RAC TO THE FUTURE: WHAT CAN MEDICARE PROVIDERS AND SUPPLIERS EXPECT FROM RECOVERY AUDIT CONTRACTORS?

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Introduction

The Centers for Medicare and Medicaid Services ("CMS" or "Medicare") Recovery Audit Contractor ("RAC") program has been made permanent and is expanding nationwide, beginning this year, in 2008. Medicare providers and suppliers should begin now to prepare for RAC auditing activity. Adopting and implementing appropriate compliance programs is an important first step to prepare for increased Medicare scrutiny. However, even with appropriate compliance programs in place, Medicare providers and suppliers still may experience claim denials made by RACs. Many of these denials can be successfully appealed through the Medicare appeals process. This article will provide an overview of the RAC program and will provide guidance to legal counsel representing Medicare providers and suppliers that may soon find themselves subject to RAC audits.

Recovery Audit Contractors

The History... RAC Demonstration Program

Section 306 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA"), directed the Department of Health and Human Services ("HHS") to conduct a three-year demonstration program using RACs. The demonstration began in 2005 in the three states with the highest Medicare expenditures: California, Florida and New York. In 2007, the RAC demonstration program expanded to include Massachusetts, South Carolina and Arizona. The RACs were tasked to identify and correct Medicare overpayments and underpayments, and were compensated on a contingency fee basis based on the principal amount collected from and/or returned to the provider or supplier. There were two types of RACs in the demonstration program: Claim RACs and Medicare Secondary Payor ("MSP") RACs. The purpose of the demonstration was to determine whether the use of RACs would be a cost-effective way to identify and correct improper Medicare payments.

The RAC demonstration program proved highly "cost effective" from the continued on page 3
The Section held its annual Washington Healthcare Summit November 17-18 at the Pentagon City Ritz-Carlton in Arlington, Virginia. As always, the chance to hear from our colleagues in government and leaders in our field was particularly engaging as well as timely. Though the two-day event covered a wide-range of speakers and topics, I have highlighted two seminar presentations which captured the Summit’s most prominent themes.

The program began with an interesting panel of Congressional Staffers who emphasized the impact of the troubled economy on healthcare in America. Significant job losses are most often accompanied by the loss of healthcare benefits which ultimately impacts states’ abilities to handle Medicaid and Medicare responsibilities. As one panelist noted, states have two options - they can either raise taxes or cut expenses. The last time the United States underwent a recession, it took 47 months to get back to the previous level of jobs, which indicates we’re likely to endure several more months of significantly low revenues throughout the country. The panel, however, believed President Obama’s administration will move Congress to take action on healthcare early in his administration in light of his regularly acknowledged commitment to seriously addressing the intensifying issue.

All agreed that Congress faces a daunting agenda, with healthcare reform high on the priority list. Other issues likely to find their way onto the Congressional front-burner include improving private insurance markets, food and drug safety importation, and biologically engineered drugs, especially with respect to patent issues. With a Democratic-controlled Congress, the panel also thought there might be some movement on SCHIP.

Other issues the panel addressed included pay for performance and quality of services. The enormous budget deficit facing the incoming administration will lead to more emphasis on value, particularly in the care of chronic diseases.

Lastly, the panel touched upon the recent Rand study which outlines the premise that increased spending does not equate to better health outcomes. The panel also touched on the problem that since physician reimbursement issues decided on a year-to-year basis consume large amounts of time, there is a need to figure out a better way of managing this issue. The two main problems facing healthcare reform in the coming years remain privacy issues and funding. The panel felt that HIT and privacy are vital in attaining better quality.

Senator Kent Conrad (D-ND), chair of the Budget Committee, also offered his insights related to healthcare in America. From his perspective, things are in bad shape and...
point of view of CMS. Over the course of the three-year demonstration, the RACs identified and collected more than $1.03 billion in improper payments. According to CMS, factoring in the underpayments returned to providers and suppliers, the claims over-turned on appeal, and the operating costs of the demonstration program, the RAC program was successful in returning $693.6 million to the Medicare Trust Funds. CMS estimates that the RAC demonstration program cost approximately 20 cents for each dollar returned to the Medicare Trust Funds.

More to Come… RAC Permanent Program

Section 302 of the Tax Relief and Health Care Act of 2006 made the RAC program permanent and required its expansion nationwide by no later than 2010. CMS is beginning to move forward with this expansion. According to its most-recently published “Expansion Schedule,” CMS planned to expand to 19 states by October 1, 2008, four more states by March 1, 2009, and the remaining states by August 1, 2009 or later.

On October 6, 2008, CMS announced the names of the RAC vendors for the permanent program, and identified the initial states for which each will be responsible:

- Diversified Collection Services, Inc., of Livermore, California is the RAC for Region A, including Maine, New Hampshire, Vermont, Massachusetts, Rhode Island and New York;
- CGI Technologies and Solutions, Inc. of Fairfax, Virginia is the RAC for Region B, including Michigan, Indiana and Minnesota;
- Connolly Consulting Associates, Inc. of Wilton, Connecticut is the RAC for Region C, including South Carolina, Florida, Colorado and New Mexico; and
- HealthDataInsights, Inc. of Las Vegas, Nevada is the RAC for Region D, including Montana, Wyoming, North Dakota, South Dakota, Utah and Arizona.

Before the permanent RACs begin their auditing activities, the RACs will hold “Town Hall”-type outreach meetings at which the RACs will meet with representatives from CMS and with Medicare providers and suppliers. These outreach meetings were originally scheduled to take place beginning in November and December 2008, but have since been delayed possibly until February 2009. Soon after these outreach meetings are completed, Medicare providers and suppliers in the first 19 states (listed above) can expect to receive requests for medical records and/or overpayment demand letters from the RACs.

Although the RACs are tasked with correcting underpayments in addition to overpayments, it is the process of identifying and recouping alleged overpayments that is of particular significance to Medicare providers, suppliers and their legal counsel. Over the course of the three-year demonstration, the RACs identified and collected $992.7 million in overpayments and ordered repayment of just $37.8 million in underpayments to Medicare providers and suppliers. Thus, approximately 96 percent of the alleged improper payments identified were overpayments, as opposed to underpayments.

RACs are permitted to attempt to identify improper payments resulting from:

- Incorrect payments;
- Non-covered services (including services that are not reasonable and necessary);
- Incorrectly coded services (including DRG miscoding); and
- Duplicate services.

RACs engage in two types of reviews in order to identify improper payments: “automated review” and “complex review.” An “automated review” is a review of claims data without a review of records, which may be only conducted in cases where there is certainty that a claim includes an overpayment. A “complex review” consists of a review of medical or other records, and is used in situations where there is a high probability (but not a certainty) that a claim includes an overpayment.
RAC to the Future: What Can Medicare Providers and Suppliers Expect...

continued from page 3

2003\(^{15}\) and the RAC Statement of Work, RACs are prohibited from selecting claims at random to review. Instead, RACs are charged with using proprietary “data analysis techniques” to determine claims likely to contain overpayments, a process known as “targeted review.”\(^{16}\) Although there is no way to predict with certainty which providers or suppliers may be targeted for review, one result of RACs engaging in these “targeted reviews” is that certain types of claims and certain provider types may see more RAC auditing activity than others.\(^{17}\) In conducting its reviews, RACs are required to comply with all National Coverage Decisions (“NCDs”), Coverage Provisions in Interpretive Manuals, national coverage and coding articles, Local Coverage Decisions (“LCDs”), and local coverage and coding articles in their respective jurisdictions.\(^{18}\)

During the course of the demonstration project, Medicare providers and suppliers raised significant concerns with certain aspects of the RAC program. CMS has made efforts to address these concerns and adopted numerous changes to be implemented in the permanent program. Some of these changes include the following:

- Under the RAC demonstration program, the RACs were not required to employ a physician medical director or coding expert. However, under the permanent program, when performing coverage or coding reviews of medical records requested from a Medicare provider or supplier, registered nurses or therapists are required to make determinations regarding medical necessity and certified coders are required to make coding determinations. The RACs are not required to involve physicians in the medical record review process; however, the RACs are required to employ a contractor medical director (“CMD”), who is a doctor of medicine or doctor of osteopathy, and arrange for an alternate CMD in the event that the CMD is unavailable for an extended period. The CMD will provide services such as providing guidance to RAC staff regarding interpretation of Medicare policy.\(^{20}\) Legal counsel representing Medicare providers and suppliers subject to RAC audits may find it advantageous to meet with the CMD to advocate on behalf of their clients and gain insight regarding claim denials.

- CMS compensates RACs on a contingency fee basis, based on the principal amount of collection or the amount paid back to a provider or supplier. Under the demonstration program, the RACs were entitled to keep their contingency fees if a denial was upheld at the first stage of appeal, regardless of whether a provider prevailed at a later stage of the appeals process. Significantly, many providers were successful at later stages of the appeals process. This fee arrangement provided incentive to the RACs to aggressively review and deny claims, contributing to the perception within the Medicare provider and supplier community that the RACs were acting as “bounty hunters.” For their efforts, the RACs earned $187.2 million in contingency payments over the course of the demonstration (or approximately 14.4 percent of all alleged improper payments identified).\(^{11}\) In a significant change from the demonstration program, under the permanent RAC program if a provider files an appeal disputing an overpayment determination and wins this appeal at any level, the RAC is not entitled to keep its contingency fee and must repay CMS the amount it received for the recovery.\(^{22}\) The RAC contingency fees for the permanent program range from 9 percent to 12.5 percent, depending on the particular RAC.\(^{23}\)

Additional Medicare Provider and Supplier Concerns with the RAC Demonstration Program

Although CMS has acknowledged certain concerns raised by Medicare providers and suppliers and has taken steps to address these concerns in the permanent program, it is CMS’s belief that most Medicare providers and suppliers generally were satisfied with the RAC demonstration program. A Gallup Organization telephone survey performed during Summer 2007\(^{24}\) found that:

- 71 percent of poll respondents believed RAC reviewers to have correctly applied Medicare policies in conducting reviews, and
- 74 percent of poll respondents felt that CMS’s efforts to recoup alleged overpayments were fair and reasonable.\(^{25}\)

Certain groups strongly and vocally disagree with the Gallup Organization’s reported findings. These groups believe that, during the course of the demonstration program, RAC reviewers failed to appropriately apply Medicare policies in
conducted claim reviews and improperly recouped alleged overpayments.

Concerns raised by the California Hospital Association:

One group that strongly disagrees with the Gallup Organization’s reported findings is the California Hospital Association (“CHA”). The CHA believes that the RAC operating in California failed to appropriately apply Medicare policies while reviewing (1) inpatient rehabilitation facility (“IRF”) claims and (2) inpatient hospital short-stay claims.

- With respect to IRF claims, during the demonstration program, the RAC assigned to California denied 5,237 IRF claims for the reason that the beneficiary did not require the intense level of services provided, and care should have been rendered in a less-intensive setting.26 Amid arguments championed by the CHA that the RAC did not appropriately apply Medicare policy in reviewing these claims, CMS “paused” the RAC’s authority to further review IRF claims and commissioned a different and independent contractor to review a sampling of IRF claims previously reviewed by the RAC. The independent contractor disagreed with approximately 40 percent of the determinations made by the RAC. In response to these findings, CMS stated: “[It] is clear that the RAC, fiscal intermediary, our independent review entity, as well as appeal contractors involved have not consistently applied our coverage and payment policies...”27 CMS then provided training to all contractors reviewing IRF claims in California, and instructed the RAC to re-review all of the claims it had previously denied. Of the 5,237 total IRF claims initially denied, over 27 percent (1,454 claims) of the denials were overturned by the RAC upon re-review. These cases amounted to approximately $14 million.28

- With respect to inpatient hospital short-stay claims, the RAC denied many claims for the reason that the services should have been billed as “observation” services, rather than “inpatient” hospital services. Based upon communications with its members, CHA found that the RAC based many of these denials upon InterQual Level of Care criteria, not upon published Medicare policy.29 The CHA notified CMS that its members were receiving this type of inappropriate denial, and CMS agreed to research this issue as well. Additionally, where the RAC found that inpatient services should have been billed as observation services, the RAC denied payment for the services rendered altogether and did not re-code the services to be paid at the lower level. During the RAC demonstration program, CMS permitted Medicare providers to re-bill these claims at the observation level of care. At this time, it is unclear whether this opportunity will be granted in the permanent program.

AnMed Health v. Leavitt:

In addition to concerns raised by the CHA, providers in South Carolina also have expressed dissatisfaction with the RAC program. On July 3, 2008, a complaint filed jointly by 32 South Carolina hospitals asserts that CMS improperly recouped $30 million in alleged overpayments. The complaint specifically alleges that CMS wrongfully recouped RAC-identified overpayments before plaintiff hospitals had received decisions at the reconsideration level of appeal, contrary to Section 935 of the MMA.30 Section 935 of the MMA generally mandates that CMS refrain from taking recoupment action until a decision is rendered at the reconsideration stage of appeal.31 In fact, in most cases, the Intermediary recouped the RAC-identified overpayments before or at the same time it provided notice to the providers of the alleged overpayments (and thus before the providers had any opportunity to appeal). The complaint further alleges CMS allowed the RAC to apply different standards for evaluating medical necessity than it requires the providers to use.32

In contrast to the arguments set forth by the South Carolina hospitals, CMS has taken the position that it need not refrain from recouping alleged overpayments at all times before an appellant has received a reconsideration decision. CMS recently published a MLN Matters article educating providers and suppliers regarding Medicare’s policy concerning the recoupment of funds related to overpayment determinations. The article also addresses the manner in which interest will be assessed to an overpayment determination during the appeals process.

With respect to the manner in which Medicare will enact recoupment activities, the MLN Matters article states the following:

- Once the Intermediary or Carrier renders an unfavorable initial determination, finds an overpayment to exist, and issues a demand letter, withholding will begin on the 41st day following the demand letter, unless the Medicare provider or supplier files its request for redetermination within 30 days from the date of the initial demand letter. Once a provider files a request for redetermination, Medicare will cease its withhold activities, but interest will continue to accrue. Notably, pursuant to the federal regulations governing the Medicare appeals process, a provider has 120 days from the date of initial determination to file its request for redetermination. However, if the provider chooses to utilize this entire time period, then the provider must be aware that Medicare will begin withholding until the request for redetermination is filed.

- If a redetermination decision results in a full or partial affirmation of the overpayment, then the

continued on page 6
Intermediary or Carrier may begin withholding funds beginning as soon as 61 days after giving notice, unless the Qualified Independent Contractor ("QIC") first receives the provider's request for reconsideration. The Intermediary or Carrier may not initiate, and must cease, recoupment once a valid and timely request for reconsideration has been filed. Notably, pursuant to the federal regulations governing the Medicare appeals process, a provider has 180 days from the date of redetermination decision to file its request for reconsideration. However, as noted above, the Intermediary may begin withholding 61 days from the date of redetermination decision. It may be tempting for providers to quickly appeal an unfavorable redetermination decision to stop the Intermediary from withholding funds. However, it may be advantageous for the provider to take additional time to carefully put together its appeal. The regulations require providers to present all evidence, allegations of fact or law related to the issues in dispute, and explain its reasons for disagreement when filing a reconsideration request. Absent good cause, the failure of a provider to submit evidence prior to issuance of the reconsideration decision precludes subsequent consideration of the evidence.

- If the qualified independent contractor issues an unfavorable reconsideration decision, the Intermediary or Carrier may begin recoupment, regardless of whether the provider subsequently proceeds to the third stage of appeal and requests an Administrative Law Judge hearing.15

While a Medicare provider or supplier is appealing an overpayment determination or claim denial, interest will continue to accrue, even if Medicare suspends its recoupment activities during the first stages of appeal. As a practical matter, legal counsel representing Medicare providers and suppliers subject to RAC or other Medicare audits should keep CMS's recoupment policy in mind, as some providers and suppliers may wish to file appeals before the timeframe for appeal has elapsed to ensure that CMS does not initiate a withhold for cash flow purposes. In addition, because interest continues to accrue on overpayment determinations during the appeals process, legal counsel representing Medicare providers and suppliers together with their clients may make a strategic decision to expedite the appeals process by filing appeals early to avoid accruing additional interest.

Medicare Recovery Audit Contractor Moratorium Act of 2007:

As a result of concerns arising during the RAC demonstration program, on November 7, 2007, H.R. 4105, the “Medicare Recovery Audit Contractor Moratorium Act of 2007” was introduced to Congress. If enacted, H.R. 4105 would direct the Secretary of HHS to enact a one-year moratorium of the RAC program, during which time (1) CMS would further evaluate the RAC program for Congress; and (2) the Comptroller General would prepare a report to Congress on the use of RAC auditors. 34 H.R. 4105 has strong support from Medicare provider and supplier groups, including the American Medical Association,35 American Hospital Association36 and the California Hospital Association.37 As of the date of this publication, H.R. 4105 has been referred to the House Ways and Means Committee and the House Energy and Commerce Committee for deliberation.

Despite the challenges associated with the RAC demonstration program, CMS is moving forward with the nationwide RAC expansion, and Medicare providers, suppliers and their legal counsel must be prepared. Although CMS adopted certain changes to be implemented in the RAC permanent program designed to address some of the challenges arising during the demonstration program, significant challenges remain. Particularly given that the RACs will continue to be compensated on a contingency-fee basis during the permanent RAC program, many of the challenges encountered during the demonstration program (which were in part due to the RACs aggressively seeking claim denials in a manner many providers and suppliers believe were violative of existing statutes, regulations and Medicare guidance), will likely resurface in the permanent program. The objectivity of the RAC auditors may be compromised by the contingency-fee payment structure of the RAC program. Legal counsel representing Medicare providers and suppliers must be cognizant of this potential bias, and must work proactively to hold the RAC auditors to the requirements of existing statutes, regulations and Medicare policy guidance. This could mean establishing communications with RACs and with CMS when problems are identified (as exemplified by the CHA during the demonstration program); utilizing the court system (e.g. AnMed Health v. Leavitt); and/or becoming engaged in political activism (e.g. H.R. 4105).

RAC Planning and Compliance

Although providers and suppliers cannot stop RAC audits from happening, they can immediately get systems in place for tracking record requests and timely responding, and they can implement appropriate compliance programs and make efforts to understand available audit defenses. Specifically, Medicare providers and suppliers can begin to prepare for the RACs by dedicating resources to:

- Responding to record requests within the required timeframes.18
• Internally monitoring protocols to better identify and monitor areas that may be subject to review;
• Implementing compliance efforts, including, but not limited to, documentation and coding education; and
• Properly working up appeals to challenge denials in the appeals process. With regard to medical necessity and similar denials, this will clearly entail physician involvement.

Although it cannot be predicted with certainty the areas that will be subject to review during the permanent RAC program, the Office of Inspector General (“OIG”) annually publishes a Work Plan document, setting forth various projects to be addressed during the upcoming fiscal year, including areas of planned audit activity. In addition, reviewing the types of denials made during the RAC demonstration program is a helpful tool for Medicare providers and suppliers to identify potential target areas for the RACs operating in the permanent program.

During the RAC demonstration program:
• The vast majority (85 percent) of claim denials involved inpatient hospital claims;
• Six percent of claim denials involved inpatient rehabilitation facility (“IRF”) services;
• Four percent of claim denials involved outpatient hospitals;
• The remaining denials involved the claims of physicians, skilled nursing facilities, durable medical equipment suppliers and ambulance, laboratory or other providers.40

In addition to reviewing the types of denials made during the RAC demonstration program, Medicare providers, suppliers, and their legal counsel must keep current with CMS announcements, which can help guide compliance efforts. For example, on October 6, 2008, CMS announced that it plans to focus its upcoming review activities on home health agencies (which were exempt from the RAC demonstration program) and durable medical equipment suppliers.40

Of the denials made during the demonstration program:
• 35 percent of the improper payments identified were the result of incorrect coding;
• 40 percent were denied because the claims did not meet Medicare’s medical necessity criteria;
• Eight percent were denied for the reason, “no/insufficient documentation” (meaning the RAC requested the information but the entity did not respond timely or completely), and
• 17 percent were denied for “other” reasons, including that claims were paid based on outdated fee schedules, duplicate claims, and the like.41

Medicare providers and suppliers can expect to see these types of denials in the RAC permanent program as well.

Medicare providers and suppliers are advised to adopt and implement compliance policies and procedures to address these and other areas of Medicare scrutiny now, before the RACs begin nationwide auditing.

Appeal of RAC Denials—the Medicare Appeals Process

If a Medicare provider or supplier receives a claim denial, or a finding of overpayment is made as a result of a RAC review, this denial will be subject to the uniform Medicare Part A and Part B appeals process. The regulations governing this process are contained at 42 C.F.R. § 405.900 et seq.42

Stage 1: Redetermination

The first level in the appeals process is redetermination. Providers must submit redetermination requests in writing within 120 calendar days of receiving notice of initial determination. There is no amount in controversy requirement.43

Stage 2: Reconsideration

Providers dissatisfied with a redetermination decision may file a request for reconsideration to be conducted by a QIC. This second level of appeal must be filed within 180 calendar days of receiving notice of the redetermination decision. There also is no amount in controversy requirement for this stage of appeal.44

Of particular note, providers must submit a full and early presentation of evidence in the reconsideration stage. When filing a reconsideration request, a provider must present evidence and allegations related to the dispute and explain the reasons for the disagreement with the initial determination and redetermination. Absent good cause, failure of a provider to submit evidence prior to the issuance of the notice of reconsideration precludes subsequent consideration of the evidence. Accordingly, providers may not be permitted to introduce evidence in later stages of the appeals process if such evidence was not presented at the reconsideration stage.45

Stage 3: Administrative Law Judge Hearing

The third level of appeal is the Administrative Law Judge (“ALJ”) hearing. A provider dissatisfied with a reconsideration decision may request an ALJ hearing. The request must be filed within 60 days following receipt of the QIC’s reconsideration decision. In addition, if the QIC fails to render its reconsideration decision within the required timeframe, a provider may request an ALJ hearing.46 The request must meet an amount in controversy requirement for this stage of appeal.47 ALJ hearings can be conducted by video-teleconference (“VTC”), telephone or in person. The regulations require the hearing to be conducted by VTC if the technology is available; however, the ALJ may offer to conduct a hearing by telephone upon request by one of the parties or if the

continued on page 8
RAC to the Future: What Can Medicare Providers and Suppliers Expect...

record suggests that a telephone hearing would be more convenient for one or more of the parties. In addition, if VTC is unavailable, or in other “special or extraordinary circumstances,” the ALJ may hold an in-person hearing.58

Stage 4: Medicare Appeals Council Review

The fourth level of appeal is the Medicare Appeals Council (“MAC”) Review. The MAC is within the Departmental Appeals Board of HHS. A MAC Review request must be filed within 60 days following receipt of the ALJ’s decision. A provider also may request MAC review of the claim the ALJ fails to render its decision within the required timeframe.49 Among other requirements, a request for MAC Review must identify and explain the parts of the ALJ action with which the party disagrees. Unless the request is from an unrepresented beneficiary, the MAC will limit its review to the issues raised in the written request for review.50

Stage 5: Federal District Court

The final step in the appeals process is judicial review in federal district court. A request for review in district court must be filed within 60 days of receipt of the MAC's decision. In addition, if the MAC fails to render its decision within the required timeframe, a provider may request federal district court review of the claim.51 The request must meet an amount in controversy requirement of $1,180.52 In a federal district court action, the findings of fact by the Secretary of HHS are deemed conclusive unless contradicted by substantial evidence.53

In addition, in certain situations, Medicare providers, suppliers or beneficiaries may obtain expedited access to judicial review (“EAJR”). Pursuant to 42 C.F.R. § 405.990, a Medicare provider, supplier, or beneficiary may be granted EAJR in lieu of an ALJ hearing or MAC review if a review entity (comprised of up to three reviewers who are ALJs or members of the Department Appeals Board) certifies that the MAC does not have authority to decide a question of law or regulation and no material facts are in dispute. If there is more than one party to the reconsideration, ALJ hearing, or MAC review, each must concur in writing with the request for EAJR. The review entity has 60 days to issue a certification for EAJR or to deny the request. Notably, a review entity’s decision is not subject to review by the Secretary of HHS. This regulation also states that if the review entity fails to act within the required time frame, the requester is permitted to bring a civil action in federal district court within 60 days of the end of the time period.54

Strategies for Defending Medicare Audits

Medicare providers and suppliers subject to RAC or other Medicare audits and claim denials should understand that many strategies exist that can be employed successfully in the appeals process to effectuate meaningful results.55 These strategies involve effectively advocating the merits of the underlying services as well as employing legal defenses.

Advocating the Merits

When advocating the merits of a claim, it is useful to draft a position paper outlining the factual and legal arguments in support of payment for a disputed claim. Additionally, in many cases it is advantageous to engage the services of a qualified expert, particularly when an audit or claim denial involves issues of medical necessity. Other strategies that can prove successful include the use of medical summaries, illustrations, and color-coded charts or graphs depicting the claims at issue that are user-friendly for the decision maker.

Audit Defenses

In addition to advocating the merits of a claim through various techniques, certain legal defenses are available. Defenses that have proven valuable for providers and suppliers challenging Medicare audit determinations include: invoking the treating physician rule, arguing the “Waiver of Liability” defense, arguing the provider is without fault, challenging the timeliness of the audit and/or claim denial, and challenging the statistical extrapolation (if one was involved).

Treating Physician Rule

It may be appropriate in many audit settings to assert the “treating physician rule.” The treating physician rule involves the legal principle that the treating physician, who has examined the patient and is most familiar with the patient’s condition, is in the best position to make medical necessity determinations. The treating physician rule, as adopted by some courts, reflects that the treating physician’s determination that a service is medically necessary is binding unless contradicted by substantial evidence, and is entitled to some extra weight, even if contradicted by substantial evidence, because the treating physician is inherently more familiar with the patient’s medical condition.56 As noted above, RACs utilize the services of registered nurses to conduct reviews regarding medical necessity. Providers and suppliers should reference the treating physician rule to demonstrate that the treating physician’s judgment as to the medical necessity of the services provided should prevail against substantial contradictory evidence.

Waiver of Liability

Pursuant to the Medicare “waiver of liability” defense, providers and suppliers may be entitled to payment for claims deemed not reasonable and necessary by CMS or its contractors during an audit. The statutory authority for waiver of liability is set forth in Section 1879(a) of the Social Security Act.57 Under waiver of liability, even if a service is
determined to be not reasonable and necessary, payment may be rendered if the provider or supplier did not know, and could not reasonably have been expected to know, that payment would not be made. The relevant inquiry focuses on whether the provider "knew or could have reasonably been expected to know" payment would not be made. Therefore when challenging an audit determination, providers and suppliers must have access to all relevant Carrier or Intermediary communications with the provider and supplier community and with the particular provider or supplier. For example, in situations where a provider or supplier receives an overpayment demand, if the provider or supplier had been previously subject to claim reviews or a Medicare audit where similar claims were approved, then these decisions can be used to demonstrate that the provider or supplier did not have reason to know payment would not be made in a same or similar case. Waiver of liability generally only applies to determinations that a service was not medically necessary.

**Provider without Fault**

Additionally, the "provider without fault" defense may be employed in the case of post-payment review denials. The Medicare provider without fault provisions, Section 1870 of the Social Security Act, state that payment will be made to a provider if the provider was without "fault" with regard to billing for and accepting payment for disputed services.58

As a general rule, a provider or supplier will be considered without fault if it exercised reasonable care in billing for and accepting payment, i.e., the provider complied with all pertinent regulations, made full disclosure of all material facts, and on the basis of the information available, had a reasonable basis for assuming the payment was correct.59

"Fault," for purposes of the provider without fault provision, is defined as follows:

(a) An incorrect statement made by the individual which he knew or should have known to be incorrect; or
(b) Failure to furnish information which he knew or should have known to be material; or
(c) With respect to the overpaid individual only, acceptance of a payment, which he knew or could have been expected to know, was incorrect.60

In addition to the communications Medicare contractors disseminate to the provider and supplier community generally, in some cases, a Medicare contractor may have had communications with a specific provider or supplier (or the provider or supplier could seek out such communications) that prove valuable in crafting a Provider without Fault argument. For example, to the extent a provider has had a specific favorable conversation with a Medicare contractor regarding a specific matter, legal counsel should advise the provider to maintain written records documenting the conversation. This documentation could be used to demonstrate that the provider could not have been expected to know payment would not be made for a claim.

In addition, providers and suppliers will be deemed to be without fault in the absence of evidence to the contrary, if the overpayment was discovered subsequent to the third calendar year after the year of payment.61 As noted herein, under the RAC demonstration program, RACs were permitted to reopen claims up to four years following the date of initial payment.62 Many providers and suppliers were successful arguing that this four year look-back period violated the "provider without fault" provisions of the Social Security Act.

**Reopening Regulations**

Medicare regulations recognize that, in the interest of equity, Medicare providers and suppliers must be able to rely on coverage determinations. Thus, Medicare regulations place restrictions on the permissible timeframe for reopening initial determinations. Pursuant to 42 C.F.R. § 405.980 (b), a contractor may reopen and revise its initial determination:

1. Within 1 year from the date of the initial determination for any reason;
2. Within 4 years of the date of the initial determination for good cause as defined in Sec. 405.986.
3. At any time if there exists reliable evidence as defined in Sec. 405.902 that the initial determination was procured by fraud or similar fault as defined in Sec. 405.902.

4. At any time if the initial determination is unfavorable, in whole or in part, to the party thereto, but only for the purpose of correcting a clerical error on which that determination was based.

Pursuant to 42 C.F.R. § 405.986, "good cause" may be established when:

1. There is new and material evidence that—
   i. Was not available or known at the time of the determination or decision; and
   ii. May result in a different conclusion; or
2. The evidence that was considered in making the determination or decision clearly shows on its face that an obvious error was made at the time of the determination or decision.63

Further, according to the Medicare Financial Management Manual, "If an overpayment is determined based on a reopening outside of the above parameters, the FI or carrier will not recover the overpayment.64

Although providers and suppliers have experienced success challenging reopenings under these regulations during the RAC demonstration, providers and suppliers should be aware that a recent MAC decision has found that the ALJs and MAC lack jurisdiction to consider challenges to reopenings under the Medicare appeals process.65

continued on page 10
Certain ALJs have taken the position that as a result of this MAC decision, they may no longer consider the argument that a reopening was conducted in violation of the above-cited regulations. Nonetheless, an argument exists that even if a provider or supplier may not challenge the Medicare contractor’s authority to “reopen” a claim, they may still be able to challenge the Carrier’s or Intermediary’s decision to “revise” that claim following the reopening.

Challenges to Statistics

In many post-payment audits, CMS will audit a small sample of a provider’s or supplier’s records, and if it finds an overpayment, CMS will extrapolate the overpayment to the provider’s or supplier’s entire patient population. The MMA sets limits regarding when statistical extrapolation may be used, and the Medicare manuals establish guidelines for CMS to follow when performing an audit based upon a statistical sample. If an extrapolation is flawed, it may be successfully challenged, bringing the total dollars at issue to the “actual” alleged overpayment, and not the extrapolated alleged overpayment.

Pursuant to Section 935 of the MMA:

(1) LIMITATION ON USE OF EXTRAPOLATION. –A Medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise, unless the Secretary determines that –

(A) there is a sustained or high level of payment error; or

(B) documented educational intervention has failed to correct the payment error. 66

CMS guidelines for statistical extrapolations are set forth in the Medicare Program Integrity Manual (CMS Pub. 100-08, Chapter 3, §§ 3.10.1 through 3.10.11.2). Notably, the RACs are authorized to use extrapolation, provided that they adhere to the above-referenced statute and Manual provisions. 67 CMS and its contractors must follow these guidelines in conducting statistical extrapolations. If they fail to do so, a Medicare provider may have success challenging the validity of the extrapolation.

In order to best challenge a statistical sample and extrapolation, many providers and suppliers have found it useful to engage the services of a qualified statistician expert witness to testify regarding the sample chosen and statistical extrapolation performed. For example, if CMS were to conduct an audit and find an “actual” overpayment of $25,000, and then extrapolate this amount to a figure of $1.5 million, the use of a qualified statistician expert witness could assist the provider to successfully challenge this suspect statistical extrapolation. An ALJ could find the methodology of the statistical extrapolation to be in error and overturn the extrapolation.

Conclusion

Medicare providers and suppliers should be ready for increased Medicare auditing activity as the RAC program expands nationwide. They should make efforts now to evaluate their compliance with Medicare policies. Should a provider or supplier be subject to a RAC or other Medicare audit, effective strategies are available that can be successfully employed in the appeals process to defend Medicare audits.

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Letters to the Editor...
Endnotes

1. RACs are an additional means for CMS to identify overpayments and underpayments. Prior to the establishment of the RAC program, Carriers, Fiscal Intermediaries, Program Safeguard Contractors, and in some cases the Office of Inspector General ("OIG") and law enforcement entities had responsibility to identify potential overpayments. All of these options remained available to CMS to identify overpayments during the RAC demonstration program and will remain available during the permanent program. However, to avoid duplication, RACs are prohibited from reviewing claims subject to post-payment medical review and/or fraud investigation by one of the other entities listed above. See "Statement of Work for the Recovery Audit Contractors Participating in the Demonstration" at p. 5 and "Statement of Work for the Recovery Audit Contractor Program," at p. 10 available at https://www.fbo.gov/index?s=opportunity&mode=form&id=1889ce7b8672a9e2c1cbe5a07d9cdeb&tab=core&cvie=1.


4. Id., at p. 15.


7. The most recently published RAC Expansion Schedule is available from the CMS website at http://www.cms.hhs.gov/rac/, by selecting "RAC Expansion Schedule."

8. Id. Note that the RAC Expansion Schedule indicates the four RAC regions, labeled A, B, C and D.

9. In early November 2008, two companies that unsuccessfully bid for contracts under the permanent RAC program, PRG Schultz (the RAC for California during the RAC demonstration program) and Viant, Inc., filed formal protests of the RAC contract awards with the Government Accountability Office ("GAO") under the Competition and Contracting Act of 1984 ("CICA"). As a result of these protests, CMS was mandated to issue an automatic stay of all contract work of the RACs, pending a decision by the GAO. Under CICA, the GAO must issue its decision within 100 days. Therefore, the RAC contracts, and all work performed thereunder, may be in abeyance until February 2009. See http://www.cms.hhs.gov/RAC (last accessed November 11, 2008) and http://www.gao.gov.

10. 2008 RAC Fact Sheet, available at http://www.cms.hhs.gov/apps/media/press/fact_sheet.asp?Count=52922&intNumPerPage=1&checkDate=&checkKey=&srchOpt=0&srchData=&keyWordType=All&chkNewsType=6&kintPage=&showAll=1&kYear=2008&kDesc=&kOrd=er date


12. Many providers who have experienced traditional Carriers or intermediary audits have seen that typical bases for denials of claims include denials based upon the medical necessity of the services provided or lack of documentation.


14. Id.


16. Id.


18. Id. As will be discussed in greater detail later in this article, Medicare providers and suppliers subject to RAC review during the demonstration complained that the RACs failed to abide by Medicare policies in conducting claim reviews in multiple situations.


23. The contingency fee for Region A is 12.45 percent, Region B is 12.50 percent, Region C is 9 percent and Region D is 9.49 percent. https://www.fbo.gov/index?s=opportunity&mode=form&id=5c8c74db022934b57a94d7474d640a&checkDate=&checkKey=&srchOpt=0&srchData=&keyWordType=All&chkNewsType=6&kintPage=&showAll=1&kYear=2008&kDesc=&kOrd=er date


29. Medicare’s guidance regarding inpatient hospital admissions is set forth in the CMS Internet Only Publication (IOP-S2), Medicare Benefit Policy Manual, Chapter I, Section 10. Notably, InterQual Level of Care criteria are published by a private company, McKesson Health Solutions, LLC, not by Medicare, and are not formally adopted or even referenced by Medicare by way of published guidance documents. InterQual Level of Care criteria are more specific than Medicare’s published guidance regarding inpatient hospital admissions. As a result, when the RACs based certain inpatient hospital denials on InterQual Level of Care criteria, not on the guidance set forth in the Medicare Benefit Policy Manual, the CHA raised complaints that hospitals were being held to more strin- continued on page 12
RAC to the Future: What Can Medicare Providers and Suppliers Expect...

continued from page 11

<table>
<thead>
<tr>
<th>Type of Provider</th>
<th>Description of Item or Service</th>
<th>Amount Collected Less Cases Overturned on Appeal (Million Dollars)</th>
<th>Number of Claims with Overpayments Less Cases Overturned on Appeal</th>
<th>Location of Problem</th>
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<td>Surgical procedures in wrong setting (medically unnecessary)</td>
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<td>NY</td>
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<td></td>
<td>Excisional debridement (incorrectly coded)</td>
<td>66.8</td>
<td>6,092</td>
<td>NY, FL, CA</td>
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<td></td>
<td>Cardiac defibrillator implant in wrong setting (medically unnecessary)</td>
<td>04.7</td>
<td>2,216</td>
<td>FL</td>
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<tr>
<td></td>
<td>Treatment for heart failure and shock in wrong setting (medically unnecessary)</td>
<td>33.1</td>
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<td></td>
<td>Respiratory system diagnoses with ventilator support (incorrectly coded)</td>
<td>31.6</td>
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<td>Inpatient rehabilitation Facility</td>
<td>Services following joint replacement surgery (medically unnecessary)</td>
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<td>558</td>
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<td>Speech-language pathology services (medically unnecessary)</td>
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<td>Durable Medical Equipment</td>
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<td>38,357</td>
<td>NY, FL, CA</td>
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</table>

30 Section 935 of the MMA requires the following:

In the case of a provider of services or supplier that is determined to have received an overpayment under this title and that seeks a reconsideration by a qualified independent contractor on such determination under section 1869(b)(1), the Secretary may not take any action (or authorize any other person, including any Medicare contractor, as defined in subparagraph (C)) to recoup the overpayment until the date the decision on the reconsideration has been rendered. If the provisions of section 1869(b)(1) (providing for such a reconsideration by a qualified independent contractor) are not in effect, in applying the previous sentence any reference to such a reconsideration shall be treated as a reference to a redetermination by the fiscal intermediary or carrier involved.


31


38 Providers who are not prepared for the potential large volume of record requests could find themselves facing denials for failure to timely respond. Providers who fail to follow the required response procedures could lose their appeal rights with respect to these denials.


Over the course of the three-year demonstration, the top services with overpayments included the following:


42 The Medicare appeals process described herein was effective May 1, 2005 for claim denials and unfavorable audit determinations issued by Medicare and its contractors. This appeals process was available for claim denials arising in the RAC demonstration program, and remains available to providers and suppliers subject to claim denials in the RAC permanent program.


50 42 C.F.R. § 405.1100 et seq. (2007).


59 Medicare Financial Management Manual (CMS Pub. 100-06), Chapter 3, § 70.3.


63 See also Medicare Claims Processing Manual (CMS-Pub-100-04), Chapter 29, § 90 and Medicare Financial Management Manual (CMS-Pub-100-06), Chapter 3, § 80.1

64 Medicare Financial Management Manual (CMS-Pub-100-06), Chapter 3, § 80.1.


Doctors as Hired Hands

That most lay people believe that doctors are hired by hospitals to take care of people can be substantiated to some degree by the appearance in hospital lobbies of notices informing the reader that most if not all of the physicians taking care of patients are not employees (and hence, theoretically, their negligence is not the hospital’s fault.) If nothing else, hospitals may be able to reduce their budgets for risk management signs in future. The increase in physician employment by hospitals, reported occasionally in the popular press, presents issues for medical staff organizations, their hospitals, their counsel, and the hospitals’ counsel.

Physicians in some areas and attorneys peripherally involved in healthcare matters may be surprised to learn of the trend, presuming that states’ laws prohibit corporations from employing physicians. In general terms, the corporate practice of medicine ban prevents a corporate entity from profiting from the practice of medicine, due to the conflict of duties to patients as opposed to shareholders. Most states outlaw the corporate practice of medicine for the public good. As noted in a recent Minnesota decision,

(a)mong the public policy considerations in applying the corporate practice of medicine doctrine are “concerns raised by the specter of lay control over professional judgment, commercial exploitation of health care practice, and the possibility that a health care practitioner’s loyalty to a patient and an employer will be in conflict.” The Granger court emphasized these public policy considerations when it stated, “[w]hat the law intends is that the patient shall be the patient of the licensed physician, not of a corporation or layman. The obligations and duties of the physician demand no less. There is no place for a middleman.”

However, exceptions developed over time, through hospital industry lobbying in the legislatures and as parties and amici curiae in the courts have seriously weakened the corporate practice ban. “A typical exception allows hospitals to employ physicians because hospitals are formed for the specific purpose of treating patients and providing health care services and are themselves licensed entities.” The reason for this major exception lay in the fact that hospital is not a hospital without a medical staff making the decisions about quality care. As the court in Berlin v. Sarah Bush Lincoln Medical Center held, “We find the public policy concerns which support the corporate practice doctrine inapplicable to a licensed hospital in the modern health care industry. The concern for lay control over professional judgment is alleviated in a licensed hospital, where generally a separate professional medical staff is responsible for the quality of medical services rendered in the facility.

Given the extraordinary economic market in which hospitals operate, where revenue sources are third party insurers who pay for services the hospitals provide to a patient ‘customer’, the concerns the labor movement historically raised about the company doctor and the medical profession’s ethic of patient over profit loom over the hospital-owned-and-operated physician.

It should be noted that these issues occur often in the absence of hospital and medical staff collaboration, and often, without notice to, much less inclusion of, the medical staff organization. Issues presented in this article are followed by sample medical staff bylaws provisions to resolve issues proactively.

Medical Staff Organization Issues

Physician employment and other close physician-hospital economic relationships affect the medical staff organization, which traditionally is comprised of physicians with no economic relationship to the hospital. Medical staffs have a duty to self-governing. Self-governance becomes more challenging when the hospital controls medical staff members financially.

Hospitals Denying Medical Staff Membership to Competitors

Medical staff membership is fundamental to the medical staff organization. Hospitals using economics as the sole criterion in denying not only medical staff membership but also clinical privileges by denying applicants who have an economic interest that could compete with those of the hospitals disrupts the medical staff organization and interferes with patient care, referral patterns and patient access. In a recent example, Baptist Health in Arkansas implemented a unilaterally-adopted economic conflict of interest policy barring physicians with direct or indirect competing financial interests. The policy was deployed to deny privileges to an obstetrician whose surgeon husband had a share in a competing specialty hospital, giving rise to litigation that subsequently settled.

Similar action by the same system remains the subject of litigation in Baptist Health v. Murphy. The physicians, cardiologists who were partners in Little Rock...
Cardiology Clinic, P.D., were not permitted to continue their medical staff membership and clinical privileges by Baptist on the grounds that they held minor indirect interests in Arkansas Heart Hospital, in which Little Rock Cardiology Clinic, P.D. had a 14.5% interest, and also held even smaller (less than 3%) interests themselves as individuals. The physicians sued. On appeal, the Arkansas court supported the argument that Baptist was deliberately and tortiously interfering with professional relationships, writing “Baptist’s economic interest, as advanced by the policy, is substantially outweighed by the irreparable harm arising out of the disruption of the physicians’ relationships with their patients and with referring physicians, and with the physicians’ ability to provide proper health care to their patients, to the detriment of the doctor-patient relationship.” The case provides clear precedent for prioritizing the physician-patient relationship above the for-profit interests of non-profit hospitals, which may come into play in other cases around the nation as hospitals continue to emphasize revenue enhancement.

Medical staffs can obviate such tactics by removing from medical staff bylaws, rules and regulations any obligation for members and privileges holders to be bound by hospital policies. Self-governing medical staffs should be governed through medical staff-adopted governance documents rather than unilaterally imposed policy.

Medical staffs can obtain more specific protection with more specific bylaws amendments. For example, the Massachusetts Medical Society Model Medical Staff Bylaws provides:

“Economic credentialing is not used in medical staff membership or privileging decisions. Medical staff membership, participation in medical staff activities, clinical privileges, access to resources or patients will not be restricted or terminated or denied because the member’s financial or professional interests or plans compete with those of the hospital or system.”

Access to medical staff membership for a physician translates directly as access to hospital care for patients of that physician.

**Hospitals Denying Membership and Privileges to Non-Employees/Non-Contractors**

**Limiting Privileges by Contract**

Physicians and hospitals have engaged in exclusive contracts and consequently, in litigation over exclusive contracts, throughout the history of health law. Generally, the “exclusive” in exclusive contract applies to the privileges awarded, although in some circumstances the exclusivity attempted is that over access to resources instead. (See subsection 4, below)

The medical staff plays an important role in the decision to limit privileges by an exclusive due to the effect on quality that such limitation creates. Specifically, under Joint Commission standard MS Element of Performance 2 for JC standard LD 3.50, “Clinical leaders and medical staff have an opportunity to provide advice about the sources of clinical services that are to be provided through contractual agreement (sic).” AMA Policy further supports direct involvement of the medical staff, stating:

“The AMA believes that the medical staff should review and make recommendations to the governing body related to exclusive contract arrangements, prior to any decision being made, in the following situations: (1) the decision to execute an exclusive contract in a previously open department or service; (2) the decision to renew or otherwise modify an exclusive contract in a particular department or service; (3) the decision to terminate an exclusive contract in a particular department or service; and (4) prior to termination of the contract the medical staff should hold a hearing, as defined by the medical staff and hospital to permit interested parties to express their views on the hospital’s proposed action.”

Consistent with Joint Commission standards and AMA policy, the Medical Association of Georgia Model Medical Staff Bylaws provides a process for medical staff quality review of such contracts:

**Contract Privileges**

Medical staff members may provide services under contract with the hospital subject to the following conditions.

A member providing services pursuant to a hospital contract, exclusive or otherwise, must qualify for and be granted clinical privileges and satisfy the same medical staff membership qualifications in the same manner, and must fulfill all of the obligations of the appropriate membership category, as any other applicant or medical staff member.

Prior to the issuing of any new or renewed exclusive contract, the medical executive committee must review the quality of care ramifications of continued exclusivity or of imposition of exclusivity on any department/service or privileges and make a recommendation to the Board as to whether exclusivity is appropriate. (footnote omitted.) The medical executive committee shall collect information from the members of medical specialties that would be affected, from the hospital administration, and from other interested parties, in order to make an informed recommendation; (footnote omitted.) however, the actual terms of the contract and any financial information related to the contract, including but not limited to the remuneration to be paid to medical staff members under contract, are not relevant and therefore shall neither be disclosed to the medical executive.
Physician Employment and Alternative Practice Strategies: Avoiding...

continued from page 15

committee nor discussed as part of this exclusive contracting evaluation process. (footnote omitted.)

No privileges will be terminated by operation of any hospital contract for reasons pertaining to the quality of care provided by the medical staff member without the same rights of hearing and appeal as are available to all members of the medical staff. (footnote omitted.)

Limiting Privileges by Specialty

Hospitalists, physicians whose practice is limited to inpatient care, are increasing in number, range and impact on the medical staff organization. Physicians whose practices combine outpatient and inpatient care may find the combination no longer workable, or may be forced out of their hospital practices, enabled or required by the hospitals’ relationships with hospitalists. Medical staff organizations have to address the effect of hospitalists and other employees/contractees within their organizational structure. In order to prevent access to privileges from being restricted to hospitalists or any certain specialty, the Massachusetts Medical Society Model Medical Staff Bylaws provides:

“Admitting privileges are not exclusive to hospital employees, members with hospital contracts, or to any single specialty.”

Limiting Privileges by Denying Resources

Medical staffs and hospitals continue to engage over limiting the use of privileges by limiting the privileges holders’ access to resources as a means to avoid hearing and appeals rights, despite the fact that privileges are in fact adversely affected. While this has routinely been accomplished via contract, hospitals have attempted to limit privileges without the actual expense of monetary consideration by limiting access to resources needed to actually exercise privileges granted. Such schemes, referred to as “sham privileges,” have been the subject of litigation. Illinois hospital licensing law blocks denial of resources to those granted privileges by defining “Privilege” as “permission to provide medical or other patient care services and permission to use hospital resources, including equipment, facilities and personnel that are necessary to effectively provide medical or other patient care services. This definition shall not be construed to require a hospital to acquire additional equipment, facilities, or personnel to accommodate the granting of privileges.” A recent addition to Joint Commission standards calls for resources to be allocated in connection with the privileging process. To assure that the assessment is made in the course of the medical staff’s privileging process, the Medical Association of Georgia Model Medical Staff Bylaws provide:

“For every privileges request, the department’s recommendation for clinical privileges affirms that hospital has the ability at the time or will have at a specified time to provide adequate facilities and supportive services for the applicant.”

Protecting Medical Staff Self Governance

To meet its professional obligation to govern itself, members of the medical staff select and remove its own leadership so that it can best account to the board for the quality of patient care. Control of the leadership by the hospital affects the ability of the medical staff organization to maintain its professionalism. Given this threat, medical staff organizations need to adopt conflict of interest rules to protect its leadership selection process. The California Medical Association Model Medical Staff Bylaws calls for disclosure of hospital business relationships potential conflicts, allowing voting members to make informed choices:

“All nominees for election or appointment to medical staff offices, department chairships, or the medical executive committee shall, at least [20] days prior to the date of election or appointment, disclose in writing to the medical executive committee those personal, professional, or financial affiliations or relationships of which they are reasonably aware, including contractual, employment or other relationships with the hospital, which could foreseeably result in a conflict of interest with their activities or responsibilities on behalf of the medical staff.”

Note that the sample would not bar employed or contractual relationships with the hospital. Nor would such a bar be logical given increasingly spreading hospital employment. To provide cover to the members with employment or other close financial relationships, the Medical Association of Georgia Model Medical Staff Bylaws provides:

“Medical staff members cannot be fired from hospital employment or lose their hospital contracts as a result of good-faith participation in medical staff activities or leadership roles or otherwise fulfilling duties of medical staff membership.”

Conflicts of Interest in Peer Review

Clinical Basis for Peer Review

Protecting peer review, the main function of the medical staff organization, from undue influence by hospital fiscal demands is as important as protecting the organization’s leadership and membership structures. Recent changes to Joint Commission standards refocus its customer hospitals on the necessity of clinical standards for peer review by plac-
ing the responsibility for the standards on the medical staff organization. Specifically, under its requirements for granting initial privileges, “Focus Professional Practice Evaluation” (known as “FPPE”), “the organized medical staff develops criteria to be used for evaluation the performance of practitioners when issues affecting the provision of safe, high quality patient care are identified.”

Similarly, under the Joint Commission standards for maintaining privileges, “Ongoing Professional Practice Evaluation” (known as “OPPE”), “the process for the ongoing professional practice evaluation includes the following: the type of data to be collected is determined by individual departments and approved by the organized medical staff.”

Medical staffs need to be vigilant to avoid having standards thrust upon them by corporate headquarters. The Massachusetts Medical Society Model Medical Staff Bylaws provides for the medical staff through its departments and sections to set its clinical standards, as follows:

Each department and section establishes and updates standards of care to be met by each professional holding privileges, based on generally accepted clinical guidelines and practices, (footnote omitted) including criteria for measuring members’ compliance with the standards set (footnote omitted) and triggers for corrective action. (footnote omitted) Standards and any updates to the standards are reviewed and adopted by the medical executive committee. Standards are available at all times to all members. (footnote omitted)

The penchant for collecting patient satisfaction survey responses to be used to determine who gets to practice medicine in hospitals challenges the clinical basis for peer review in the standards, and may not even be preferred by patients in the final analysis. At a minimum, patient satisfaction survey responses should not be calculated into any peer review decision without review and action by peers. Raw marketing data should not be confused with peer review. The Massachusetts Medical Society Model Medical Staff Bylaws address the problem as follows:

“No patient survey or customer satisfaction information is placed in credentials files or used in credentialing unless it has been reviewed by the appropriate committee or department and determined to serve to document the member’s qualifications.”

Processes for Impartial Review

Biased peer review is a long-standing concern for medical staff organizations and their leaders, and for hospitals, due in part to the liability exposure it yields. Federal immunity is contingent on impartial peer review, established by compliance with the federal Health Care Quality Improvement Act or by otherwise establishing that the peer review has been fair.

Disclosure

The financial relationship the member has with the hospital is one facet of bias that must also be disclosed and considered. The Massachusetts Medical Society Model Medical Staff Bylaws calls for those conducting medical staff peer review to disclose “Hospital contracts, employment, lease, ownership interest, joint venture, or other financial relationship with the hospital or hospital system or any management company operating the hospital…”

Transparency

Disclosure helps to achieve transparency but will not resolve problems if only those with a financial relationship with the hospital are permitted to serve as peer reviewers. Occurrence has risen to the level that the issue has been addressed by the American Medical Association, which adopted this policy statement: “Our AMA encourages peer review of the performance of hospital medical staff physicians, which is objective and supervised by physicians. Membership on peer review committees and hearing panels should be open to all physicians on the medical staff and should not be restricted to those physicians who have an exclusive contract with the hospital, salaried physicians, or those on the faculty.”

External Review

One means of promoting impartiality is to obtain professional review from a source outside the medical staff. The Rationale section explaining Joint Commission Standard MS.4.30 states:

“The focused evaluation process is defined by the organized medical staff. The time period of the evaluation can be extended, and/or a different type of evaluation process assigned. Information for focused professional practice evaluation may include chart review, monitoring clinical practice patterns, simulation, proctoring, external peer review, and discussion with other individuals involved in the care of each patient …”

To implement this option as necessary, but under clear parameters so that peer review is not outsourced as a matter of course, but is nonetheless available to promote partiality, the Medical Association of Georgia Model Medical Staff Bylaws provides:

External peer review will take place as part of focused review, investigation, application processing, or at any other time only under the following circumstances, if and only if deemed appropriate by the relevant medical staff department, the medical executive committee or the board:

- Vague or conflicting recommendations from committee or department review(s) where conclusions from this review could directly and adversely affect an individual’s membership or privileges.

continued on page 18
• Lack of internal expertise, in that no one on the medical staff has adequate expertise in the clinical procedure or area under review.
• When the medical staff needs an expert witness for a fair hearing, for evaluation of a credentials file or for assistance in developing a benchmark for quality monitoring.
• To promote impartiality in peer review.
• A subject matter expert or investigator can request the hospital or medical staff to obtain external peer review.14

It is not possible to overemphasize that external review informs but does not replace peer review to prevent the taint of opinion-shopping that has marked the expert witness market while preserving the availability of impartial review sources.

Conclusion

At a minimum, hospital financial control of physicians must be offset by basic precautions to assure patient care is not suborned to profit. For each of the challenges briefly described above, bolstering the medical staff organization offers the solution. Making the most of existing state and federal statutory immunities, medical staff organizations can carry out impartial peer review by updating processes to address the economic relationships between members and hospitals. Well-drafted medical staff bylaws can cure company doctor syndrome.

A frequent speaker on medical staff legal issues, Ms. Snelson has participated in programs sponsored by the American Medical Association and various national specialty societies and state medical associations, the American Health Lawyers Association, the American Bar Association, and other organizations. After eight years at the California Medical Association, where her responsibilities included oversight of the consolidated Joint Commission-CMA hospital survey process, she returned home to the Midwest and resumed private practice. Ms. Snelson is a past president of the American Society of Medical Association Counsel.

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Endnotes

3 Isles Wellness, Inc., n/k/a Minneapolis Wellness, Inc., et al., Appellants, vs. Progressive Northern Insurance Co., Supreme Court Of Minnesota, LEXIS 849 (December 7, 2006)
4 Granger, 190 Minn. at 27, 250 N.W. at 723; see In re Otemmes, 181 Minn. 254, 257, 232 N.W. 318, 319 (1930) (stating that “neither a corporation nor a layman not admitted to practice can practice law nor indirectly practice law by hiring a licensed attorney to practice law for others for the benefit or profit of such hirer.”)
8 Joint Commission standards call upon hospitals to collaborate with self-governing medical staffs. Element of Performance 1 for Joint Commission standard MS 1.10 states: “The organized medical staff is self-governing as referenced in the bullets defining self-governance on page MS-8,” which bullet provides: “Self-governance of the organized medical staff includes the following and is located in the medical staff’s bylaws:
• Initiating, developing and approving medical staff bylaws and rules and regulations
• Approving or disapproving amendments to the medical staff bylaws and rules and regulations
• Selecting and removing medical staff officers
• Determining the mechanism for establishing and enforcing criteria for delegating oversight responsibilities to practitioners with independent privileges
• Determining the mechanism for establishing and maintaining patient care standards and credentialing and delineation of clinical privileges
• Engaging in performance improvement activities.”

JOINT COMMISSION ON THE ACCREDITATION OF HEALTHCARE ORGANIZATIONS, COMPREHENSIVE ACCREDITATION MANUAL FOR HOSPITALS: THE OFFICIAL HANDBOOK (2008). Accreditation by The Joint Commission is more than voluntary recognition, however, as it is recognized in most states as certification for Medicare participation, under 42 U.S.C.§1395eb (1994).

According to AMA’s Principles for Strengthening the Physician-Hospital Relationship, “The organized medical staff, a self-governing organization of professionals, possessing special expertise, knowledge and training, discharges certain inherent professional responsibilities by virtue of its authority to regulate the professional practice and standards of its members and assumes primary responsibility for many functions, including but not limited to: the determination of organized medical staff membership; performance of credentialing, privileging and other peer...

Statutory and regulatory requirements for medical staff self-governance include California’s medical staff self-governance statute, which provides:

(a) The medical staff’s right of self-governance shall include, but not be limited to, all of the following:

(1) Establishing, in medical staff bylaws, rules, or regulations, criteria and standards, consistent with Article 11 (commencing with Section 800) of Chapter 1 of Division 2, for medical staff membership and privileges, and enforcing those criteria and standards.

(2) Establishing, in medical staff bylaws, rules, or regulations, clinical criteria and standards to oversee and manage quality assurance, utilization review, and other medical staff activities including, but not limited to, periodic meetings of the medical staff and its committees and departments and review and analysis of patient medical records.

(3) Selecting and removing medical staff officers.

(4) Assessing medical staff dues and utilizing the medical staff dues as appropriate for the purposes of the medical staff.

(5) The ability to retain and be represented by independent legal counsel at the expense of the medical staff.

(6) Initiating, developing, and adopting medical staff bylaws, rules, and regulations, and amendments thereto, subject to the approval of the hospital governing board, which approval shall not be unreasonably withheld.

(b) The medical staff bylaws shall not interfere with the independent rights of the medical staff to do any of the following, but shall set forth the procedures for:

(1) Selecting and removing medical staff officers.

(2) Assessing medical staff dues and utilizing the medical staff dues as appropriate for the purposes of the medical staff.

(3) The ability to retain and be represented by independent legal counsel at the expense of the medical staff.

(c) With respect to any dispute arising under this section, the medical staff and the hospital governing board shall meet and confer in good faith to resolve the dispute. Whenever any person or entity has engaged in or is about to engage in any acts or practices that hinder, restrict, or otherwise obstruct the ability of the medical staff to exercise its rights, obligations, or responsibilities under this section, the superior court of any county, on application of the medical staff, and after determining that reasonable efforts, including reasonable administrative remedies provided in the medical staff bylaws, rules, or regulations, have failed to resolve the dispute, may issue an injunction, writ of mandate, or other appropriate order. Proceedings under this section shall be governed by Chapter 3 (commencing with Section 525) of Title 7 of Part 2 of the Code of Civil Procedure.” CAL. BUS. AND PROF. CODE §2282.5.


10 Baptist Health v. Murphy, No 04-4430, 2006 Ark. LEXIS 58 (Ark. 2006)


13 AMA H-225.985 Medical Staff Review of Quality of Care Issues Prior to Exclusive Contract


15 “Some hospitals are modifying their bylaws to give full privileges only to primary care physicians who admit a certain number of patients.” Will Bylaws’ Clash Change Physicians’ Admitting Privileges?, ACP OBSERVER (The American College of Physicians) April, 2005.


17 See section 1, above.

18 See, Lewisburg Community Hospital v. Alfredson, 805 S.W. 2d 756 (Tenn. 1991).

The Health Law Section has added a new feature to its website: The Widget. The Widget is a box located at the upper right hand corner of the page, connecting you with the latest health law-related news as reported in the ABA Journal. By pulling headlines of stories with health law keywords, the Widget displays updated information on an almost daily basis. Recent headlines have included “When Hospitals Apologize for Errors, Lawsuits Drop,” “Tough Times for Expert Witnesses Sued By Own Clients for Negligence,” and “Worse than Prison: Inmate Medical Care.” Users can access http://www.abanet.org/health/ to browse the latest headlines.
EVERYONE PAYS THE PRICE WHEN HEALTHCARE PROVIDERS WAIVE PATIENTS’ CO-INSURANCE OBLIGATIONS

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Recently, the Comptroller for the State of New York identified eight million dollars in over-payments by the state self-funded health benefit plan to eight large healthcare providers, caused by the providers’ waiver of patient co-insurance obligations.¹ These out-of-pocket costs are the expenses a health plan member is required to pay a provider by his or her health insurance plan—usually in the form of a deductible, co-pay or co-insurance payment. These expenses are meant to give members pause before seeking medical treatment by imposing a small financial cost for each medical encounter in order to prevent over-use of health benefits. Some providers routinely waive the out-of-pocket costs because they can still profit from receiving the insurance company’s payment, and also attract more patients due to the cost savings provided.² But this practice actually frustrates the purpose of these costs and does damage across the entire spectrum of the healthcare delivery system.

There are only a few legal opinions discussing the impact that waiver of patient co-insurance costs has on the private healthcare industry. This is surprising because routine waiver of out-of-pocket costs by providers produces a number of problems, not the least of which is interference with an enrollee’s contractual obligations to make the payments to the providers. Issues of unfair competition also arise when co-insurance payments are waived by some providers, while others abide by the rules — and lose patients in the process. There is also a dearth of authority explaining the financial consequences of this practice for insurance companies, self-funded groups and governmental entities that generally pay the medical claims.

Nonetheless, the economic impact on insurance companies as a result of such waivers is significant. In fact, providers’ waiver of their patients’ out-of-pocket costs results in: (1) inflation of provider billed charges; (2) interference with health plan insurers’ relationships with network providers; and (3) overutilization of medical services and procedures. These consequences lead to higher healthcare costs for everyone, and ultimately damage the delicate financial balance between healthcare service providers, the patients they treat, and those who pay for these medical services.

The Healthcare Payment System

Most private health insurance companies offer two types of coverage—in-network coverage and out-of-network coverage. In-network coverage involves using only those providers who appear in a directory provided by the insurance company. Insurance companies create these networks by contracting with providers of healthcare services to accept certain cost controls, which include: accepting an agreed-upon rate for services; collecting co-payments from patients (generally a nominal amount of $10 to $15 per visit); and obtaining insurance company pre-certification before rendering certain services.

In return for agreeing to these conditions, providers receive direct payment from the insurance company (generally within a set time-period) and a higher volume of patients, or steerage. Steerage occurs because the use of in-network providers is usually less expensive to the member. Generally, a token co-insurance payment is the only financial obligation patients incur in order to receive covered services. Patients also avoid the “red tape” hassles of paying the provider, completing claim forms, and pursuing reimbursement from the insurance company.

Insurance companies also often provide out-of-network coverage for services a member receives from providers with which it does not have a contractual relationship.³ The insurance provided is designed to compensate the insured for the expense of these out-of-network services. There are usually strict limitations on this type of coverage. Generally, the patient must satisfy a financial deductible before any benefits are paid by the insurer. A deductible can be significant, ranging anywhere from $500 to $2,000, before any benefits are paid. The deductible significantly lowers premiums and as the amount of the deductible increases, the premium charged will decrease.

In addition, after the deductible is exhausted, a member is responsible for co-insurance, which is a percentage of the allowable charge, and may be as much as 20 percent to 30 percent of the overall bill. As a result, for $3,000 worth of services received from an out-of-network provider, a patient may owe a $500-$2,000 deductible, plus 20-30 percent of the remaining bill. Because out-of-network services can be quite expensive, patients tend to gravitate to in-network providers, who cost less, or forego unnecessary treatment altogether.

Providers sometimes agree not to collect their patients’ required out-of-pocket payments. When such arrangements are made, the economic disincentives created by these costs controls are removed. In other words, there is no longer a financial incentive to utilize in-network services when the out-of-network provider waives the out-of-pocket costs the members owe. With respect to in-network services, patients may be drawn to a provider because he or she waives the applicable co-payment. Regardless of whether the services received are out-of-network or in-network, however, waiving patient...
co-pays or co-insurance removes the economic disincentives to over-utilizing health and medical services. Thus, patients may obtain healthcare services that are not necessary because the healthcare provider waives their out-of-pocket expenses.

In recent years, as a result of federal legislation, many plans now offer high deductible health plans (“HDHP”). With a HDHP, the enrollee is responsible for a deductible even if he or she receives the services in-network. The plan is usually established in conjunction with a health spending account (“HSA”) funded with pre-tax dollars by the enrollee. These plans generally offer the same coverage, but require greater out-of-pocket costs in the form of a high deductible in exchange for lower premiums. The risk of co-insurance waivers in HSA/HDHP is small because participants bear the entire cost of all healthcare services until their deductible is satisfied. Once the deductible is satisfied, however, the same motivations to waive co-insurance payments will be present. Furthermore, these motivations will always be present if a patient incurs medical claims that exceed the deductible.

Relevant Law Concerning the Economic Impact Of Patient Co-Insurance Waivers

Waiver of Patient Co-Insurance Payments Results In An Overstatement Of Provider Billed Charges

One of the first cases to expose the economic problems caused by waiver of out-of-pocket costs was *Feiler v. New Jersey Dental Assoc.* In Feiler, the New Jersey Dental Association sought to enjoin the plaintiff dentist from continuing to undercut other dentists in his area by waiving out-of-pocket patient costs. The Association claimed it had standing to pursue an injunction on behalf of its members, who were being placed in the untenable position of either similarly waiving coinsurance or watching their practices dwindle. The plaintiff dentist claimed he was entitled to bill his “schedule of charges” to insurance companies for the services he rendered and that he was only waiving the patient’s out-of-pocket obligation if the insurance companies paid him directly.

The Superior Court of New Jersey disagreed with the plaintiff dentist, stating that “a dentist’s statement is untrue that asserts he charges $100 for a procedure if he intends that he will forgive co-payment upon receipt of $80 and if he almost always receives such part payment.” The New Jersey Superior Court further noted this practice not only results in an overstatement of billed charges, but the “dentist’s statement enables its author to achieve an advantage over other dentists by relieving the patient of the burden of his co-payment.” The Court enjoined the dentist to notify the insurance companies and third-party payors that he intended to waive the deductibles and co-payment amounts.

When a provider routinely waives out-of-pocket payments from his patients, it results in overstatements of his billed charges. As the *Feiler* Court noted, if the provider actually considers $80 to be acceptable as payment in full, then the provider’s correct billed charge for the service is $80—not $100.

A number of states and the federal government have taken action against providers who waive patient out-of-pocket cost sharing obligations. Some states have passed statutes to bar the practice. Others characterize it somewhat differently and require that providers collect the co-insurance and deductibles owed by the patient. Some states have issued opinion letters warning providers of the problems caused by this practice. For example, the New York Insurance Department’s General Counsel issued an opinion letter stating that the regular practice of waiving out-of-pocket cost sharing obligations is a fraudulent act under New York’s penal code. Specifically, the Attorney General stated:

A physician who, as a general business practice, waives otherwise applicable co-insurance, co-payments or deductibles, where such waiver would affect the amount the insurer would pay, would be guilty of insurance fraud. For example, if an individual were to be insured under a health insurance policy obligating the insurer to reimburse the insured 80% of the physician’s usual and customary charge for a procedure was $100, the insurer would, in anticipation that the physician would require the patient too pay him or her $20, reimburse the insured $80. If however, the physician were to, as a general business practice, waive the $20 co-payment, the physician’s usual and customary charge would be $80. Under those circumstances, the obligation of the insurer would be $64.

Other states have similarly concluded that waiver of cost sharing obligations, as a general business practice, results in an overstatement of billed charges.

While a substantial number of states remain silent on the issue, only California’s Attorney General has reached the opposite conclusion, stating that a provider who advertises it will waive patient co-insurance obligations is not participating in a deceptive practice. California, however, stands in the clear minority on this issue. Thus, for the most part, those states addressing the issue have concluded that waiver of co-insurance and deductibles as a business practice results in an overstatement of billed charges and, consequently, is improper.

The United States Congress also passed legislation making the routine waiver of member cost sharing obligations improper with regard to Medicare covered patients. A provider treating Medicare and Medicaid enrolled patients may be liable for waiver of co-insurance obligations. The Office of Inspector General has opined that a provider may be liable for violations of the anti-kickback statutes under the Health Insurance Portability and Accountability Act and Social Security Act. 

*continued on page 22*
Even the American Medical Association (“AMA”) has concluded that a physician’s regular waiver of co-payments is improper.18 The AMA explains in its Ethical Opinions that a waiver of out-of-pocket costs as a professional courtesy or based upon financial hardship may be acceptable; however:

Under the terms of many health insurance policies or programs, patients are made more conscious of the cost of their medical care through copayments. By imposing copayments for office visits and other medical services, insurers hope to discourage unnecessary health care.19

The same Ethical Opinion also recognizes the significant economic impact that a routine waiver of out-of-pocket costs has on medical costs.20 In fact, AMA research reflects that providers who routinely waive patient co-insurance also perform medically unnecessary services to increase their profits. The AMA has warned that such “activity exacerbates the high cost of health care, [and] is unethical. . .”21

It is also worth noting that most health insurance plans include indemnity coverage for out-of-network services; meaning that the plans only reimburse the insured for the money he or she is legally obligated to pay.22 If a patient is not obligated to pay the provider a stated amount, the insurance company does not have any obligation to do so either. In most cases, a provider will state that the member has the legal obligation to pay the entire bill until it receives payment from the insurer. It is at the point that waiver of a co-insurance obligation often occurs. Some providers argue that this distinction allows them to legally waive co-insurance payments.

The Seventh Circuit rejected this artificial distinction when it was posited as an argument by a provider who routinely waived patient co-insurance costs. In Kennedy v. Connecticut General Life Ins. Co.,23 the provider, a chiropractor, accepted a written assignment of benefits for services rendered that released his patient from any liability for money not collected from the insurance company. Under the terms of the applicable health insurance plan, the patient-member was obligated to pay 20 percent of the billed charge directly to the provider, leaving the insurance company to pay the remaining 80 percent of the charges. The plan also stated that it was not responsible for amounts the patient was not legally obligated to pay. The plan refused to pay any money until it received assurance that the member paid his 20 percent of the charges.

The provider commenced a breach of contract action, seeking payment of his billed charge less the 20 percent due from the patient. The plan presented evidence that the provider did not collect the required 20 percent co-insurance payment from the patient because of an agreement relieving him of any obligation to pay his co-insurance amounts once the plan paid the balance of the charges. While the provider argued that what he agrees to take from his patients was irrelevant to the plan’s payment obligations, the Seventh Circuit disagreed, stating:

[wh]en a provider routinely waives co-payments, a fee stated as 80% of the charge is a phantom number. Instead of charging $100, collecting $20 from the patient and $80 from the insurer, the provider may announce a fee of $125, waive the co-payment, and collect $100 from the insurer.24

The plan argued that if the member was not liable to pay any portion of provider’s bill, then the “billed charge” was overstated. The provider did not agree that his billed charge was overstated, even though he routinely did not collect the 20 percent owed by his patients. As a result, the Seventh Circuit noted a “delicious circularity” in the provider’s argument.25 The provider’s “contract is designed to eliminate co-payments,” and the insurer’s “policy require[s] co-payments in order to maintain incentives that hold down the cost of medical care.”26 The Seventh Circuit held that “[w]e could not break the circle in favor of reimbursement without abrogating the co-payment requirement.” As a result, the court ruled in favor of the plan,27 finding that the provider could only recover 80 percent of his billed charge if he collected the 20 percent of charges due from the patient. Since he waived all of the member’s obligations to pay out-of-pocket costs, the court found that the provider was entitled to nothing from the insurer.

Waiver Of Patient Co-Insurance Payments Interferes With Provider Networks

Waiver of out-of-pocket costs also damages network relationships between insurance companies and providers. When providers agree to become in-network providers, they receive certain benefits (including direct payment of their invoices by the insurance companies) in return for accepting additional obligations. One obligation generally requires providers to collect co-payments from member patients. When out-of-network providers waive all patient out-of-pocket costs, agree to submit their bills to the insurer and recover payment directly from the insurance company through an assignment of benefits, the provider removes the incentives—economic or otherwise—for a patient to use in-network providers and unfairly places the out-of-network provider in a better market position than in-network providers.

In-network providers who waive co-payments will also have a detrimental effect on an insurance company’s relationship with its other network providers because waiver of co-payments will cause patient steerage away from the other providers in the network due to the economic incentive for patients to pay less for the same or similar treat-
Out-of-Network Providers Have An Unfair Advantage Over In-Network Providers If They Waive Patient Co-Insurance Payments

As the Court noted in Feiler, supra, by waiving patients’ out-of-pocket charges, the provider removes any economic disincentive to accessing health benefits and healthcare services received out-of-network. The provider, by waiving the out-of-pocket costs, has an unfair advantage over providers who do collect the co-payment. A patient will certainly be more inclined to use a provider who does not require him or her to pay out-of-pocket costs. This inhibits the growth of provider networks, since this practice, if left unchecked, will remove any reason for providers to join networks in the first place.

One way to combat this problem is the use of clauses in health insurance plans prohibiting patient assignments of benefits to providers. In general, a patient may assign his or her right to receive payment from his or her health insurer to an out-of-network provider, allowing the provider to seek direct payment from the insurer. In these cases, the provider will write off the patient’s out-of-pocket costs and be satisfied with the direct payment of benefits from the insurance company. Anti-assignment provisions prevent patients from assigning their right to receive the benefits without written consent from the insurance company. These clauses allow insurers to protect the integrity of their networks and prevent abuse by unscrupulous out-of-network providers.

In Davidowitz v. Delta Dental Plan of Cal., Inc., the Ninth Circuit Court of Appeals upheld such an anti-assignment provision. The insurer provided in-network and out-of-network coverage for dental services that paid 70 percent of the costs of the services, leaving the patient responsible for the remaining 30 percent of these charges. For out-of-network services, the insurance company paid the members directly, requiring them to make full reimbursement to the providers. The anti-assignment provision prevented the member from transferring his or her right to receive payment directly to the out-of-network dentist. A group of non-participating dentists challenged the enforceability of this anti-assignment provision. In response, the defendant health insurer argued that:

[the primary purpose of] non-assignment clauses is to police co-payment waivers by non-participating dentists. Co-payments introduce beneficiary cost-sensitivity into the dental services market, which is lacking if a third party pays the entire cost of dental treatment. Beneficiaries, who must pay some portion of their own dental bills are more inclined to shop competitively for dental services, and not overuse them.

The problem unearthed in this case was that out-of-network providers could inflate their charges by 30 percent and still get the same amount of business as in-network providers. Additionally, plan members were more inclined to go to out-of-network providers because they were not being asked to pay even the nominal co-payments required by in-network providers.

Manifestly, out-of-network providers can achieve the same benefits as being in-network, without assuming any of the duties of such contracts, by merely waiving patient out-of-pocket costs and increasing their charges to offset the amounts waived. This practice harms the network relationships established by insurance companies and could cause collapse of the provider networks if allowed to persist.

In-Network Providers Who Waive Patient Co-Insurance Payments Will Have An Economic Advantage Over Other In-Network Providers

In Reynolds v. California Dental Service, a class of patients who received dental services covered under a pre-paid dental plan brought suit challenging the requirement that the dentist recover co-payments from their patients. Plaintiffs argued that the co-payment required by the pre-paid dental service plan was part of an illegal price fixing scheme and violative of anti-trust laws. Specifically, plaintiffs objected to the contractual prohibition on in-network dental care providers against waiving patient co-payment obligations. The defendant plan presented evidence that it offered a variety of different plans, all of which limited its payment obligation to a percentage of the full charge, leaving the remainder as a coinsurance obligation of the plan members. The court recognized that “[m]ost subscribers choose a plan requiring less than 100 percent of [the defendant’s] payments because such plans cost the subscriber less.”

While the court ruled that the restriction on the waiver of co-payments is not anti-competitive, plaintiffs’ claims in this suit demonstrate how patients chose providers based on whether or not they will forgive co-payments. Thus, waiver by an in-network provider damages network relationships because providers who collect co-pays will likely lose patient steerage to those who do not, which undermines the very purpose of joining the network in the first place.

Waiver of Out-of-Pocket Costs Results In Overutilization

As also noted by the Court in Feiler, supra, a patient may be more willing to seek procedures that he or she may not otherwise obtain if obligated to pay a portion of the cost. Thus, co-insurance waivers can result in overutilization of provider services. Significantly, when providers waive out-of-pocket costs, patients may be more inclined to pursue services that may not even provide any medical benefit.

Even in the case of in-network services, where the co-payment may be a minimal amount, it is well-established that waiver of co-payments can lead to overutilization. In Reynolds, supra, certain dentists supporting the patients’ assignments submitted affidavits stating
they would charge less for the procedures rendered if they did not have to collect a co-payment.46 In opposition, the dental plan submitted affidavits from dentists reflecting that patient co-payment requirements help prevent overutilization.37 The court found that “a copayment tends to keep down costs by reducing the patient’s incentive to overuse dental services.”38

By removing the economic disincentives to seeking more treatment than might otherwise be necessary, the provider may become focused on his or her own profits and not necessarily treatment in the best interests of the patient. Having agreed to accept lower rates by waiving a portion of the cost of his or her services, a provider may even encourage overutilization of services to increase income.

Conclusion

As healthcare costs continue to rise, insurance companies need to be vigilant in guarding against improper practices that have significant impact on the industry. The Agency for Healthcare Research and Quality (“AHRQ”) prepared a study in 2004 proposing that healthcare costs must not be examined only from the perspective of premiums charged, but rather by looking at all costs as a whole, which include whether an insured is required to pay a deductible, the amount of the deductible, and the size of the co-pays.39 This study also concluded that the average healthcare plan deductible for a single person was $545.00, and $1,120.00 for families of enrollees in employee-sponsored health plans. The average co-insurance percentage was 18.6 percent for enrollees and 45 percent for enrollees in employee-sponsored health plans.40 The court found that “a copay averaged $18.01 per visit.40

The cost of overutilization is another factor that eludes simple quantification. However, statistics gathered by the AHRQ show that patients required to pay co-insurance of 18.6 percent of charges or even a co-pay of $18.01 will be sensitized to the cost of the service and, potentially discouraged from seeking unnecessary treatment.41 If every patient foregoes even one in-network visit, the resulting savings is equal to $1.1 billion in co-payments.45

While losses may be small when looked at on an individual patient basis, the overall costs of co-insurance waiver to the healthcare industry are staggering. Thus, it is economically advantageous for the healthcare industry to police waiver issues, because this will reduce overstatements of charges, strengthen the integrity of the provider networks and reduce overutilization of services.

Other economic impacts caused by co-payment waivers, such as the effect on the network relationships between providers and insurance companies, cannot be easily quantified. Simple common sense economics, however, leads to the conclusion that patients will make medical choices with their wallets and be steered toward providers who cost less. Accordingly, providers who agree to abide by network rules find less incentive to remain in-network when they can achieve better results out-of-network. Similarly, in-network providers may find it economically advantageous to waive the average $18.01 co-pay per visit because it may lead to more patient steerage, with resulting increase in revenue.

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Endnotes

1 See James Bernstein, NY: 3 Li Health Firms Inflated Bills, NEWSDAY, Dec. 4, 2007, at A-55.
In the October 2008 article by Charles M. Key, “The Role of PSQIA Privilege in Medical Error Reduction” (The Health Lawyer, vol. 21, no. 1, pp. 24-28), the author reported that the United States Department of Health and Human Services (“DHHS”) had not, at the time of the article’s submission, implemented a process for certifying patient safety organizations (“PSO’s”) under the Patient Safety and Quality Improvement Act of 2005 (“PSQIA”). The author has provided the following update.

On October 14, 2008, DHHS, through its Agency for Healthcare Research and Quality (“AHRQ”), published a notice of availability of Interim Guidance that now permits organizations to apply for PSO certification. See Notice of Availability, 73 Fed. Reg. 60705. AHRQ's release of the Interim Guidance was followed quickly by the designation of the first PSOs, with AHRQ reporting that 15 had been designated as of November 19, 2008.

Final rules implementing PSQIA were published November 21, 2008, to be effective January 19, 2009. 73 Fed. Reg. 70732, 70796-70814. When effective, the final rules will supersede the Interim Guidance, but in the meantime, AHRQ will continue to receive and process PSO applications under the Interim Guidance. PSOs listed during this interim period will be expected to comply with the final rules as of their January 19, 2008 effective date. See AHRQ website, http://www.pso.ahrq.gov/listing/listprocess.htm, accessed by the author 11/21/08.

These developments are especially significant for purposes of the PSQIA privilege, the author points out, in that reporting of information to a PSO is a necessary step to securing the broadest possible protection for patient safety information (“patient safety work product”) under the PSQIA’s evidentiary privilege. A full explanation of the privilege is provided in the October 2008 article, and further information is expected to be provided in future articles in The Health Lawyer.
Stark is implicated by hospital marketing of physicians who are not hospital employees because marketing has value to independent physicians and medical groups. Moreover, it is likely that the recipient of such value — the physician or group — is also a source of Medicare-reimbursed DHS referrals for the hospital. Accordingly, in order to be protected, the arrangement must meet a Stark exception. The three Stark exceptions that apply to marketing are the Incidental Benefits Exception, the Nonmonetary Compensation Exception, and the Payments by a Physician Exception.

The Incidental Benefits Exception allows a hospital to provide compensation in the form of items or services (not including cash or cash equivalents) to a member of its medical staff when the item or service is used on the hospital's campus. According to CMS commentary, a simple listing or identification of the medical staff on a hospital's web site is an incidental benefit that is reasonably anticipated and falls within the exception. Such listing or inclusion should be provided for all members of the medical staff, with similar practice area and contact information provided for each. However, where the marketing activity or advertisement goes beyond such limited incidental benefit, these arrangements would have to either fit into the Nonmonetary Compensation Exception or the hospital would have to charge fair market value for the advertising in accordance with the Payments by a Physician Exception.

Finally, to the extent a marketing activity would not meet the limited Incidental Benefits Exception or the Nonmonetary Exception, a hospital may provide such services so long as the services are furnished at a price that is consistent with fair market value, pursuant to the Stark exception for Payments by a Physician. This is one of the few Stark Law compensation exceptions that does not require a written agreement. However, it would be prudent for the hospital to have a policy that will ensure fair market value is paid by the hospital.

It is important to note that CMS would preclude a hospital from marketing or advertising a physician and not charging for such services under the Nonmonetary Compensation Exception if the physician (or a practice staff member) directly solicits such support from the hospital. Accordingly, in the event a hospital would like to offer marketing services such as shared advertising with members of the Medical Staff, and not charge for same to the extent the value does not exceed $338 (or such higher amount as may be applicable in the future), it would need to offer this service rather than respond to requests for such services. Moreover, for compliance purposes, such benefit should be offered at the same level to all medical staff members.

HOSPITAL-PHYSICIAN JOINT MARKETING COMPLIANCE GUIDELINES

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Introduction

Hospitals often engage in certain marketing of the physicians who are members of their medical staffs. While such activity may be appropriate, even at no cost to physicians, the scope and type of marketing must be monitored to ensure compliance with fraud and abuse and physician self-referral laws. This article focuses on two key areas of enforcement as it relates to this area: the Stark Law and the Federal Anti-Kickback Statute.

Federal Self-Referral Statute (“Stark”) Implications

The Stark Law prohibits physicians from referring Medicare patients for the provision of designated health services (“DHS”) to entities with which the physician (or an immediate family member) has a financial relationship, unless an exception applies. DHS includes inpatient and outpatient hospital services, thereby implicating arrangements between hospitals and members of their medical staffs. Stark also prohibits entities from billing governmental payors for such prohibited referrals. It is a strict liability statute, which means that if a particular arrangement implicates the statute but does not meet an exception, the arrangement is illegal.

Sanctions for a prohibited referral under Stark include denial of payments, or a refund if payment has been made, for any related services that are delivered under the Medicare program. While the Government's primary remedy for Stark violations is non-payment of claims without penalties, the Centers for Medicaid and Medicare Services (“CMS”) has advised that wrongful conduct may be punished through recoupment and penalties under false claims laws as well.

The Stark Law prohibits enti-
The Federal Anti-Kickback Statute ("AKS") makes it a crime to provide anything of value to a referral source (either directly or indirectly) with the intent of inducing a referral or inducing the purchase of items or services paid for by a government health plan payor, such as Medicare, Medicaid, or TriCare.\textsuperscript{12} Penalties for violation of the AKS may include fines, exclusion from governmental payor programs and imprisonment.

For the purposes of the AKS, "remuneration" includes the transfer of anything of value, directly or indirectly, covertly or overtly, in cash or in kind. Since advertising would be of value to physicians trying to grow and develop (or retain) their practices, providing free or discounted advertising services to referral-source physicians would implicate the AKS. Therefore, the hospital should not be providing free advertising or marketing support to physicians, except as such support may meet the more nominal value exceptions further discussed in the Stark Law analysis above.

As recommended for Stark Law compliance, in the event that a hospital engages in support that goes beyond that addressed in the Stark Incidental Benefits and Nonmonetary Compensation Exceptions, it should establish the fair market value and charge for such services, keeping a record thereof. Also, the hospital should not differentiate among whom it may provide marketing support for based on any volume or value of referrals differential.

Moreover, the Office of Inspector General ("OIG"), which enforces the AKS, has expressed concerns that advertising activity "like any marketing" implicates the AKS because it is intended to recommend the use of a particular product, service or provider.\textsuperscript{13} Therefore, as a hospital includes physicians in its marketing activity (websites, print ads etc.), or otherwise advertises on a physician's behalf, it should exercise due care in how it presents information. In assessing marketing activities, the OIG will consider a number of factors, including:

- The identity of the party engaged in the marketing activity and the party's relationship with its target audience;
- The nature of the marketing activity;
- The item or service being marketed;
- The target population; and
- Any safeguards to prevent fraud and abuse.

The OIG has concluded that customary, accurate and non-deceptive print advertising in general circulation media (such as periodicals or broadcast media) does not raise anti-kickback concerns. In determining a particular advertising approach reasonably acceptable under the AKS, the OIG noted that "[m]ost importantly, the advertising would be essentially passive in nature, in that any contact with the Advertiser must be initiated by the customer."\textsuperscript{14} The OIG also noted the importance of a provider compensating a managed care organization ("MCO") for the value of the advertising when a provider advertised on the MCO's website.

Similarly, in its advisory opinion assessment of another proposal that included marketing, the OIG noted the importance of a certification "that all advertising and promotional activity under the proposed arrangement would comply with all applicable Federal and state laws and regulations, including, but not limited to, compliance with consumer laws prohibiting false advertising, unfair and/or deceptive advertising, and consumer fraud."\textsuperscript{15}

Finally, safe harbors under the AKS protect certain arrangements that may otherwise implicate the statute. Unfortunately there is not a safe harbor specific to marketing support. Whereas under the Stark Law any marketing support must meet an applicable Stark exception, there is no parallel requirement that such support meet an AKS safe harbor to avoid illegality because the AKS is not a strict liability statute. Rather, AKS safe harbors serve to protect certain arrangements and to provide guidance for others where a specific safe harbor does not exist. In commentary to safe harbor regulations, regulators have indicated that "[i]n many instances, prosecutorial discretion would be exercised not to pursue cases where the participants appear to have acted in a genuine good-faith attempt to comply with the terms of a safe harbor..."\textsuperscript{16} Accordingly, following the guidance summarized above will facilitate AKS compliance.

**State Law Implications**

Hospitals should also comply with any relevant state laws that may be implicated by marketing support. While frequently Stark Law and AKS provisions are paralleled in state law, it is necessary to consult applicable state laws to determine if state requirements are more stringent than those imposed under federal law. For example, the Illinois Insurance Claims Fraud Prevention Act is a civil law that largely parallels the AKS in its prohibitions, except that it applies to all insurance

Continued on page 28
payments, making it a more broadly applicable law. Accordingly, where a hospital might consider instituting a marketing program for physicians who do not participate in governmental programs, such a program would still be governed by anti-kickback rules, calling for an approach similar to the one outlined above under federal law.

Conclusion and Recommendations

A hospital may engage in shared marketing, or in marketing or advertising on behalf of the members of its medical staff, so long as such activity meets the various parameters discussed herein. More limited activities such as including medical staff members on physician lists, and providing limited background and contact information on the hospital website, would be permissible absent payment from physicians. However, such limited marketing should be equally applied to all members of the medical staff without consideration of volume or value of referrals and the description for each member should be similar. For example, a primary care physician should enjoy the same type of listing as a cardiologist or neurosurgeon. In addition, general rosters should not recommend or promote individual physicians but rather simply present information so that the patient may review and decide whether to contact any particular physician.

Again, to the extent a particular marketing activity is not covered under the Stark Law Incidental Benefits Exception or the Nonmonetary Compensation Exception, the hospital should charge physicians fair market value for its services. While a written agreement is not required, physicians should understand up front that they will be charged a certain amount. Furthermore, the hospital should maintain documentation on such activity, amounts charged and payments received.

Exhibit A
Sample Marketing Guidelines

Shared Ads or Ad Placement by the Hospital

Most advertisements consist of three elements: text, logo and graphics. As such, the amount of space attributable to each party-specific element should be in direct proportion to the percent of the cost borne by that party.

For example, if each party pays fifty percent (50%) of the cost of the ad, the space in the ad attributable to text, logo and graphics for each party should be the same for each party. Similarly, if the Hospital pays seventy-five percent (75%) of the cost, the Hospital should receive this same proportion of total ad space for its text, logo and graphics.

To the extent the Hospital lines up advertising that does not market or promote the Hospital but rather focuses on one or more independent physicians or groups, it should allocate all costs to the physician(s)/group(s) and include a handling surcharge (i.e., a reasonable charge that will address the time and effort spent by Hospital staff in arranging for the ad).

If a graphic is used that is neither Hospital nor physician-specific, (i.e., a picture depicting both a hospital facility and a physician), then the space attributable to such a graphic should be added to each party's proportionate space on a fifty/fifty basis.

This same allocation approach should be applied to radio and television ads as well.

In general, the Hospital should follow a logical approach to implementing joint advertising. This approach should seek to assure a fair and equitable allocation of advertising expense and advertising space. Again, in the event the Hospital is simply a “placement” go-between, it should not only allocate all advertising costs to the physician(s) but also include a reasonable fee for its pro rata efforts on behalf of the physician(s).

Documentation

The Hospital should keep a log of any marketing activity or advertising that it provides for independent physicians or groups, the value of each such activity or service as calculated in accordance with these Marketing Guidelines, and evidence of payment for same (e.g., a check number). Such log shall not apply to listing physicians (and relevant contact information) in general marketing, such as the website for the Hospital, so long as these listings address all members of the Medical Staff.

In determining fair market value of a particular marketing activity, and otherwise engaging in shared or direct marketing of physicians, the hospital should defer to the Marketing Guidelines attached hereto as Exhibit A which factor in regulatory guidance in this matter. In following these guidelines where the Incidental Benefits Exception or the Nonmonetary Compensation Exception would not apply to a particular marketing activity and a hospital will provide shared marketing or marketing on behalf of a physician, this will ensure Stark Law compliance under the Stark exception for Payments by a Physician and facilitate compliance with the AKS per OIG guidance in such matters.
Lynn Gordon’s practice focuses in the area of corporate health law, with a particular emphasis on the transactional, regulatory and operational legal counsel needs of hospitals, health systems, and specialty provider groups, including mergers and acquisitions, healthcare joint ventures, contract drafting and negotiations, physician recruitment and regulatory compliance. She is a graduate of Loyola University Chicago School of Law (J.D., health law concentration, 1996), North Carolina State University (M.A., 1991) and Michigan State University (B.A., 1988). She may be reached at lgordon@uhlaw.com.

Chair’s Corner

continued from page 2

only getting worse. For example, the early stage of baby boomers will dramatically increase the amount of debt, which healthcare costs significantly aid. Forty million persons are currently eligible for Medicare services, but by 2050 the number is expected to rise to over 80 million. It is estimated that in the year 2050, 37 percent of expenses will come from healthcare. Despite the grim picture for the future, Senator Conrad touched on a few courses of action that can offset rising issues, such as greater organization in providing care and cutting the number of medications a patient needs. Provider incentives, including a change from compensation for procedures to compensation for outcomes may help. A commitment to e-health most likely can alleviate many costs and issues in the healthcare market. Most importantly, however, Senator Conrad made it clear that both parties in government must come together to address the ever-serious issues in healthcare.

In all, the 6th annual Washington Healthcare Summit was an overwhelming success and seems to have truly hit its stride this year. The Summit was well attended and offered engaging programming for its participants. We thank all who made this year’s event a success and are looking forward to next year.

Of course, the Holiday season is already underway and cooks are often concerned about what to do with all of that leftover holiday turkey. In Kentucky, we have a tradition called the “Hot Brown”, a recipe developed by the historic Brown Hotel located in downtown Louisville, Kentucky. The Brown Hotel enjoys a worldwide reputation even today.

According to local lore, the Hot Brown was created in the 1920’s when the Brown Hotel would draw over 1,200 guests each evening for its dinner dance. After hours of dancing, the guests would retire to the restaurant for a bite to eat. Diners grew tired of the traditional ham and eggs, so Chef Fred Schmidt created something new ---an open-faced turkey sandwich with bacon and a delicious Mornay sauce. A Kentucky tradition was born!

The Legendary Hot Brown Recipe

**Ingredients:**

- 4 oz. Butter
- Flour to make a Roux (about 6 tablespoons)
- 3 - 3 1/2 cups Milk
- 1 Beaten Egg
- 6 tablespoons Grated Parmesan Cheese
- 1 oz. Whipped Cream (optional)
- Salt and Pepper to Taste
- Slices of Roast Turkey
- 8-12 Slices of Toast (may be trimmed)
- Extra Parmesan for Topping
- 8-12 Strips of Fried Bacon

Melt butter and add enough flour to make a reasonably thick roux (enough to absorb all of the butter). Add milk and Parmesan cheese. Add egg to thicken sauce, but do not allow sauce to boil. Remove from heat. Fold in whipped cream. Add salt and pepper to taste.

For each Hot Brown, place two slices of toast on a metal (or flameproof) dish. Cover the toast with a liberal amount of turkey. Pour a generous amount of sauce over the turkey and toast. Sprinkle with additional Parmesan cheese. Place entire dish under a broiler until the sauce is speckled brown and bubbly. Remove from broiler, cross two pieces of bacon on top, and serve immediately. (I also add a couple of slices of tomato to the top of the sandwich before placing it under the broiler)

www.brownhotel.com

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The Health Lawyer
Program Agenda

WEDNESDAY, FEBRUARY 18, 2009

12:00 pm – 5:00 pm
Registration and Information Desk Open

1:00 pm – 4:00 pm
CONCURRENT PRE-CONFERENCE SESSIONS
Breast Cancer Legal Advocacy Workshop
One in eight women will be diagnosed with breast cancer. This means the chances are high that you or someone you know has had or will have direct experience with this disease. Cancer patients face a variety of legal problems related to their illness, including issues related to coverage and payment for treatment and employment-related issues. This seminar will provide information to assist attorneys who do not ordinarily handle cases of this type become aware of laws, practices, and procedures to help them assist breast cancer patients with legal problems resulting from their illness.
Moderator: Priscilla Keith, Health & Hospital Corp. of Marion County, Indianapolis, IN
Speakers: Julie Conrad, Wishard Health Services, Indianapolis, IN
Elisabeth L. Dupont, MD, Watson Clinic Women’s Center, Lakeland, FL
Christopher S. Sears, Ice Miller LLP, Indianapolis, IN

1:00 pm – 4:00 pm
Fundamentals of Providing Healthcare: Regulation, Payment, and Fraud & Abuse Considerations for Providers and Suppliers
This session will explore the fundamental issues presented when a hospital, physician groups, and a commercial payor provide services and pursue business opportunities in Middletown, USA. An experienced panel will review the basics on how providers and suppliers are regulated, how they are paid for services, what business opportunities they may pursue, and what fraud and abuse limitations they must consider. The panel will then offer several scenarios for interactive discussion among the panel and attendees. The session will be geared toward attorneys who are new to health law or who want to broaden the focus of their practice.
Speakers: William W. Horton, Haskell Slaughter Young & Rediker, LLC, Birmingham, AL

6:00 pm – 7:00 pm
Reception Honoring Young Lawyers
All registrants are welcome to attend.

THURSDAY, FEBRUARY 19, 2009

7:30 am – 5:00 pm
Registration & Information Desk Open

7:30 am – 10:00 am
Continental Breakfast

8:00 am – 9:30 am
PLENARY SESSION
Fraud and Abuse Enforcement: Recent Developments and Future Direction
This panel will discuss recent developments and future directions in civil, criminal, and administrative healthcare fraud enforcement. The discussion will cover recent False Claims Act activity, including major settlements, notable case decisions, legislative activity, and the increasing importance of state false claims acts. The discussion will also cover DOJ’s Medicare Fraud Strike Force and other criminal healthcare fraud enforcement initiatives as well as the latest information on OIG enforcement, self disclosure, and corporate integrity agreements.
Moderator: Jonathan Diesenhaus, Hogan & Hartson LLP, Washington, DC
Speakers: John S. (Jay) Darden, U.S. Department of Justice, Washington, DC
Gregory E. Demske, U.S. Department of Health & Human Services, Washington, DC
Andy J. Mao, U.S. Department of Justice, Washington, DC

9:30 am – 9:45 am
Break

9:45 am – 11:00 am
CONCURRENT INTEREST GROUP CLE SESSIONS
Genetics, Race, and Diversity in Clinical Trials
Medical Research, Biotechnology & Clinical Ethical Issues

Several conceptual and practical issues emerge from clinical research involving genetics and race. Recent debate has centered on whether race is a social construction or is biologically identifiable through genetic techniques. The Federal Government
played an interesting role in this debate recently when the Food and Drug Administration and the US Patent and Trademark office sanctioned the use of race as a biological category in their approval of the heart failure drug Bidil® and its associated patent. This session will focus on the larger implications and ethical questions that arise from this approval. Additionally, the panel will discuss other “research review issues” related to genetics and race from an IRB and ethical perspective when a clinical trial occurs. Background on scientific and ethical reviews of research projects will be followed by discussion of the practical and operational aspects of such reviews.

Moderator: Kirk L. Dobbins, King & Spalding, LLP, Washington, DC
Speakers: Brian A. Gladue, Ph.D., University of North Texas Health Science Center, Fort Worth, TX
Daniel Stearsman, Pharm.D., University of Florida, College of Pharmacy, Lakeland, FL

New Developments in Antitrust
Healthcare Litigation & Risk Management Interest Group
This session will review the latest developments in antitrust law, including pending class actions alleging that hospitals and healthcare associations have conspired to fix nurse and other employee salaries; new law arising from legal challenges brought by small institutions against their rivals over managed care contracting practices; and new approaches the Federal Trade Commission is taking to challenge hospital mergers.
Moderator: Martin J. Thompson, Manatt Phelps & Phillips LLP, Costa Mesa, CA
Speakers: Sylvia Kundig, Federal Trade Commission, San Francisco, CA
John J. “Jeff” Miles, Ober Kaler Grimes & Shriver, PC, Washington, DC

Practice on the Edges: Coming to a Neighborhood Near You—Whether You Like it or Not
Payment & Reimbursement Interest Group and Physician Issues Interest Group
This interactive program will explore the current blurring of the lines of professional practice between Physicians and Physician Assistants, Nurse Practitioners, CRNA’s, and other Auxiliary Healthcare Professionals. The speakers will examine the scope of practice and ethical issues that arise at the edges of the practices of different categories of providers, as well as the economic pressures and access concerns which are pushing these issues to the forefront.
Moderator: William E. Hopkins, Brown McCarroll LLP, Austin, TX
Speakers: Carolyn Buppert, Carolyn Buppert, P.C., Bethesda, MD
Astrid Meghrigian, California Medical Association, Sacramento, CA

11:00 am – 11:15 am
Break
11:15 am – 12:45 pm
PLENARY SESSION
Current Developments in Physician/Hospital Joint Ventures
With the demise of many traditional doctor/hospital contractual relationships (for example, “under arrangements” and “per click” transactions), healthcare providers are developing creative ways of partnering to enhance the quality and efficiency of healthcare delivery. This program will focus on two types of joint ventures currently in vogue. First, the panel will explore the growing trend of hospital acquisitions of physician practices, followed by employment. The myriad issues involved in the acquisition (e.g., valuation and key contract terms) will be analyzed, as well as physician compensation methodologies. Second, the panel will address the continued development of hospital syndications, with an emphasis on the special issues that arise when a not-for-profit institution desires to share ownership with potential referral sources. The panel will include a healthcare lender who will survey the impact of the current credit and lending environment on healthcare providers seeking capital and financing.
Moderator: Leigh Walton, Bass, Berry & Sims PLC, Nashville, TN
Speakers: Thomas D. Anthony, Frost Brown Todd LLC, Cincinnati, OH
C. Mitchell Goldman, Duane Morris LLP, Philadelphia, PA
Kevin Lavender, Fifth Third Bank, Nashville, TN

12:45 pm – 1:00 pm
Break
1:00 pm – 2:30 pm
INTEREST GROUP LUNCHES
- Employee Benefits & Executive Compensation
- Healthcare Fraud & Compliance
- Managed Care & Insurance
- Medical Research, Biotechnology & Clinical Ethical Issues
- Payment & Reimbursement
- Public Health & Policy

2:30 pm – 2:45 pm
Break
2:45 pm – 4:15 pm
PLENARY SESSION
Ethical Interactions Between Providers and Vendors
Physicians and hospitals play a valuable role in developing, testing, and training on the use of new drugs and medical technologies, but their involvement and compensation for these efforts can create difficult conflicts of interest.
This session will explore tools to legally and ethically manage interactions between healthcare providers and vendors (such as pharmaceutical and medical device manufacturers) in order to effectively control potential conflicts of interest, reduce risk, and promote organizational and individual integrity. Topics discussed will include enforcement activity, best practices and voluntary standards, implementation challenges, recommended approaches to documentation, and accountability.

Moderator: Lisa D. Taylor, Stern & Kilcullen, LLC, Roseland, NY
Speakers: Gary Keilty, Deloitte Financial Advisory Services LLP, Tampa, FL
    William T. Mathias, Ober Kaler Grimes & Shriver, PC, Baltimore, MD
    Lynn A. Stansel, Montefiore Medical Center, Bronx, NY

4:15 pm – 4:30 pm
Break

4:30 pm – 5:45 pm
CONCURRENT INTEREST GROUP CLE SESSIONS

Recovery Audit Contractors: Compliance and Appeals Strategies
Payment & Reimbursement Interest Group
The demonstration project has been completed, the national contractors have been selected, and the permanent RAC program is now up and running. This session will offer tips for integrating a proactive RAC strategy into an organization’s compliance program. The panel will also discuss successful appeals strategies and will identify additional legal issues arising from the RAC program.

Speakers: Jennifer O’Brien, Halleland Lewis Nilan & Johnson, PA, Minneapolis, MN
    Andrew B. Wachler, Wachler & Associates PC, Royal Oak, MI

Tax-Exemption Update: The New Form 990 and Other Ongoing Compliance Efforts
Tax & Accounting Interest Group
With the implementation of the redesigned 2008 Form 990, for the first time tax exempt hospitals will be required to report standardized information on community benefit, charity care, bad debt policies, and other information related to assessing and responding to community need. This session will discuss disclosure requirements under the new Form 990, Schedule H, and their accompanying instructions, which were finalized in August of 2008. The Form 990 is one of many ongoing compliance efforts affecting tax-exempt hospitals, including the Executive Compensation Compliance Project, the Hospital Compliance Project, and the Political Activity Compliance Initiative. This session will address these and other new developments and IRS compliance initiatives.

Moderator: Laura Gabrys, Fulbright & Jaworski LLP, San Antonio, TX
Speakers: Gerald M. Griffith, Jones Day LLP, Chicago, IL
    Ronald J. Schultz, Internal Revenue Service, Washington, DC

Using Deferred Compensation to Incent On-Call Coverage
Employee Benefits & Executive Compensation Interest Group and Healthcare Fraud & Compliance Interest Group
The Emergency Medical Treatment and Active Labor Act (EMTALA) requires hospitals to provide a screening exam and stabilizing medical services to individuals presenting with emergency medical conditions. Sometimes this requires hospitals to ensure that specialist physicians are on call at odd hours to examine and stabilize patients. Hospitals often struggle with ways to incent non-employed physicians to take this call. This session will discuss hospitals’ obligations under EMTALA and the difficulties with EMTALA compliance, especially with the call requirements. The speakers will discuss emerging tools to incent physicians to take call through employee benefits, particularly deferred compensation. Deferred compensation programs can provide a tax-advantaged and attractive method of compensating physicians for call coverage. This session will also discuss pitfalls to avoid in designing deferred compensation plans for physicians.

Speakers: Sarah E. Coyne, Quarles & Brady LLP, Madison, WI
    Christopher S. Sears, Ice Miller LLP, Indianapolis, IN

6:00 pm – 8:00 pm
Emerging Issues Conference Reception Honoring Program Faculty and Planning Committee Members

FRIDAY, FEBRUARY 20, 2009

7:30 am – 4:00 pm
Registration & Information Desk Open

7:30 am – 10:00 am
Continental Breakfast

8:00 am – 9:00 am
ETHICS SESSION
“To Whom Should I be True?” Legal Ethics and Client Loyalty in a Changing World
Lawyers are frequently confronted with difficult issues that turn on the question of to whom the lawyer owes a duty of loyalty, particularly with increased lawyer and client mobility, law firm mergers, and law firm implosions. This session will consider recent developments in conflicts of interest, including proposed Model Rules amendments on “screening lawyers” to avoid imputation of conflicts, as well as the representation of corporate entities and their constituencies. Can your new
firm represent the physician if you used to represent the hospital? Can you represent both sides of the joint venture? Do you even know who your real client is? Maybe not, but you’ll have a better idea after this exciting ethics hour.

Speakers: Andrew J. Demetriou, Fulbright & Jaworski LLP, Los Angeles, CA
Willard William Horton, Haskell Slaughter Young & Rediker, LLC, Birmingham, AL

9:00 am – 9:15 am
Break

9:15 am – 9:30 am
State of the Section Address
Section Chair Vickie Yates Brown will discuss the activities, achievements, and aspirations of the ABA Health Law Section.

9:30 am – 11:00 am
PLENARY SESSION
Telemedicine: Licensing and Credentialing Challenges for Providers
Among the formidable barriers to the broad expansion of telemedicine services in the United States is the current need for multiple state licenses for providers who practice across state lines. Similarly, problematic are the multiplicity of requirements for institutional credentialing and the granting of medical staff privileges, which also affect the delivery of services via telemedicine technologies. This presentation will explore the need for legislation at the state, territorial, and tribal levels to provide for mutual state telemedicine licensure recognition. Under such a system, a physician with a current, valid, and unencumbered license in any state could file a single application which would permit the physician to practice telemedicine in some or all other states subject to continuing compliance with those states’ licensure fees, discipline, and other applicable laws and regulations, as well as adherence to professional standards of medical care. The presentation also will address the necessity for reasonable and consistent telemedicine credentialing requirements.

Moderator: David H. Johnson, Bannerman & Williams, PA, Albuquerque, NM
Speakers: John D. Blum, MPH, Loyola University, Chicago School of Law, Chicago, IL
Lynn D. Fleisher, Ph.D., Sidley Austin LLP, Chicago, IL

11:00 am – 11:15 am
Break

11:15 am – 12:30 pm
CONCURRENT INTEREST GROUP CLE SESSIONS
Master Class in e-Health Crisis Investigation and Management for Healthcare Attorneys
eHealth, Privacy & Security Interest Group
In this “eHealth Master Class,” presenters will discuss the wisdom of making advance preparation for potential inadvertent disclosures of patient healthcare information, and will review things lawyers can learn from communications professionals regarding crisis communications. The presentation will also discuss ways lawyers and communications professionals can work together to develop a Crisis Communications policy and toolbox, as well as the selection and use of outside consultants and communications professionals. The session will also explore an extended case study examining the access and release of a hypothetical patient’s medical records over the Internet, with a focus on how to—and how not to—communicate during an e-Health crisis.

Speakers: Marc D. Goldstone, Community Health Systems, Franklin, TN
Debbie Landers, Community Health Systems, Franklin, TN

Respecting Rights of Conscience: An Emerging Area at the Intersection of Healthcare & Employment Law
Employee Benefits & Executive Compensation Interest Group and Medical Research, Biotechnology & Clinical Ethical Issues Interest Group
This presentation will discuss emerging statutory and common law which protects the rights of conscience of healthcare workers. The discussion will also review examples of — and highlight significant variations in — federal and state legislation and case law on this subject. Additionally, this presentation will discuss how respecting rights of conscience may mesh with duties owed to employees under broadly-applicable civil rights statutes such as Title VII, particularly the duty owed by employers to make reasonable accommodations of their employees’ religious beliefs and practices. Lastly, this presentation will seek to address how this area of law may be affected by HHS’ recently proposed regulations regarding the rights of conscience of federally funded healthcare providers.

Speaker: R. Reid McKee, Watkins & Eager PLLC, Jackson, MS

Retail-Based Clinics and the Convenient Care Delivery Model: Legal and Operational Issues
Employee Benefits & Executive Compensation Interest Group and Managed Care & Insurance Interest Group
Retail-based health clinics, also known as convenient care clinics, are a new delivery model for providing non-acute, episodic care through a variety of settings from drug stores to grocery stores. Proponents of this model maintain that it offers easier access to basic health services at less expense to consumers and the health system overall because it relies on nurse practitioners and physician assistants to provide a limited set of services and treatments. While convenient care has been criticized by some physicians and healthcare providers, other physician groups and health systems are
joining the trend and developing their own clinics. The present-ers will describe recent developments in the convenient care model and related legal and operational issues, including scope of practice, collaborative practice arrangement requirements, confidentiality of information, referral relationships, commercial payor contracts, and Medicare and Medicaid reimbursement.

Speakers: Ruth E. Granfors, K&L Gates LLP, Harrisburg, PA
Tine Hansen-Turton, MGA, JD, Convenient Care Association and Public Health Management Corporation, Philadelphia, PA

12:30 pm – 1:45 pm
Interest Group Lunches
• Business & Transactions
• eHealth, Privacy & Security
• Healthcare Facility Operations
• Healthcare Litigation & Risk Management
• Physician Issues
• Tax & Accounting

1:45 pm – 2:00 pm
Break

2:00 pm – 3:30 pm
PLENARY SESSION
Clinical Research Trials and Tribulations
Ligation involving clinical research trials has escalated rapidly in recent years – in part due to increased research, in part due to an increasingly entrepreneurial research environment, in part due to increased regulatory scrutiny, in part due to increased media attention and public awareness, and in part due to the development of novel claims brought against an expanded scope of defendants. This session will: (1) provide an overview of liability exposure risks faced by researchers, research institutions, and research sponsors; (2) highlight the landmark Diaz v. Hillsborough County Hospital Authority case, in which the “dignitary harm” claim was first recognized; (3) relay key portions of witness examination and cross examination in the Diaz case in “mock-trial” fashion, performed by the lead attorney in the case; and (4) provide practical advice for minimizing clinical trials liability exposure.

Speakers: Stephen J. Hanlon, Holland & Knight LLP, Washington, DC
Robyn S. Shapiro, Drinker Biddle & Reath LLP and Center for the Study of Bioethics, Medical College of Wisconsin, Milwaukee, WI

3:30 pm – 3:45 pm
Break

3:45 pm – 5:00 pm
CONCURRENT INTEREST GROUP CLE SESSIONS
Disruptive Practitioners and the New 2009 Joint Commission Standards
Healthcare Facility Operations Interest Group and Healthcare Litigation & Risk Management Interest Group
The 2009 standards for hospitals issued by the Joint Commission include a new Standard LD.03.01.01, which requires hospital leadership to evaluate the culture of safety and quality regularly; to have a code of conduct that defines acceptable, disruptive, and inappropriate behaviors; and to create and implement a process for managing disruptive and inappropriate behaviors. This session will discuss issues raised by the new standard, how it affects peer review processes, and options for hospital counsel to consider in order to deal effectively with disruptive behavior.

Moderator: Denise Glass, Fulbright & Jaworski LLP, Dallas, TX
Speakers: Michael C. Guanzon, Clement & Wheatley, PC, Danville, VA
Jonathan M. Joseph, Christian & Barton LLP, Richmond, VA

Expedited Partner Therapy: Exploring the Legal Landscape
Public Health & Policy Interest Group
Expedited partner therapy (“EPT”) involves the delivery of medications or prescriptions to gonorrhea and chlamydia patients for their partners without a clinical assessment. EPT has been shown to be an effective strategy for the treatment of these two STDs, and laws in most jurisdictions either expressly permit EPT or do not prohibit it. However, EPT raises ethical and legal issues pertaining to informed consent, confidentiality, and patient safety due to the absence of the traditional doctor-patient relationship. This session will explore the ABA resolution on EPT and describe the science, law, and policy behind EPT as a public health tool.

Moderator: Montrece Ransom, MPH, Centers for Disease Control and Prevention, Atlanta, GA
Speakers: Heidi Bauer, MD, MS, MPH, California Department of Public Health, Richmond, CA
Amy Pulver, MA, MBA, Centers for Disease Control and Prevention, Atlanta, GA
Melisa Thombley, MPH, Centers for Disease Control and Prevention, Atlanta, GA

The New Stark Rules: Analysis and Application
Healthcare Fraud & Compliance Interest Group
With the 2009 Final IPPS rule, CMS finalized critically important revisions to the Stark physician self-referral regulations, including: (1) physician “stand in the shoes” provisions, (2) the expanded definition of a DHS “entity,” which affects “under arrangement” and other transactions; (3) per unit of service
space and equipment lease transactions; and (4) percentage-based lease arrangements. In addition, CMS has also finalized revisions to the anti-markup rule, which limits payment for diagnostic testing services that are often performed in the physician office setting. The panel will examine the revised rules from the government and private practice perspectives, illustrate application of the rules, and discuss some of the resulting compliance challenges.

Moderator: Joel Wakefield, Coppersmith Gordon Schermer & Brockelman PLC, Phoenix, AZ

Speakers: Joan Dailey, U.S. Department of Health & Human Services, Washington, DC
Carol A. Poindexter, Shook, Hardy & Bacon LLP, Kansas City, MO

5:00 pm

CLE Program Adjourns

The Health Law Section is pleased to welcome the following new members:

David J. Armstrong, Boca Raton, FL
Gloryvette Arroyo, Mayaguez, PR
Cynthia H. Beaudoin, Albany, NY
Barbara C. Bentrup, Saint Louis, MO
Randall M. Best, Raleigh, NC
Melany Birdsong, Little Rock, AR
Craig L. Boeck, Indianapolis, IN
Heidi Amanda Bramson, Newark, NJ
Martin G. Brownstein, Sacramento, CA
Binh Quoc Bui-Oliver, Snellville, GA
Kristin Dawn Byrd, Saint Louis, MO
John Harlan Callis III, Prestonsburg, KY
Taylor Casey, Jacksonville Beach, FL
Michelle Renee Caswell, Stone Mountain, GA
Stephanie Bailey Cavender, Memphis, TN
Judy Chan, Chicago, IL
Amanda J. Chaves, Boston, MA
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Julie Kristen Lappas, Washington, DC
Bria Barker Lewis, Commerce Township, MI
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Margaret Winnick, Greta, NE
Margaret A. Zonca, Chicago, IL
Frederick R. Zufelt, Raleigh, NC
Margaret Winnick, Greta, NE
Margaret A. Zonca, Chicago, IL
Frederick R. Zufelt, Raleigh, NC

SATURDAY, FEBRUARY 21, 2009
8:00 am – 11:30 am
Open Council Meeting
All members are welcome to attend the Section Open Council Meeting

12:30 pm – 6:00 pm
10th Annual Margarita Cup Golf Scramble
Disney’s Palm Golf Course
Round trip shuttle transportation will be provided from the hotel to the golf course.

7:00 pm – 9:00 pm
Margarita Cup Reception Hosted by Section Chair Vickie Yates Brown
All meeting attendees are welcome!
SECTION CALENDAR
For more information on any of these programs, call the Section at 312/988-5532 or visit the Section web site at www.abanet.org/health

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
<th>Location</th>
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<tbody>
<tr>
<td>January 15, 2009</td>
<td>Fundamentals of Medical Staff and Peer Review*</td>
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<tr>
<td>February 5, 2009</td>
<td>Stark Law Basics*</td>
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<tr>
<td>February 18-20, 2009</td>
<td>10th Annual Conference on Emerging Issues in Healthcare Law</td>
<td>Disney’s Yacht Club Resort</td>
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<tr>
<td>March 12, 2009</td>
<td>Anti-Kickback Law Basics*</td>
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<td>April 23, 2009</td>
<td>Reimbursement &amp; False Claims Act Fundamentals*</td>
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<td>May 21, 2009</td>
<td>Fundamentals of Tax-Exempt Healthcare Organizations*</td>
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<tr>
<td>June 11, 2009</td>
<td>Physician-Legal Issues Conference</td>
<td>American Bar Association Conference Center Chicago, IL</td>
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<tr>
<td>June 18, 2009</td>
<td>Fundamentals of Insurance and Managed Care*</td>
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<tr>
<td>October 26-27, 2009</td>
<td>7th Annual Washington Healthcare Summit</td>
<td>Ritz-Carlton, Pentagon City Arlington, VA</td>
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* Call the ABA Service Center at 800/285-2221 for information