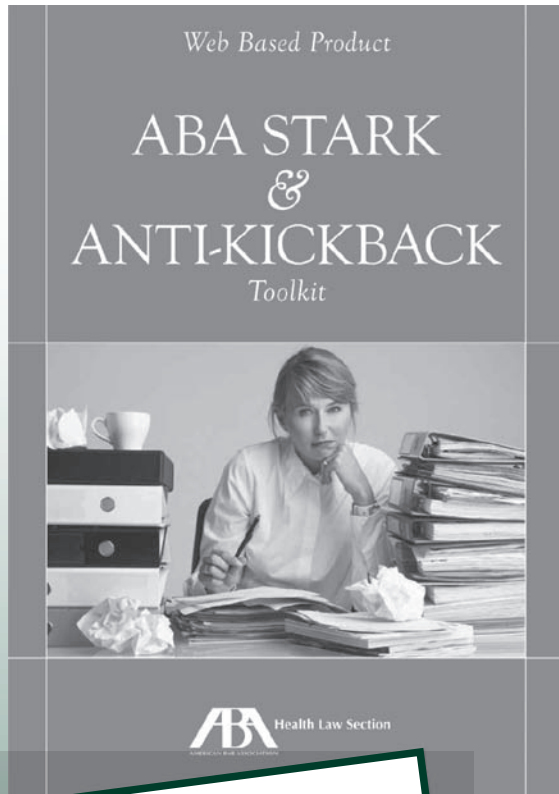
To view the final comments, please visit the Section's website at www.americanbar.org/health.

If you are interested in getting involved in providing feedback regarding health law-related policy decisions, please contact Simeon Carson, Associate Director, at simeon.carson@americanbar.org.

REMINDER:

ABA Health Law Section members can access past issues of *The Health Lawyer* on the Section's website. To access back issues and *The Health Lawyer's* full index, go to http://www.americanbar.org/publications/health_lawyer_home.html.

Coming Soon! The New Stark & Anti-Kickback Toolkit!



The new *Stark & Anti-Kickback Toolkit* is the first in a series of practical electronic tools to be generated by the ABA Health Law Section. Reduce the mountain of paper on your desk with this one-of-a-kind resource offering subscribers a centralized location to electronically search administrative materials relating to the Stark and anti-kickback laws. The toolkit searchable database for health lawyers includes:

- Narrative Summaries
- Statutes
- Administrative History
- Regulations
- Administrative Materials
- Links to CMS website for Stark advisory opinions; OIG website for anti-kickback advisory opinions; and several ABA Health Law Section publications

The *Stark & Anti-Kickback Toolkit* is **extremely affordable**. At the retail price of \$1,250 for a one-year subscription, that is only \$104 a month - less than the value of one hour of an associate's time. As a Health Law Section member you save 20%. Your price is \$995 for a one-year subscription saving you \$255!

**FOR LESS THAN
\$3 A DAY,**
you'll save time and
money with this innovative
electronic resource!

To receive advance notice of the launch of this one-of-a-kind resource, please contact Simeon Carson, Associate Director, at simeon.carson@americanbar.org.



AMERICAN BAR ASSOCIATION

Health Law Section

321 N. Clark Street
Chicago, IL 60654-7598

Volume 24, Number 3
February 2012

Nonprofit Organization
U.S. Postage
PAID
American Bar Association

SECTION CALENDAR

For more information on any of these programs, call the Section at 312/988-5532
or visit the Section website at www.americanbar.org/health

2/9/2012

Language Access in Healthcare
Settings: A Legal Primer
Webinar

2/16/2012

Stark Law Basics
Webinar

2/22/2012 – 2/25/2012

13th Annual Emerging Issues in
Healthcare Law
Hilton San Diego Bayfront
San Diego, CA
Registration now Open!

3/8/2012

ACOs from the Physician Perspective
Webinar

3/15/2012

Medicare's Revalidation Requirements:
Update on Enrollment Procedures
for Providers and Suppliers
Webinar

3/22/2012

Anti-Kickback Law Basics
Webinar

4/5/2012

New Rulemaking for Human Research
Subjects: Beyond the Common Rule
Webinar

4/19/2012

Healthcare Antitrust Fundamentals
Webinar

4/26/2012

The Crime of Doing Nothing:
New Threats for Corporate Officers
Webinar

5/17/2012

Reimbursement and False Claims
Act Fundamentals
Webinar

6/7/2012

HITECH and HIPAA Fundamentals
Webinar

6/14/2012 – 6/15/2012

Physician Legal Issues Conference
Radisson Blu Aqua Hotel
Chicago, IL

7/26/2012

Fundamentals of Medical Staff
and Peer Review Issues
Webinar

9/20/2012

FDA Public Health Clinical
Trials Fundamentals
Webinar