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Health Law Alert®

Spring 2009

In This Issue

CMS

What Providers Must Know When Appealing RAC Audit Findings

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Section 306 of the Medicare Modernization Act of 2003 instructed CMS to identify both Medicare overpayments and underpayments through the use of new agents called recovery audit contractors (RACs). Launched in March of 2005, the three-year RAC pilot project focused only on California, Florida, New York, Massachusetts, and South Carolina health care providers and suppliers. Because of the enormous success experienced by the RACs in these states, Section 302 of the Tax Relief and Health Care Act of 2006 directed CMS to expand the RAC audits into all states by 2010. CMS announced its plan to implement the RAC program nationwide beginning the summer of 2008. However. its revised plan to expand the program effective 2009 was further delayed by bid protests filed by unsuccessful RAC applicants.

Despite complaints and concerns raised by the medical community in the states affected by the RAC reviews through the conclusion of the demonstration in March 2008, CMS remains very supportive of the results of the RAC audits. According to CMS, the RACs overall have identified almost $440 million in

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From the Chair

Okay, the election is over, Barack Obama is the 44th President of the United States and he serves with a Congress that is controlled by the Democrats. What will this mean to the health care industry? What will this mean to health lawyers?

In the words of one of my mentors, "Who knows?" I suspect that, based upon the theme of the election, it will mean "change." What change, and how that change will be developed and implemented, remains to be seen. Suffice it to say, however, that if history is any predictor, we should expect more regulation and perhaps even greater investigative and enforcement activity.

As we anticipate and prepare for this change, life goes on. This issue of the *Health Law Alert* includes articles which address continuing developments regarding RAC audits and our experience appealing those audits, the new PRRB rules for Medicare Part A appeals, AHRQ regulations creating patient safety organizations, and a variety of other issues. You will also find a discussion of the final 2009 Inpatient Prospective Payment System rules which happen to contain a number of significant changes to the Stark regulations.

We could add more, but we have stopped there in an effort not to overwhelm you with an extraordinarily lengthy *Health Law Alert*. Instead, we

will be issuing a separate *HLA Supplement* to accommodate summaries of the numerous OIG Advisory Opinions issued during 2008, along with summaries of the CMS Stark Advisory Opinions.

With respect to developments at Ober|Kaler, I am pleased to announce that effective January 1, 2009, Donna Senft was elected principal in our firm. Additionally, *Nightingale's* recently recognized several of our "outstanding" attorneys in its 2008 rankings. Alan Arville was named as one of the outstanding young health lawyers; Steve Smith was recognized as one of the outstanding health care transactional lawyers; Bill Berlin received a nod as one of the outstanding health care antitrust lawyers; and Paul Weidenfeld was named one of ten outstanding health care litigators.

Finally, please stay tuned for an announcement regarding the expansion of the efforts of our investigative and enforcement team, including Rich Westling, Paul Weidenfeld, James Holloway, and Chelsea Rice.

We value the comments and suggestions we receive from our readers and incorporate them into our efforts to maintain the quality and utility of the *Health Law Alert*. Please let us hear from you in that regard.

Sandy Teplitzky, Department Chair

Appealing RAC Audit Findings... FROM PAGE 1

overpayments. What CMS does not state, because CMS does not know yet, is how much of the $440 million will withstand administrative and judicial review. RACs have been overly aggressive in identifying overpayments largely because, as mandated by Congress, the RACs are paid on a contingency-fee basis. This means that the RACs will receive their compensation for each overpayment amount identified and upheld at the first level of the appeal process. In other words, the RACs will keep their fees even if their decisions are overturned at subsequent levels of the appeal process.

> *"Despite complaints and concerns raised by the medical community in the states affected by the RAC reviews through the conclusion of the demonstration in March 2008, CMS remains very supportive of the results of the RAC audits."*

Appeal Process after a RAC Finding

The Medicare claims appeal process, as revised in March 2005, requires providers and suppliers to pursue a four-step administrative review process prior to appealing to a federal court. Specifically, the first level of appeal is called a Redetermination, which is requested from the local contractor (e.g., carrier, fiscal intermediary, or Medicare Administrative Contractor) and is due within 120 days from the date that the initial denial notice is received. The local contractor is required to render a decision within 60 days. The next level of appeal is called a Reconsideration, which is requested from a qualified independent contractor (QIC) and is due within 180 days from the date the Redetermination is received. The QIC must issue a decision within 60 days.

If the decision from the QIC is unfavorable, then a request for a hearing before an administrative law judge (ALJ) of the Office of Medicare Hearings and Appeals (OMHA) can be made within 60 days from the date the Reconsideration is received. The ALJ will not consider any new evidence unless good cause is demonstrated. The ALJ must issue a decision within 90 days. If the ALJ's decision is unfavorable, then an appeal can be filed with the Medicare Appeals Council (MAC) of the Departmental Appeals Board (DAB) within 60 days from the date the ALJ's decision is received. The MAC generally has 90 days to render a decision. Finally, an unfavorable MAC decision can be appealed to a federal court within 60 days from the date that the unfavorable MAC decision is received.

In particular, five points should be noted about the RAC appeals:

- First, although a provider or supplier may request that the RAC rereview its decision before filing the first-level appeal (the Request for Redetermination), such rereviews by the RACs have not been very fruitful.

- Second, the local contractors surprisingly and consistently have agreed with the decisions of the RACs to essentially revise their prior initial determinations.

- Third, the second-level appeal (the Request for Reconsideration) is especially significant because, at this stage, the Medicare claims appeal regulations require a full and early presentation of all of the evidence that the provider or supplier plans to utilize for the remainder of the appeal process. Therefore, providers and suppliers must ensure that a complete record is filed with the QIC, including any new evidence that was not submitted or available at the lower appeal levels.

- Fourth, the ALJ hearing may be held live in one of the four field offices of OMHA (Arlington, Virginia; Cleveland, Ohio; Irvine, California; and Miami, Florida), by videoteleconference (VTC), or via telephone.

- Fifth, because of the backlog of appeals, some ALJs may request a waiver of the 90-day requirement. Not surprisingly, it can be quite difficult for OMHA to coordinate all of the participants in scheduling the hearing, hold the hearing, and then render a decision, all within 90 days from the date the appeal is received by OMHA.

ALJ Reviews of RAC Appeals

The earliest of the RAC audits recently reached the ALJ level of the appeal process and, despite the lack of success at the lower appeal levels, providers and suppliers have begun to see some relief from the ALJs. In addition, the RACs no longer will participate in ALJ hearings. It remains to be seen if CMS will continue to limit the RAC's participation. Furthermore, many of the RAC appeals that have reached the ALJ hearing level have been reversed based on the RAC's failure to demonstrate good cause to reopen claims that have been paid more than one year ago. Some ALJs rule favorably on the record based on this issue without even scheduling a hearing. Some ALJS schedule a preliminary hearing to solely address this issue.

> *"Unfortunately, until Congress or CMS reacts to the outrage of the medical community, providers and suppliers need to brace themselves for allocating and expending sufficient resources to address these RAC audits."*

In a decision dated February 29, 2008, the MAC ruled that the ALJ erred by requiring the local carrier to demonstrate good cause for reopening old claims pursuant to a post-payment probe audit *(In the case of Critical Care of North Jacksonville,* www.hhs.gov/dab/macdecision/Reopening 022908.pdf). This case raises three interesting questions:

- First, will the MAC, on its own motion as it did in this case, open and review some of the favorable ALJ decisions that were based on the RAC's lack of good cause to reopen old claims?

- Second, how will the MAC rule when some of the RAC cases finally reach the MAC appeal level?

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Guide to Terms

The following guide to frequently used acronyms may assist you in reading this issue of the *Health Law Alert*.

ALF	Assisted Living Facility
BIPA	Benefits Improvement and Beneficiary Protection Act of 2000
BBA	Balanced Budget Act of 1997
BBRA	Balanced Budget Refinement Act of 1999
CMP	Civil Monetary Penalty
CMS	Centers for Medicare and Medicaid Services
DME	Durable Medical Equipment
DOJ	U.S. Department of Justice
DRA	Deficit Reduction Act of 2005
EHR	Electronic Health Records
EMTALA	Emergency Medical Treatment and Active Labor Act
FCA	Federal False Claims Act
GAO	Government Accountability Office
HHA	Home Health Agency
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
HMO	Health Maintenance Organization
MCO	Managed Care Organization
MMA	Medicare Prescription Drug, Improvement and Modernization Act of 2003
OIG	Office of Inspector General of the Department of Health and Human Services
PAP	Patient Assistance Program
PPS	Prospective Payment System
SNF	Skilled Nursing Facility

Appealing RAC Audit Findings… FROM PAGE 3

- Third, how will the ALJs rule now, given this new and recent MAC decision?

Despite this daunting decision from the MAC, there are several and various ways to address and counter arguments questioning the ALJ's authority or jurisdiction to consider evidence regarding good cause. What remains clear is that other MAC decisions have reached different conclusions with respect to the issue of reopening old claims, some of which directly contradict the Critical Care decision. Also, the RACs have begun to articulate different and lengthier reasons for reopening old claims. Hence, providers and suppliers should continue to raise the issue of good cause to the local contractors, the QICs and the ALJs, even though the ALJ hearing most likely will be the first forum at which this argument will be addressed.

> *"Despite the availability of some relief pursuant to the appeal process, providers and suppliers should be proactive and attempt to prevent claims from being subject to the RACs through careful medical documentation and correct coding practices."*

Recently, some of the ALJs have begun to retain the services of independent experts to assist in determining whether or not the service denied by a RAC was reasonable and necessary. Fortunately, these expert witnesses generally have been favorable to the providers and suppliers to date. Thus, in addition to successful preliminary legal challenges, the use by the ALJs of their own experts may offer further relief through the appeal process.

Despite the availability of some relief pursuant to the appeal process, providers and suppliers should be proactive and attempt to prevent claims from being subject to the RACs through careful medical documentation and correct coding practices.

RAC Statement of Work

It should be helpful that CMS has promulgated an amended Statement of Work (SOW) in November 2007, which will define what RACs are expected to do under their contracts with CMS. More importantly, the amended SOW imposes some specific limitations and restrictions on RACs that should help reign in these bounty hunters for the permanent RAC program.

RAC responsibilities. CMS has announced that the CC area will be divided into four regions and that there will be one RAC per region. Each RAC will be required to submit a project plan to CMS in which it identifies the issues the RAC will be focusing on that year. As new issues are identified, the RAC must update the project plan to describe the vulnerability issue to CMS. Conference calls between the RAC's key project staff and CMS must occur twice per month, indicating close CMS oversight of RACs. As part of these monthly meetings, each RAC must submit both administrative and financial progress reports to CMS. In its administrative reports, RACs will be expected to identify problems experienced and recommend corrective actions to CMS, such as changes to local coverage determinations (LCDs), system edits, or provider education. Financial progress reports will keep CMS apprised of the amount of improper payments identified on a continuing basis and track the timeliness of medical reviews.

Review limited to Medicare fee-for-service program. Under the new SOW, RACs may attempt to identify improper payments that result from:

(1) Incorrect payment amounts;
(2) Noncovered services, such as a lack of medical necessity;
(3) Incorrectly coded services; or
(4) Duplicate services.

RACs, however, may not attempt to identify improper payments arising from services provided under any program other than a Medicare fee-for-service program. For example, RACs may not investigate a Medicare managed care program or a Medicare drug card program or drug benefit program. RACs also are prohibited from looking into the cost report settlement process and, therefore, may not attempt to identify improper payments that result from indirect medical education (IME) or graduate medical education (GME) payments.

Review of older claims. CMS also has limited the ability of RACs to review older claims. Under the amended SOW, RACs may not attempt to identify improper payments relating to any claims paid more than three years before the date the RAC issues its written request for medical records. Significantly, this three-year look back period is further curtailed in that all claims with paid dates prior to October 1, 2007, will be considered time-barred. So, for example, a request for medical records made by a RAC in December 2008 will only be permitted to request records for claims paid between October 1, 2007, and December 31, 2008.

Limitation on number of medical records. In addition to limiting the time period during which a RAC may investigate claims, CMS also will place restrictions on the number of medical records a RAC may request. They will vary

depending on the provider involved and the time period covered by the request. As an example of what the limits will look like, the SOW states that a RAC would be prohibited from requesting more than 50 medical records from a 150-249 bed hospital within the same 45-day period.

Obtaining medical records. RACs may obtain medical records either by going onsite to a provider's location or by requesting the provider to copy and transmit the records. If a RAC representative shows up onsite, however, the provider should not permit that individual to have access to medical records. There are several reasons to defend the perimeter from a RAC attack in this manner.

First, the new SOW expressly states that: "If the RAC attempts an onsite visit and the provider refuses to allow access to the facility, the RAC may not make an overpayment determination based upon the lack of access." Instead, the RAC will be required to request specific records in a letter. This will permit the provider to have a record for purposes of barring older claims under the three-year look back provision, keep a record of what claims have been reviewed by the RAC, and may be the only way to make sure the RAC limits its review to the quantity of records directed by CMS.

Second, RACs are required under the new SOW to pay most providers for copying medical records. Allowing them to access medical records onsite may not permit the provider to capture these charges.

Finally, requiring RACs to request medical records without seeing them first ensures the records requested are not "hand picked" for review. RACs generally have 60 days from receipt of medical records to complete their reviews. Extensions of time will require the RAC to obtain a waiver from CMS.

Conclusion

Unfortunately, until Congress or CMS reacts to the outrage of the medical community, providers and suppliers need to brace themselves for allocating and expending sufficient resources to address these RAC audits. Specifically, providers and suppliers should identify and task at least one individual to centrally coordinate and track the record request from the RAC. Likewise, the appeal process should be diligently documented so that untimely Redetermination and Reconsideration decisions may be followed up. Given the volume of claims appeals, including those not stemming from RAC audits, some correspondences from the Medicare contractor and QIC inevitably may become lost or misdirected, forcing the provider or supplier to demonstrate good cause to pursue an unfavorable decision to the next appeal level. Finally, providers should take advantage of the right to submit all evidence, including new information, to the QIC. A consultant's analysis and report of the medical records (if not the beneficiary), albeit recent, may just be what is needed to help establish medical necessity. ■

This article is based on two articles that Mr. Kim collaborated on for Ober|Kaler's e-newsletter Payment Matters™. *Those articles, "RAC Attack" (October 24, 2007) and "RAC Attacks: News from the Front" (December 4, 2007) are available at www.ober.com/shared_resources/news/newsletters_archives/newsletters_pm/.*

Congratulations

Donna J. Senft *has been elected a principal at Ober|Kaler. Donna joined the firm's Health Law Group in 2000 as a law clerk and became an associate the following year. Focusing her practice on health care regulatory matters, she represents various providers, including nursing facilities, home health agencies, hospices, adult day care centers, rehabilitation agencies and DME suppliers, in Medicare and Medicaid certification and compliance issues, billing and reimbursement, and state licensure. She also advises providers and practitioners regarding acquisitions and internal reorganizations, coding and payment issues, licensure matters, peer review and professional standards. Prior to law school, Donna used her degree in physical therapy to provide more than twenty years of clinical and administrative services to rehabilitation departments in various health care settings, including five years of consultative services to nursing facilities and other long term care settings throughout the country. Donna is a graduate of the University of Baltimore School of Law (J.D.,* magna cum laude, *2001) and the University of Pittsburgh (B.S.,* summa cum laude, *1978).*

CMS

Will Online Medicare Enrollment Facilitate Processing?

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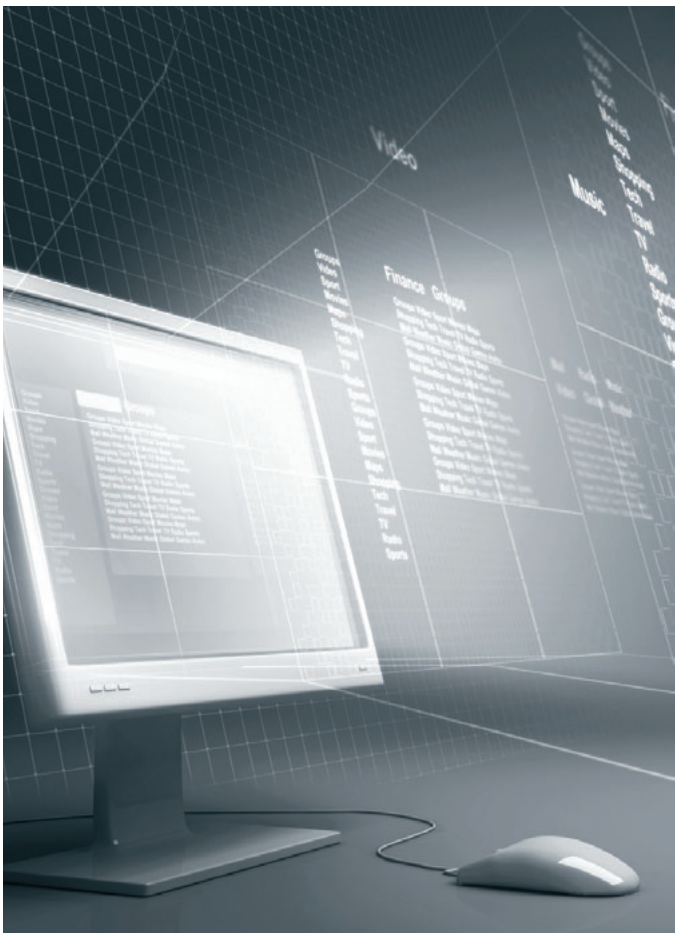

Although previously announced as a 2008 initiative, CMS delayed the roll-out of its online enterprise enrollment applications to early this year. The online enrollment process is designed to allow fee-for-service providers and non-DMEPOS suppliers to enroll in Medicare, access enrollment data, and provide updates to an existing enrollment via the Internet. CMS has not announced whether DMEPOS suppliers will be eligible for an online enrollment process in the future, only that there are no online enrollment applications for DMEPOS suppliers at this time. This article focuses on the registration process to become an approved user to access the online applications.

For purposes of discussing the online enrollment process, CMS refers to both Part A providers and Part B non-DMEPOS suppliers collectively as providers. This common reference to providers, however, appears to be the only aspect of this new enrollment process that has been simplified. In addition to rather complex educational materials and guides, CMS has created numerous defined terms which must be learned to master the registration process. For example, organization may include a physician or other individual practitioner and not just enrolled entities such as institutional providers and group practices. The following is a list of these key terms:

IACS-PC or *Individuals Authorized Access to the CMS Computer Services – Provider Community* is a combination of the security system CMS uses to register users and control the issuance of user identifications, passwords, and specific access to web-based applications (IACS); and reference to the provider and supplier communities (PC) that will be required to use the online system to access data.

Organization includes providers and suppliers such as hospitals, HHAs, SNFs, IDTFs, ASCs, ambulance companies and physician group practices, in addition to individual physicians and nonphysician practitioners who want to delegate staff to conduct transactions on their behalf.

Security Official or *SO* refers to the individual who can register the organization in the IACS and update the organization's profile information. The SO must register and become an approved user and then will be able to authorize others to register as certain types of users. The system allows for only one SO per organization.

Back-up Security Official or *BSO* is an optional user type and may include one or more individuals who, once approved as a user, may assist the SO in authorizing others to register as certain types of users.

User Group Administrator or *UGA* refers to the individual or individuals that may have access to the online applications, depending upon the specific role designated for each application. The UGA will establish a User Group and will be able to authorize End Users for that group.

End User refers to a staff member or contractor working for an organization trusted to access the online applications. An individual may be an End User for multiple organizations. For example, an organization that operates a hospital, SNF and HHA may have the same corporate employee function as an End User for each of the organization's User Groups.

Surrogate User Group applies to situations in which the organization wants to delegate online work to individuals or a company outside of the provider organization, such as clearinghouses, credentialing departments and independent contractors. The Surrogate User Group has a contractual business relationship with the organization but not with CMS. A Surrogate User Group may be associated with multiple organizations. For example, many providers request Ober|Kaler to prepare and file Medicare enrollment updates, currently done via completion of the CMS 855 forms. The same Ober|Kaler attorney could serve as the UGA of a Surrogate User Group that is associated with multiple providers.

Application Approver refers to the one or more persons that will approve each Application User's request for a specific role applicable to a particular online application. For each online application, an organization is to designate an Application Approver. The role of Application Approver is often filled by the UGA, but should an organization fail to designate an Application Approver for any enrollment application, the SO or BSO will become the Application Approver by default. The Application Approver is not able to access the online applications, however, which is why neither the SO or BSO is granted such access. Individual practitioners who do not designate staff to assist in completing online enrollments do not have an Application Approver, since the practitioner personally completes the application.

Application User refers to the individual or individuals granted the right to access a particular online application. Within the category of Application Users, different rights may be granted to the user. Some Application Users may be granted only viewing and printing rights, while other Application Users would be approved to enter, edit and submit data to CMS.

CMS will notify provider communities as the web-based applications become available, with clear instructions regarding which provider types should register in IACS. Prior to receiving this notification, providers should not attempt to register. This is a change from the initial series of MLN Matters articles on this subject that encouraged providers to register early, before access to the online services was available. Providers will be able to both access and update enrollment data, in addition to authorizing others to conduct certain transactions on the provider's behalf, such as a clearinghouse or credentialing department. CMS expects users will periodically access the provider enrollment data and, therefore, determined that a user password will expire if the system is not accessed over a 60-day period. Should the password expire, the user will be prompted to create a new password the next time the user logs into the system.

The first step in the registration process will be for to register as a user, which will require the SO to disclose information about the organization in addition to the SO's social security number and date of birth. Once the SO is an approved user, the SO will be able to authorize the BSO, if applicable, the UGAs and Application Approvers to register. Once the UGA is a registered user, the UGA will be able to authorize End Users to register. CMS recognizes that an individual may serve in more than one user role for an organization, so at a minimum the organization will need at least two authorized users, i.e., an SO and UGA, with only the UGA having access to the online applications in this situation. When the plan is to serve in multiple roles, an individual will register under one role and will then be able to add roles once an approved user. Irrespective of how an individual becomes an authorized user for the organization, CMS intends to hold the SO accountable for the behaviors of any approved organization user.

> *"CMS's online enrollment process is designed to allow fee-for-service providers and non-DMEPOS suppliers to enroll in Medicare, access enrollment data, and provide updates to an existing enrollment via the Internet."*

CMS has issued three MLN Matters articles that provide an overview of the IACS system and registration procedures. These articles have undergone some updates, the most recent being July 30, 2008. The first article (MLN Matters No. SE0747) provides an overview of the IACS-PC registration process and registration instructions for SOs and individual practitioners. The second article (MLN Matters No. SE0753) provides instructions for registering BSOs, UGAs, and End Users. The third article (MLN Matters No. SE0754) discusses the final steps in accessing CMS enterprise applications. The articles are supplemented by a series of Quick Reference Guides that are designed to assist the various user types to navigate through IACS. Additionally, CMS has a Reference Chart for Organizations that provides a one-page overview of the various user roles, including who can authorize the individual to access IACS and become an approved user, and the ability of each user type to access the online applications. These reference materials are available on CMS's website at www.cms.hhs.gov/IACS/04_Provider_Community.asp. ■

HOSPITALS

AHRQ Regs Create Patient Safety Organizations

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On November 21, 2008, HHS's Agency for Healthcare Research and Quality (AHRQ) issued final regulations creating patient safety organizations (PSOs) to implement certain provisions of the Patient Safety and Quality Improvement Act of 2005, Pub. L. 109-41, 119 Stat. 424, which was signed into law on July 29, 2005 (the Act). *See* 73 Fed. Reg. 70,732 (Nov. 21, 2008). The Act addresses the issues of improving patient safety and reducing the incidence of events that adversely affect patient safety, and contemplates the establishment of a system for voluntary reporting of patient safety information to PSOs. The proposed regulations were issued on February 12, 2008, and the comment period ended on April 14, 2008. *See* 73 Fed. Reg. 8112 (Feb. 12, 2008). The final rule is effective as of January 19, 2009.

While it was a long-awaited piece of legislation by the time it was signed into law, the Act left several issues unanswered — namely how the PSOs would be established; who would be responsible for overseeing the PSOs; how contracting with PSOs would work; and how the confidentiality and privilege protections would specifically apply to information collected for, reported to, and analyzed by the PSOs. The new rule attempts to address and clarify these issues. Specifically, the rule outlines the steps for the establishment and certification of PSOs and discusses in further detail the confidentiality and privilege protections that attach to patient safety work product (PSWP) that is collected for and by the PSOs. Several provisions of the final rule restate and clarify the requirements contained in the Act. Below we discuss three significant aspects of the new PSO rule: (1) certification and listing of PSOs, (2) functional reporting, and (3) patient safety evaluation systems.

Overview

The final rule permits various types of entities to become PSOs — public, private, for-profit and not-for-profit organizations. Entities that are listed as PSOs will not receive any sort of federal funding but will be permitted to offer individual and institutional providers the benefits of review and analysis of PSWP that is protected by the confidentiality and privilege protections contained in the regulations. The rule discusses the process by which an entity becomes certified and is listed as a PSO, and how and in what form information would be collected and reported to the PSOs. The PSOs aggregate and analyze the PSWP and report trends to the providers with which they have agreements, and also provide guidance to those providers regarding how to eliminate or minimize the occurrence of such errors within their organizations. Thus, not only will PSOs serve to collect patient safety information but PSOs may also assist providers in establishing effective strategies to improve patient safety as well as approaches for implementing such strategies.

Finally, as a way to encourage providers to undertake patient safety activities, the final rule, as in the Act, specifically provides for confidentiality and privilege protections for patient safety work product and provides for a civil money penalty of up to $10,000 to be imposed on persons who breach these provisions.

PSOs, Certification Requirements, and Procedures for Certification and Listing of PSOs

Who Can Seek Listing as a PSO

AHRQ intends that any provider who is capable of meeting the certification requirement may seek to be listed as a PSO, provided that the provider does not fall within the rule's list of excluded entities. Components of excluded entities (discussed further below), however, may seek to be listed as PSOs but must meet additional certification requirements, which are intended to ensure the separateness of such component organizations from their affiliated excluded entity.

Section 3.102(a)(2) of the final rule retains the statutory exclusions from listing of health insurance issuers and components of health insurance issuers and, for clarity, restates the exclusion to reflect the rule's definition of *component* so it now references a health insurance issuer, a unit or division of a health insurance issuer, or an entity that is owned, managed, or controlled by a health insurance issuer. The final rule excludes from listing any entity that (1) accredits or licenses health care providers; (2) oversees or enforces statutory or regulatory requirements governing the delivery of health care services; (3) acts as an agent of a regulatory entity by assisting in the conduct of that entity's oversight to enforcement responsibilities vis-à-vis the delivery of health care services and (4) operates a federal, state, local, or tribal patient safety reporting system to which health care providers are required to report information by law or regulation. The final rule includes two additional exclusions that were not in the proposed rule: (1) entities that serve as agents of a regulatory entity (e.g., by conducting site visits or investigation for the regulatory entity) and (2) entities that operate certain mandatory or voluntary patient safety reporting systems. AHRQ notes, however, that the latter exclusion does not apply to mandatory reporting systems operated by federal, state, local or tribal entities if the reporting requirements affect only their own workforce (defined in the final rule as employees, volunteers, trainees, contractors or other persons whose conduct, in performance of work for a provider, PSO or responsible person, is under direct control of such provider, PSO or responsible person, whether or not they are paid by the provider, PSO or responsible person) and health care providers holding privileges with the entity. Rather, this exclusion is intended to apply to federal, state, local or tribal health care facilities in which the reporting requirements applies only to its workforce and health care providers holding privileges with the facility or health care system.

Certification Requirements

In accordance with the Act, the final rule establishes an attestation-based process for initial and continued listing of an entity as a PSO. Among other things, an entity seeking listing must (1) attest that it is not subject to any of the exclusions listed in the regulations (discussed further below) and (2) attest that it will disclose to the Secretary HHS whether it has ever been denied listing or delisted, or if the officials or senior managers of the entity now seeking listing have held comparable positions in a PSO that has been delisted or has been refused listing by the Secretary.

All entities seeking initial or continued listing as a PSO must meet fifteen general certification requirements: eight requirements relating to patient safety activities (which entities certify that they have policies and procedures to follow at initial listing and at subsequent requests for continued listing) and seven requirements governing their operation (with which an entity seeking initial listing, and a PSO seeking continued listing, must certify that it is complying and will continue to comply). As an additional protection for providers who report information to a PSO, the final rule requires that a PSO inform a provider from which it received PSWP in the event the work product submitted by the provider is inappropriately disclosed or its security is breached.

> *"Entities that are listed as PSOs will not receive any sort of federal funding but will be permitted to offer individual and institutional providers the benefits of review and analysis of patient safety work product that is protected by the confidentiality and privilege protections contained in the regulations."*

Minimum Contracts

Among other things, an entity seeking initial listing and an entity seeking continued listing must certify that within the 24-month period that begins on the date of its initial listing as a PSO, and within each subsequent 24-month period thereafter, the PSO must have two bona fide contracts, each of a reasonable time period, each with a different provider for the purpose of receiving and reviewing PSWP. AHRQ states that while one contract with more than one provider would not meet this standard, two contracts with the same hospital system but with different facilities would meet the requirement, because the statutory requirement was intended to encourage PSOs to aggregate data from multiple providers. For example, one contract with a 50-hospital system would not meet this standard; however, two 25-hospital contracts with that same hospital system would meet this requirement.

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Additional Certifications for Component Organizations

In addition to the fifteen general certification requirements, the final rule, consistent with the Act, requires that component organizations meet three additional requirements to be listed as PSOs. The three additional certifications address the entity's independent operation and separateness from the larger organization or enterprise of which it is a part; the entity would certify to: (1) the secure maintenance of documents and information separate from the rest of the organization(s) or enterprise of which it is a part; (2) the avoidance of unauthorized disclosure to the organizations(s) or enterprise of which it is a part; and (3) the absence of a conflict of interest between its mission and the rest of the organization(s) or enterprise of which it is a part. A component entity, at initial and continued listing, must also submit contact information for its parent organization(s) with its certifications.

"While one contract with more than one provider would not meet the minimum contracts requirement, two contracts with the same hospital system but with different facilities would meet the standard, because the statutory requirement was intended to encourage PSOs to aggregate data from multiple providers."

Among the issues not addressed by the Act that the final rule attempts to clarify is the extent of appropriate security measures that an entity seeking listing as a component PSO must take to ensure separation of reported PSWP from the organization of which it is a part. The proposed rule contained two requirements that were deleted from the final rule: (1) the requirement for separate information systems and (2) the restriction on use of shared staff between a component entity and its parent/affiliated organizations(s). With regard to the latter requirement, the prohibition on shared staff is imposed only with respect to components of entities that are excluded from listing.

Compliance with Certification Requirements

In the final rule, AHRQ summarizes its approach to assessing compliance with the certification requirements. In recognition of the fact that for any given contractual arrangement, providers, not PSOs, will determine the tasks PSOs undertake and for which PSOs will get compensated, AHRQ states that, upon a spot check, a PSO must be able to demonstrate that is has performed all eight patient activities at some point during its three-year listing period. That is, while the Department will require demonstration that the PSO performed throughout its listing period the patient safety activities that are not dependent on a relationship with a provider or receipt of patient safety work product, compliance will be deemed if the PSO can demonstrate that it performed the requirements that are other-provider- and PSWP-dependent at some point during its listing period.

Continued Listing

The final rule requires that submissions for continued listing must be received by the Secretary of HHS no later than 75 days before the expiration of a PSO's three-year period of listing. This requirement is intended to protect providers in the event that a PSO decides not to seek continued listing and simply lets its certification expire at the end of the three-year listing period.

Expedited Revocation

The final rule contains provisions, which were not contained in the proposed rule, that establish an expedited revocation process that is available to the Secretary of HHS in three limited circumstances: (1) if the Secretary of HHS determines that a PSO is or is about to become an entity that is excluded from listing; (2) when the parent organization of a PSO is an excluded entity and the parent org uses its authority over providers to require or induce them to use the patient safety services of its component PSO; and (3) when the Secretary has determined that the failure to act promptly would lead to serious adverse consequences (i.e., if a PSO demonstrates reckless or willful misconduct in its protection or use of PSWP, or when the PSO engages in fraudulent or illegal conduct). AHRQ believes that the inclusion of this provision in the final rule will enable providers to have confidence that HHS will act in a timely manner when a PSO chooses not to meet its statutory and regulatory obligations.

Patient Safety Work Product and Functional Reporting

Patient Safety Work Product (PSWP) refers to the information to which the privilege and confidentiality protections apply. The final rule imports the statutory definition of this term. PSWP is any data, reports, records, memoranda, analyses (such as root cause analysis) or written or oral statements (or copies of any of this material) (i) which could improve patient safety, health care quality, or health care outcomes; and (A) which are assembled or developed by a provider for reporting to a PSO and are reported to a PSO; or (B) are developed by a PSO for the conduct of patient safety activities; or (ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system (discussed further below). Excluded from PSWP are a patient's original medical record, billing and discharge information, or any other original patient or provider infor-

mation and any information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. With regard to functional reporting, while AHRQ clarifies in the preamble to the final rule that reporting of information to a PSO for the purpose of creating PSWP may include authorizing PSO access, pursuant to a contract or other agreement between a provider and PSO, to specific information in a PSES and the authority to analyze and process such information, AHRQ does not believe that a formal change in the regulatory text is necessary to include such a clarification. Additionally, the final rule's definition of PSWP includes language that protects information based upon reporting to a PSO or documentation that information was collected within a PSES.

The proposed rule provided that *reporting to* means "the actual transmission or transfer of information to a PSO." Recognizing the significant transmission, management, and storage burdens imposed on providers by requiring the transmission to a PSO of every document or file related to PSWP, AHRQ sought comments on whether alternatives for actual reporting should be recognized as sufficient to meet the reporting requirement. That is, AHRQ asked whether a provider that contracts with a PSO should be deemed to have functionally reported information to a PSO if it provides access to and gives control of information to a PSO without physically transmitting information to the PSO. Though the regulatory language regarding functional reporting is unchanged, AHRQ clarifies in the preamble to the final rule that the reporting of information to a PSO for the purposes of creating PSWP may include authorizing PSO access, pursuant to a contract of equivalent agreement between a provider and a PSO, to specific information in a patient safety evaluation system (PSES) and authority to process and analyze that information, for example, comparable to the authority a PSO would have if the information were physically transmitted to the PSO.

Further recognizing the importance of the shortcomings of a strict reporting requirement in determining when the confidentiality and privilege protections should attach to certain information (thus making it PSWP), and based on the belief that such protections should attach in a manner that is as "administratively flexible as permissible to accommodate the many business processes and systems of providers," the final rule provides that information documented as collected within a PSES by a provider should be protected as PSWP. In other words, the final rule permits functional reporting.

Confidentiality and Privilege Protections

Generally, the privilege and confidentiality provisions contained in the final rule do not differ from those contained in the Act. As in the Act, the rule provides that PSWP is privileged and generally shall not be admitted as evidence in federal, state, local, or tribal civil, criminal, or administrative proceedings and shall not be subject to a subpoena or order, unless an exception (which are enumerated in the final regulation) to the privilege applies. Further, the final rule provides that PSWP is confidential and shall not be disclosed except as permitted in accordance with the disclosures described. Under the final rule, PSWP may continue to be privileged and confidential even after disclosure in certain situations, including, but not limited to, disclosure to or by the Secretary of HHS as necessary to investigate or determine compliance with or to impose a civil monetary penalty under the HIPAA Privacy Rule.

The final rule provides that the privilege and confidentiality protections continue to apply to PSWP following disclosure and also describes the narrow circumstances under which the protections terminate. The final rule does not require that PSWP be labeled or that disclosing parties provide recipients of PSWP with notice that they are receiving protected information, because AHRQ views such requirements as overly burdensome. AHRQ states its expectation, however, that providers, PSOs and responsible persons holding PSWP treat and safeguard such sensitive information appropriately and encourages such individuals to consider whether labeling or notice may be an appropriate safeguard in certain circumstances.

> *"Entities are strongly advised to document their PSES to help ensure that they are able to avail themselves fully of the significant protections provided by the Patient Safety and Quality Improvement Act and the implementing regulations."*

Patient Safety Evaluation System and Documentation

Patient Safety Evaluation System refers to the collection, management, or analysis of information for reporting to or by a PSO. The proposed rule sought comment about whether a PSES should be required to be documented. In response to the comments received, the final rule does not require such documentation. AHRQ expressly states, however, its belief that documentation is a best practice, and, therefore, encourages providers to document how information enters the PSES; what processes, activities, physical space(s) and equipment comprise or are used by the PSES; which personnel or categories of personnel need access to PSWP to carry out their duties involving operation of, or interaction with the PSES; the category of PSWP to which access is needed and any conditions appropriate

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to such access; and what procedures the PSES uses to report information to a PSO or disseminate information outside of the PSES.

Entities are strongly advised to document their PSES. The Act and the regulations provide significant protections for PSWP and documentation would help ensure that providers are able to avail themselves fully of these protections. The definition of PSWP in the final rule clarifies that documentation of a PSES clearly establishes when information is PSWP. Accordingly, providers would be well-served to document their PSES for the following reasons: (1) documentation can give providers greater assurance that the information they intend to be considered PSWP will be, in fact, considered PSWP and thus be considered confidential and privileged; (2) pursuant to such documentation, providers can ensure that the statutory requirements (for ensuring the confidentiality and privilege of their information) are fully met; and (3) documentation offers providers greater certainty that a provider's claim to the statutory protections provided by the Act for certain information, if challenged will be sustained.

> *"The opportunity for a provider to report identifiable PSWP to a PSO does not relieve a provider that is a HIPAA covered entity from its obligations under the HIPAA Privacy Rule."*

PSOs and HIPAA

The final rule states that the opportunity for a provider to report identifiable PSWP to a PSO does not relieve a provider that is a HIPAA covered entity from its obligations under the HIPAA Privacy Rule. In fact, under the PSQIA, PSOs are deemed to be business associates of providers that are HIPAA covered entities. Accordingly, such providers must enter into business associate agreements with the PSOs in accordance with their obligations under the HIPAA Privacy Rule. Such agreements may be entered into simultaneously as an agreement for the conduct of patient safety activities. To receive the protections of the PSQIA, however, a provider is not required to enter into a contract with a PSO.

The final rule requires providers, PSOs and holders of PSWP to disclose PSWP to the Secretary of HHS upon a determination by the Secretary that such PSWP is needed for the investigation and enforcement of activities related to the PSQIA, is needed in seeking and imposing civil monetary penalties, or is needed for investigation and enforcement activities with respect to the HIPAA Privacy Rule.

Conclusion

While there were issues that were left unaddressed when the Patient Safety and Quality Improvement Act was enacted in 2005, the final rule serves to fill many of these gaps with respect to PSOs. With the promulgation of this rule, providers now have a concrete idea of how the PSOs and reporting PSWP to PSOs will work. The final rule further emphasizes to providers HHS's commitment to addressing patient safety issues. With the establishment of PSOs and the confidentiality and privilege protection for PSWP, providers now have a vehicle through which they may address patient safety incidents and near misses without the fear of negative actions resulting from their attempts to better their institutions and practices. It is important for providers to establish relationships with PSOs and to begin to establish their PSESs in order to avail themselves of this opportunity to address patient safety issues and, in doing so, increase the quality of care they provide to their patients. ■

[i] *Component Organization* refers to an entity that (1) is a unit or division of a legal entity (including a corporation, partnership, or a federal, state, local, or tribal agency or organization); or (2) is owned, managed or controlled by one or more legally separated parent organizations.

[ii] *Patient Safety Activities* refers to the following activities: efforts to improve patient safety and quality; the collection and analysis of patient safety work product; the development and dissemination of information with respect to improving patient safety; the utilization of patient safety work product for the purposes of encouraging a culture of safety and providing feedback and assistance; the utilization of qualified staff; the operation of a patient safety evaluation system; the preservation of confidentiality of patient safety work product; and the provision of appropriate security measures for patient safety work product.

[iii] See definition of *patient safety activities* at n.2.

Employers Need to Know

Ober|Kaler's Employment & Labor Group has published two timely and critical alerts for employers.

- *"Revised Family and Medical Leave Act (FMLA) Regulations Take Effect" examines changes to FMLA and the steps employers can take to comply with the new rules.*

  See: *www.ober.com/shared_resources/news/newsletters/entk/employersneedtoknow-020309.html*

- *"FOIA Requests Under the Obama Administration" discusses how the new administration has changed the way the government will respond to requests for information under the Freedom of Information Act.*

  See: *www.ober.com/shared_resources/news/newsletters/entk/employersneedtoknow-012309.html*

HOSPITALS

D.C. Circuit Ruling May Imperil Future Charity Care Days Litigation

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In the recently decided *Adena Regional Medical Center v. Leavitt*, 527 F.3d 176 (D.C. Cir. 2008), the United States Court of Appeals for D.C. Circuit Court rejected the provider's inclusion of certain "Charity Care Days" (CCDs) in the calculation of Medicare Disproportionate Share Hospital (DSH) payments. The brief decision may have reversed what had seemed to be a promising trend in DSH litigation.

Medicare DSH payments are made to support hospitals who treat a disproportionate share of indigent (non-Medicare) patients. The payments, calculated on the number of "patient care days" each hospital provides to indigent patients, often prove vital to the survival of hospitals in critical service areas facing large numbers of patients who are simply unable to pay their bills.

As is usually the case in the Medicare reimbursement universe, the overarching theory behind the payments may be simple, but the devil is in the details. When Congress decided to support hospitals serving large numbers of indigent patients, it elected to use hospitals' number of Medicaid patients as a proxy for the number of indigent patients the hospital served (since Medicaid patients are, by definition, indigent). Accordingly, a formula was developed that is heavily dependant on the number of patient care days attributable to patients who, under the statutory language, are "eligible for medical assistance under a State plan approved under Title XIX."

State medical assistance plans became synonymous with "Medicaid" (and Congress, in picking its language, picked so carefully) because, before receiving federal Medicaid funds, state MA programs must submit a detailed plan as to how they are going to spend those funds (the State Plan). That state plan is reviewed by CMS to ensure that the state has planned to spend its federal funds in a way that appropriately reflects federal guidelines.

> "Adena *will likely force all DSH litigation out of D.C. courts and into other jurisdictions, where provider will face an uphill battle in their efforts to overcome the results of the* Adena *decision.*"

As part of their State Plans, many states include programs in addition to the very basic care to the most needy individuals that the federal government requires (programs often called "Medicaid" or "Traditional Medicaid"). These programs can take many forms — Charity Care days (in which care is provided free, or at a reduced rate), Medicaid expansion populations, or other "non-traditional" means of providing low- or no-income populations with necessary health care. These programs are not "Medicaid" (as that term is traditionally used) in that they are not "Traditional Medicaid" but they are Medicaid (as that term is properly used) in that they are part of a "a State plan approved under Title XIX" and are at least partially funded by monies provided by the federal Medicaid program. It is these non-traditional patient groups, specifically those who receive Charity Care, that lie at the center of the DSH debate between providers and CMS.

Battles have been fought (and lost) by the Secretary over patients who were eligible for but were not currently receiving Medicaid (*see*, e.g., *Incarnate Word Health Services Fort Worth Healthcare Corp. v. Shalala, Cookeville Reg'l Med. Ctr. v. Leavitt* (not reported in F. Supp., 1997 WL 446463 (N.D. Tex. July 25, 1997)), patients who were members of Section 1115 Waiver populations (*see*, e.g., *Portland Adventist Med. Ctr. v. Thompson*, 399 F.3d 1091 (9th Cir. 2005)), and, most recently, patients who ▸ PAGE 14

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received "Charity Care" or other "state funded" reduced-cost or no-cost hospital care. During these disputes, CMS has maintained (or maintains) a two fold position: A) the wording of the statute aside, what Congress *actually meant* was to offer DSH payments based on the number of patients who were receiving Traditional Medicaid, and B) that any form of reimbursement other than Traditional Medicaid's fee-for-service model was not, in fact, medical assistance. Accordingly, according to CMS, only recipients of Traditional Medicaid, whose hospital stays were actually paid by Traditional Medicaid, should be counted in order to arrive at each hospital's Medicare DSH amount.

CMS has been largely unsuccessful with these arguments. The district court in *Adena* (where Ohio's Charity Care program — HCAP — was under attack) wrote perhaps one of the most detailed critiques of CMS's position yet, citing to CMS's historic hostility and the clear statutory language and intent, and rejecting entirely CMS's argument that "eligible for medical assistance under a State plan approved under Title XIX" meant the same thing as "receiving Medicaid." As the district court explained:

> Congress said what it meant; if Congress had meant to restrict the Numerator to Medicaid-eligible patients, it could have explicitly done so. The phrase 'eligible for medical assistance under a state plan approved under Title XIX' is not 'long-hand' for 'eligible for Medicaid.' It is undisputed that HCAP is a 'state plan approved under Title XIX.' Accordingly, the Secretary's exclusion of HCAP patients is inconsistent with the plain language of the statute and cannot be upheld.

524 F. Supp. 2d 1, 4 (D.D.C. 2007).

Congratulations

Thomas W. Coons, S. Craig Holden, Leonard C. Homer, Howard L. Sollins *and* ***Sanford V. Teplitzky*** *have been named in* Maryland Super Lawyers 2009.

Nightingales Healthcare News *has named the following Health Law Group members in recent rankings of the nation's top attorneys:*

- ***William E. Berlin****:*
  "Outstanding Healthcare Antitrust Lawyers — 2008"
- ***Steven R. Smith****:*
  "Outstanding Healthcare Transaction Lawyers — 2008"
- ***Alan J. Arville****:*
  "Outstanding Young Healthcare Lawyer — 2008"
- ***Paul S. Weidenfeld****:*
  "Outstanding Healthcare Litigator — 2008"

Unfortunately, for providers who are currently embroiled in, or are considering bringing a DSH case revolving around a state Charity Care program, the D.C. Circuit Court did not agree. In the very first sentence of its analysis, the court substituted the word "Medicaid" for the original statutory text "medical assistance under a State plan approved under subchapter XIX…" essentially confirming CMS's position on one of the most complex and heavily debated DSH issues in a single word. Having conflated "Medicaid" and "medical assistance," the court went on to conclude that Ohio's Charity Care (HCAP) provisions were not part of a Medicaid-approved plan. HCAP (as in almost every Charity Care program) patients were, by definition, not eligible for "Traditional Medicaid," and hospitals are required to care for eligible patients "without payment" from Traditional Medicaid.

> *"As is usually the case in the Medicare reimbursement universe, the overarching theory behind Medicare DSH payments may be simple, but the devil is in the details."*

The court agreed with CMS that, in order to prevail, the hospitals would have needed to demonstrate that HCAP patients were "'eligible for medical assistance under a State plan approved under [Medicaid]' within the meaning of that phrase in the Medicare statute." The court then ruled that the term "medical assistance" must have the same meaning in Title XVIII [i.e., Medicare] as it does in Title XIX, which defines *medical assistance* as "payment of part or all of the cost" of medical "'care and services' for a defined set of individuals." Using this definition, the court concluded that HCAP patients were not eligible for medical assistance under Medicaid.

Providers who wish to challenge a CMS determination often find themselves either filing in D.C. or relying on the precedents of its well-respected and very experienced circuit court. In that respect, the recent *Adena* decision will likely force all DSH litigation out of the District of Columbia courts and into other jurisdictions. In those other jurisdictions, providers will then be faced with the task of arguing either that *Adena* was wrongly decided or that the particular state program at issue is quite different from Ohio's HCAP program. In either situation, providers now face an uphill battle. ■

REIMBURSEMENT

New CMS Regs, PRRB Rules Set Rights for Part A Appeals

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CMS published final regulations at 42 C.F.R. Part 405, Subpart R, revising procedures for Medicare Part A appeals before intermediaries and the Provider Reimbursement Review Board (PRRB). 73 Fed. Reg. 30,190 (May 23, 2008). With limited exceptions, the new regulations apply to all appeals pending as of, or filed on or after, August 21, 2008. The proposed regulations were published almost four years earlier. 69 Fed. Reg. 35,716 (June 25, 2004). In addition, in August of this year, the PRRB released new rules to replace the old instructions, effective on August 21, 2008.

> *"Many of the new regulations and rules are the codification of existing policy at the PRRB, but some constitute significant changes."*

CMS's stated reasons for the changes to the regulations were to address updates needed since the regulations were first adopted more than 30 years ago, and to reduce (or at least not add to) the backlog of appeals at the PRRB, which in essence can be interpreted to mean to restrict providers' access to appeal. Many of the new regulations and rules are the codification of existing policy at the PRRB, but some constitute significant changes. Some of the major revisions are set forth below. Although the regulations also address appeals before intermediaries, these provisions are not addressed in this article.

Provider Hearing Rights (§§ 405.1803(d), 405.1811, 405.1835)

- *Provider Dissatisfaction and Self-disallowances:* In order to meet the statutory requirement that a provider be "dissatisfied" with the determination, which is requisite to PRRB jurisdiction, effective with cost reporting periods that end on or after December 31, 2008, providers will not be granted appeal rights for items that were not either expressly claimed on a cost report or self-disallowed as a protested amount on the cost report.

  → *This is one of the most important changes that providers need to note because it requires providers to prepare for the appeal process very early on, i.e., at the time of filing the cost report. A provider must include any cost it wishes to pursue in its cost report.*

- *Audits of Self-disallowed Items:* After a provider has successfully appealed a self-disallowed item, the intermediary must audit the item in order to determine the proper reimbursement effect. This would require a second appeal by a provider if it disagrees with the audited amount determined by the intermediary.

- *Timeliness of Hearing Request:* A PRRB must receive the provider's hearing request no later than 180 days after the provider received the determination being appealed.

  → *See "Calculating Time Periods and Deadlines," below.*

- *Contents of Hearing Request:* The new rules require use of a new PRRB to file an appeal. Hearing requests that fail to include all the following criteria may be dismissed with prejudice by the PRRB:

  – A demonstration that the provider has a right to hearing (i.e., has met the dissatisfaction, amount in controversy and timely filing requirements);

  – An explanation for each disputed item and why the provider believes payment is incorrect, how and why payment should be determined differently and, if self-disallowed or protested, the nature and amount of the item, as well as payment sought;

  – A copy of the determination under appeal; and

  – If the provider has any other provider entities related to it, the name and address of its parent entity and a statement that, to the best of the provider's knowledge, no related provider has a pending PRRB hearing request on any of the same issues for the same calendar year, or a statement that such a pending appeal exists, supplying the provider name(s), number(s) and case number(s).

- *Adding Issues to Appeals:* A provider's request to add issues to a pending appeal must be received by the PRRB no later than 60 days after the expiration of the initial 180-day filing period. For appeals pending as of August 21, 2008, the deadline for adding new issues will be the later of 60 days after the expiration of the 180-day filing period or October 20, 2008. The new rules require the use of a form to add an issue.

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→ *This is a significant change in procedure. Providers should include in their initial appeal letters all potential issues they may wish to pursue. Providers can easily withdraw issues they decide not to pursue later in the process.*

Calculating Time Periods and Deadlines (§ 405.1801(a), (d))

- Date of receipt by a party, such as a provider or intermediary, is presumed to be five days after issuance, unless established otherwise by a preponderance of the evidence.

- Date of receipt by a reviewing entity, such as the PRRB, CMS Administrator or the Attorney Advisor, is date of delivery when delivered by a nationally recognized next-day courier, or the date stamped "received" by the reviewing entity when not delivered by a nationally recognized next-day courier. Determination of date of receipt by a reviewing entity is final and not subject to further administrative or judicial review.

- Time begins to be counted the day after the act or event that starts the clock running occurs.

- If the deadline falls on Saturday, Sunday, a legal federal holiday or a day on which the reviewing entity is unable to conduct business as usual, the deadline becomes the next day.

- CMS left it to each reviewing entity to determine whether it would accept faxed or electronically transmitted submission.

→ *Don't wait until the last minute to file. A late filing will likely result in a provider forfeiting its appeal rights.*

Filing Extensions (§ 405.1836)

- The PRRB may extend the 180-day filing period for good cause due to extraordinary conditions beyond a provider's control, such as fire or flood.

- No extension may be granted if the provider relies on a change in the law as its basis or if the request is received by the PRRB more than three years after the date of the determination at issue.

- Although CMS may review the PRRB's decision to grant or deny an extension, such a determination by the PRRB or CMS is not subject to judicial review.

Group Appeals (§ 405.1837)

- *Right to a Hearing:* A provider has a right to a hearing as part of a group appeal if it satisfies the dissatisfaction and timely filing requirements as established for a single provider appeal.

- *Issues:* Group appeals are limited to one legal or factual issue common to all providers in the appeal.

- *Years:* One or more providers in a group may, as a matter of right, include more than one cost year in a group appeal for the purpose of meeting the $50,000 amount in controversy requirement. One or more providers in a group may, subject to PRRB discretion, include more than one cost year in a group appeal for other purposes, such as convenience.

- *Transfer Back to Individual Appeals:* Once part of a group appeal, the provider will not be allowed to transfer its issue to an individual appeal unless the PRRB determines that the requirements for a group appeal have not been met.

> *"Providers must be sure to closely abide by the requirements for filing appeals, to avoid the risk of the appeal being dismissed with prejudice for failure to include all of the requisite information and documentation in the initial appeal letter."*

- *Mandatory/Common Issue Related Party (CIRP) Group Appeals:*

  – Related parties wishing to appeal an issue that involves a common fact or interpretation of law, arising in a cost reporting period ending in the same calendar year, with an aggregate amount in controversy of $50,000 or more, must bring the appeal as a mandatory group appeal.

  – Only related providers can be included in a mandatory group appeal.

  – If a provider in a mandatory group appeal includes more than one year in the appeal, the other related providers must also include the issue for the additional year(s) in that appeal if they wish to appeal that issue.

  - The PRRB will close the group upon notice from the group that it is fully formed, or may close the group after giving it an opportunity to demonstrate that a related party that should be in the group has not yet received its Notice of Program Reimbursement (NPR) or the deadline for appeal has not yet run. Once the group is closed, absent an order from the PRRB, no other related party may appeal the issue for the same year that is the subject of the group appeal.

- *Forms:* The rules include PRRB forms required for group appeals.

Amount in Controversy (§ 405.1839)

- In an individual appeal, the $10,000 amount in controversy jurisdictional requirement, i.e., the additional reimbursement the provider would receive if successful in the appeal, is calculated based on the aggregate amount of the adjustments being appealed by the provider for a single cost year. Providers may aggregate adjustments across multiple cost years for purposes of meeting the $50,000 amount in controversy requirement for group appeals.

- Any effect on reimbursement in a year other than the one under appeal has no bearing on the amount in controversy. Note: This would mean that future reimbursement effect based on revisions to a current cost report, e.g., resident full-time equivalent count, cannot be included in the calculation of the amount in controversy.

- The PRRB retains jurisdiction over appeals, notwithstanding that the amount in controversy falls to an amount less than $10,000, when the change in the amount in controversy is due to partial settlement, transfer of one or more issues to a group appeal or abandonment of one or more issues. If the change in the amount in controversy reflects a mistaken initial assessment, the PRRB does not retain jurisdiction.

Expedited Judicial Review (§ 405.1842)

- Upon receiving a request for expedited judicial review, the PRRB has 30 days either to rule on the request or to issue notice to the provider that it has not submitted a complete request, describing in detail the additional information that is necessary.

Parties to a Hearing (§ 405.1843)

- The PRRB determines whether an organization is a "related party" in accordance with 42 C.F.R. § 413.17.

- CMS is not a party to a PRRB hearing, even if CMS made the decision under appeal.

- The intermediary may designate a representative from the Secretary of HHS (Secretary) or CMS to represent the intermediary before the PRRB.

- CMS may file an *amicus curiae* briefing paper with the PRRB.

Quorum Requirements (§ 405.1845)

- The PRRB Chair may designate one or more PRRB members to conduct a hearing without the provider's or intermediary's consent.

- A quorum of at least three PRRB members, one of whom is representative of providers, must issue a final decision.

- The PRRB may conduct a hearing on the written record if both parties agree to waive an oral hearing.

Proceedings Prior to Hearing; (§ 405.1853)

- *Preliminary Narrowing of Issues:* Upon notice of a provider's hearing request, the intermediary must attempt to join with the provider to submit stipulations and must ensure that evidence considered by the intermediary or Secretary in making its determination are included in the record.

- *Position Papers, Generally:* The PRRB will establish due dates for position papers. Exhibits supporting jurisdiction for each issue must accompany the position paper; exhibits addressing the merits may be submitted pursuant to a schedule adopted by the PRRB.

- *Preliminary Position Papers — New Rules:*

  - Preliminary position papers must be fully developed and include all available documentation necessary to give the parties a thorough understanding of their opponent's position.

  - Parties will be given more time to file, generally allowing eight months after appeal request for the provider, twelve months for the intermediary and fifteen months for the provider's response.

  - Unless good cause is demonstrated, new arguments and documents not included in the preliminary position papers may be excluded at hearing.

- *Proposed Joint Scheduling Order (JSO) — New Rules:*

  - A JSO is a written scheduling plan covering all prehearing and hearing dates except the final position paper due date.

  - Parties have the option to file a proposed JSO in lieu of a preliminary position paper by the due date assigned for the preliminary position paper. However, a preliminary position paper must still be filed at a later date for all matters not resolved pursuant to the terms of the JSO.

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– A PRRB form is provided for a proposed JSO.

- *Final Position Papers — New Rules:*

  – Due dates are not set until a hearing date is issued, and will generally be required 90 days before the scheduled hearing for the provider, 60 days before the scheduled hearing for the intermediary, and 30 days before the scheduled hearing date for the provider's response.

  – The PRRB may exclude arguments or evidence outside the scope of the final position papers.

Discovery and Subpoenas (§§ 405.1853, 405.1857)

- The Federal Rules of Civil Procedure and Rules 401 and 501 of the Federal Rules of Evidence serve as guidance.

- No discovery or subpoena is permitted against CMS, the Secretary or any federal agency, as it could disrupt their day-to-day activities or could result in further backlog of cases before the PRRB. CMS believes the Freedom of Information process is adequate for this purpose.

- Depositions are permitted only where deponent agrees to the deposition or the PRRB determines it is necessary to secure the testimony for hearing, and must be conducted no later than 45 days before the initially scheduled hearing, unless the PRRB directs otherwise.

- Discovery requests must be served no later than 120 days before the initially scheduled hearing date, unless the PRRB extends the time, and responses must be served no later than 45 days before the initially scheduled hearing, unless the PRRB directs otherwise.

- Generally discovery and subpoena rulings are reviewable by the Administrator only as part of a final PRRB decision. However, where the ruling authorizes the discovery or subpoena, and the objection is based on privilege, other protection from disclosure such as case preparation, confidentiality or undue burden, the ruling may be reviewed immediately by the Administrator.

PRRB Actions in Response to Failure to Follow Rules (§ 405.1868)

- If a provider fails to meet filing deadlines or other requirements, the PRRB may dismiss with prejudice.

- If an intermediary fails to meeting filing deadlines or other requirements, the PRRB may issue a decision based on the written record submitted at that point.

- *Ex parte* communication with PRRB staff regarding procedural matters is not prohibited.

PRRB Hearings (§ 405.1845)

- The new rules provide for the following hearing alternatives: in-person, telephone, video, and record.

- The new rules also provide that although formal rules of evidence do not apply and hearsay is generally permitted, affidavits as to material facts in dispute will generally not be considered based on an inability to cross-examine the affiant.

PRRB Hearing Decision (§ 405.1871)

- The decision must determine whether the provider met its burden to establish its case by a preponderance of the evidence.

- If the decision departs from CMS instruction that would be dispositive, the decision must explain how it gave great weight to the CMS interpretation but did not uphold the intermediary's position.

Reinstatement of PRRB Case

- Although the old instructions required that requests for reinstatement of a case be made within 180 days of the PRRB closing the case, the new rules permit 3 years for such requests.

Administrator Review (§ 405.1875)

- The Administrator may review only final PRRB decisions, unless otherwise noted in the regulations.

Judicial Review (§ 405.1877)

- A provider is not required to seek Administrator review in order to obtain judicial review.

- Intermediary determinations that certain expenses are not covered costs are not subject to PRRB or judicial review.

- PRRB remand orders, PRRB or Administrator discovery, disclosure or subpoena rulings are limited to review within the context of a final agency decision.

Reopening of Intermediary Determination or Reviewing Entity Decision (§§ 405.1885–1889)

- Changes in CMS policy or interpretation of regulations, CMS rulings or general instructions are not bases for reopening a determination.

- CMS has the ultimate authority to direct an intermediary to reopen or not reopen a determination.

- The decision as to whether to reopen a determination is not subject to further administrative or judicial review.

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SELF-REFERRAL

Final IPPS Rule Contains Significant Stark Changes

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It came as no surprise that the final 2009 Hospital Inpatient Prospective Payment System (IPPS) rules finalized major Stark provisions that were proposed in the 2008 proposed physician fee schedule and 2009 proposed IPPS rule. The final regulations address (1) "stand-in-the-shoes" provisions; (2) percentage and per-click equipment and space leases; (3) revisions to the definition of a *designated health services (DHS) entity*; (4) an alternative method of compliance; (5) the exception for obstetrical malpractice subsidies; (6) the exception for ownership and investment interests in retirement plans; (7) the period of disallowance; and (8) the burden of proof in administrative claim appeals. The new rules went into effect October 1, 2008, with the exception of those addressing percentage-based and per-click equipment and space leases and the revised definition of a *DSH entity*, which will go into effect October 1, 2009. 73 Fed. Reg. 48,434 (Aug. 19, 2008).

"Stand in the Shoes"

One much-anticipated provision concerns the concept of "stand in the shoes." CMS initially proposed separate stand in the shoes provisions for physicians and entities, respectively. The entity stand-in-the-shoes provision, which would have affected whether DHS entities would stand in the shoes of their owned or controlled entities, was not finalized by CMS.

As proposed, the physician stand-in-the-shoes provision would be used to determine if a physician stands in the shoes of a physician organization. In such a case, any arrangement between a DHS entity and a physician group would be analyzed as if the arrangement was directly with the physicians in the group. As such, an indirect compensation analysis would not be permitted; rather, a direct compensation exception would be necessary to protect any referrals from the physician to the DHS entity. The potential effects of the physician stand-in-the-shoes provision were very troublesome for academic medical centers that often use the indirect compensation exception to protect mission support payments to faculty practice plans.

The finalized physician stand-in-the-shoes provision requires only physician *owners* to stand in the shoes of the physician-owned organization. Titular owners, however, such as physician owners in a captive PC, would not stand in the shoes of a physician-owned organization. Under the final rule, AMC faculty practice plans, which do not have "owners," would be able to continue to use the indirect compensation analysis to protect their mission support and other payment arrangements.

The final physician stand-in-the-shoes rule also permits physicians who are not owners to *choose* to stand in the shoes of their physician organization. This allows nonphysician owners to decide whether they want to use an indirect compensation analysis or direct compensation exception to protect referrals to the physician organization. For example, if a hospital has a medical director agreement with a physician group, the physician owner of the group would stand in the shoes of the group and the arrangement would need to meet a *direct* compensation arrangement exception, such as the personal services or fair market value exceptions. If, on the other hand, a hospital has a medical director agreement with a group and the physician named to serve in that role is not an owner of the group, the arrangement would be able to be analyzed *either* under the *indirect* compensation definition and exception *or* the personal services and fair market value exceptions.

Percentage Payments, Per-click and DHS Entities

Three provisions finalized with the IPPS rule, taken together, will have a significant impact on the provision of DHS by physician-owned entities. These provisions (i) expand the definition of *DHS entity*; (ii) prohibit percentage-based payments for space and equipment leases; and (iii) prohibit per-click arrangements for space and equipment leases.

Percentage Payments

In the 2008 proposed physician fee schedule, CMS noted its concern that physicians were using percentage arrangements in unanticipated ways. Specifically, CMS stated that it intended that percentage payments were only to be permissible in arrangements for physician professional services. However, lease arrangements for office space or equipment and other service arrangements have become more prevalent of late. Accordingly, the 2009 final IPPS rule prohibits percentage-based arrangements for space and equipment leases. Notably, the final rule did not prohibit other percentage compensation arrangements, e.g., billing and management services still may be established on a percentage basis. CMS has stated, however, that it will continue to review these types of arrangements and may further limit percentage-based payments in the future if it views them to be abusive.

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Per-click Payments

CMS has been similarly troubled by per-click payments because it believes that such payments are a mechanism for physicians to earn payments for each referral they make. As a result, the final rule generally prohibits per-click payments for space and equipment leases. Interestingly, CMS notes that although time-based payments remain permissible, they may be problematic if scheduled for too short of an interval (i.e., once a week for 4 hours, as noted by CMS) for the same reasons as per-click arrangements. CMS therefore plans to continue to study the issue of "block-time" leasing arrangements.

Definition of *DHS Entity*

In yet another major change coming out of the new Stark regulations, CMS has expanded the definition of *DHS entity*. Until now, the term *DHS entity* had been defined only as the entity that bills Medicare for a DHS service. In the final IPPS rule, effective October 1, 2009, CMS expanded the definition to include any entity that performs a DHS service, notwithstanding that another entity billed for the service. In situations involving one entity that bills for a service and a separate entity that furnishes the service, both entities will be considered DHS entities.

> *"By prohibiting per-click and percentage lease payment arrangements for space and equipment leases, CMS has prevented joint venture under-arrangements transactions from being restructured as equipment leasing arrangements with those common payment methodologies."*

The preamble to the IPPS rules includes commentary stating that CMS felt compelled to take this action to prohibit physician ownership in joint ventures that typically provide services "under arrangements" with hospitals. CMS has taken the view that Congress did not intend to allow physicians to have an ownership interest in a service company, when the physician would not have been able to refer patients to the company if it billed Medicare for those services. CMS provides a lengthy explanation of its concerns with such arrangements. A typical hospital under-arrangements transaction with a physician joint venture, as described by CMS, would be structured so that the joint venture would provide a complete service to a hospital. The hospital would then bill for such services under arrangements. The hospital typically would pay the joint venture for the services on a per-service basis. Commonly, the physicians who own the joint venture would be those physicians who refer their patients to the hospital for that service. For example, a group of interventional cardiologists joint venture with the hospital to create a diagnostic cath lab. The joint venture owns the space and the cath lab equipment. The cath lab leases employees from the hospital or uses its own employees. Patients who are registered at the hospital as hospital outpatients go to the cath lab, where the cath lab joint venture performs the services. The hospital bills for the services and pays the cath lab for each cath lab procedure performed.

According to the new rules, the cath lab entity would be considered to be performing a DHS service. CMS refuses to define the word *perform*, defaulting instead to the "common" meaning of *perform* to determine whether a joint venture entity has performed a service. Further commentary states that a procedure would be *performed* if the components of the services provided by the entity would otherwise permit that entity to submit a claim to Medicare. Since the cath lab joint venture in the example above is providing all of the cath lab services, it is likely that CMS would consider such a joint venture a DHS entity under the new definition.

Once it is determined that the joint venture is a *DHS entity*, any referrals by physician owners of the joint venture to the entity would need to meet a Stark exception. Few Stark exceptions apply to ownership and none apply to these arrangements, except perhaps if the entity is located in a rural area. Accordingly, such joint venture arrangements will need to be unwound or restructured.

While CMS's commentary focuses on hospital under-arrangements transactions with physician-owned joint ventures, the regulation text is much broader than such arrangements. Specifically, the regulatory text provides that any entity that performs DHS will be considered a DHS entity under the new definition. There is no requirement that such an entity have physician ownership. In the case of an entity that provides services to a physician group, which then bills for the DHS, two financial relationships must meet an exception. First, it will be necessary for the physician group to meet the in-office ancillary services exception for the DHS for which it bills and second, the DHS entity performing the service will need to meet an exception for the referrals it receives from the physicians.

In restructuring physician-owned joint venture under-arrangements transactions, (whether with hospitals or with physician group practices) it is likely that providers and physicians will necessarily move toward arrangements for which Stark exceptions already exist, e.g., space and equipment leases and management and billing services.

By prohibiting per-click and percentage lease payment arrangements for space and equipment leases, CMS has prevented such arrangements from being restructured as equipment leasing arrangements with those common payment methodologies. Clearly, CMS was aware of, and wanted to prevent, physicians restructuring their arrangements in ways that CMS still considers potentially abusive.

To effectuate these changes, CMS has added the limitations on payment methodologies to the Stark exceptions for space leases, equipment leases, fair market value and indirect compensation arrangements.

> *"Hospitals, physicians and other entities billing Medicare that have relationships with physicians should review their arrangements to ensure that they comply with these new regulations."*

The three final provisions concerning percentage payments, per-click and the definition of *DHS entity* are significant revisions to the Stark exceptions that will have a major impact on the way health care arrangements are structured. The changes are considerably broader than simply joint ventures that provide services under arrangements to hospitals, encompassing certain service arrangements for in-office ancillary services. Additionally, the prohibition of percentage and per-click payment methodologies for space and equipment leases will further limit the transactions that health care providers will be able to enter into when physicians are involved. While it will take some time to fully reveal all of the nuances of these new rules, it is clear that there will be a major shift in the way such arrangements are structured and services are provided in the future. Hospitals, physicians and other entities billing Medicare that have relationships with physicians should review their arrangements to ensure that they comply with these new regulations. Some arrangements, particularly those involving physician ownership in DHS entities, as newly defined, may require unwinding or restructuring.

Alternative Method of Compliance

CMS's alternative method of compliance rule is designed to relieve some of the unintended consequences of the Stark statute's strict liability. CMS created an alternative method of compliance that will allow missing signatures from written agreements to be corrected within 30 days if *non-inadvertent* and within 90 days if *inadvertent*, all the while allowing the arrangement to remain protected by an exception. To benefit from this method, an arrangement must otherwise be compliant with all other C[illegible] of an exception. In addition, the alternative method cannot be used more than once in a three-year period for a particular physician.

Obstetrical Malpractice Subsidies

The IPPS final rule expands the Stark exception for obstetrical malpractice subsidies. Leaving intact the previous exception, which protected arrangements that met the antikickback safe harbor requirements, CMS added a new alternative that allows hospitals, federally qualified health centers and rural health clinics to provide obstetrical malpractice insurance subsidies to a physician that routinely engages in obstetrics as part of a medical practice that is located in either (1) a primary care Health Professional Shortage Area (HPSA), a rural area, or an area with demonstrated need as determined in an advisory opinion, or (2) an area comprised of patients at least 75 percent of whom live in a medically underserved area or are part of a medically underserved population.

Ownership or Investment Interests in Retirement Plans

While CMS continues to classify a physician's ownership or investment interests in retirement plans as a compensation relationship with the retirement fund, CMS has expanded the reach of that relationship. Under the final rule, if the retirement plan invests in a DHS entity, the physician will be found to have an ownership relationship with that DHS entity. CMS was concerned that physicians were using investment vehicles to maintain ownership interests in DHS entities that otherwise would have been prohibited.

Period of Disallowance

CMS has attempted to create clarity by finalizing provisions that identify the period of disallowance that results from the submission of Medicare claims where there has been a Stark violation. The final rule, minimally modified from the proposed, provides that the period of disallowance ends no later than:

1. When the arrangement comes into compliance, if the noncompliance does not relate to compensation;

2. The date when the excess remuneration is returned, if the noncompliance relates to excess compensation; or

3. The date on which additional money is paid, if the noncompliance relates to insufficient payment.

In response to comments, CMS notes that the period of disallowance could end earlier based on specific facts and circumstances. Of significance, CMS also states in the preamble that the beginning and end dates of a financial relationship do not necessarily coincide with the beginning and end dates of a written agreement. For example, if a physician is paid more than fair market value by a hospital during the term of a personal services arrange-

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SELF-REFERRAL

Villafane Court Adopts Pragmatic Approach to Stark AMC Exception

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On April 8, 2008, the United States District Court for the District of Kentucky dismissed a *qui tam* suit filed under the FCA, finding that the defendants met the qualifications for protection under the academic medical center (AMC) exception to the federal self-referral law (Stark law), 42 U.S.C. § 1395nn. In *United States ex rel. Villafane v. Solinger*, 543 F. Supp. 2d 678 (W.D. Ky. 2008), the plaintiff, a pediatric cardiologist, filed a *qui tam* action against affiliates of the University of Louisville Medical School (Medical School), including the Medical School's research foundation (Foundation), his former practice group and other individual defendants, alleging that the defendants violated the FCA by submitting claims for Medicaid reimbursement that were falsely certified to be in compliance with, among other things, the Stark law. In dismissing the suit, the court provided the first in-depth case law discussion of the AMC exception and applied a "goal- and purpose-oriented perspective," rather than a "hyper-technical" approach, to find that the defendants met the requirements for the exception.

The plaintiff, a former University of Louisville Medical School professor, and his current medical practice filed this suit against his former medical practice group, several physician members of the Medical School's faculty, the Foundation and Norton Hospitals, Inc. d/b/a Kosair Children's Hospital (Kosair), which is the only freestanding, full-service pediatric hospital in Kentucky. The chief of staff at Kosair was also a named defendant.

The crux of the plaintiffs' FCA allegations centers around the flow of money between Kosair and the defendant doctors. As full-time members of the Medical School faculty, defendant doctors participated in the Medical School's professional practice plan, which requires the doctors to pay a percentage of their private practice revenues to the Medical School's fund. The Medical School's fund channels money to the Foundation, which is used, among other things, to support the defendant doctors' faculty salaries. Significantly, hospitals, including Kosair, also contribute to the Foundation that supports the faculty salaries. Each of the defendant doctors practice at and as a result, refer patients to, Kosair. Plaintiffs claim that this financial relationship between Kosair and the physicians violates the Stark law.

The court first noted that neither the Stark law nor the antikickback statute provide for a private right of action; however, the FCA permits individual whistleblowers to file suit on behalf of the government. The plaintiffs claimed that FCA liability arose in this case as a result of Kosair's certification in its Medicaid claims for reimbursement that it had complied with all applicable laws and regulations, including the Stark law and antikickback statute.

The Stark law generally prohibits physicians from making referrals to an entity for a designated health service if the physician (or his or her immediate family member) has a "financial relationship" with that entity, unless an exception applies. Here, the court specifically found that the financial relationship at issue falls within the AMC exception and, thus, no FCA liability, as a matter of law, could be predicated on the Stark law. The court discussed each of the elements of the AMC exception and found that Kosair and the other defendants' financial relationship fell within that exception.

First, the court analyzed the AMC exception requirements that relate to the employment and licensure status of the referring physicians. The plaintiffs argued that the defendants failed to demonstrate that the referring physicians "provide either substantial academic services or substantial clinical services . . . for which the faculty member receives compensation." Specifically, the plaintiffs' asserted that the defendants' timekeeping system was a "sham" based solely on the estimates of the defendant doctors themselves. Finding that the AMC regulations do not require a physician to use a particular timekeeping system and that there is "no indication that either Congress or HCFA/CMS intended the fate of an academic medical center would hang upon its particular timekeeping practices," the court held that the defendant doctors provided substantial academic and clinical services as evidenced in affidavits indicating they supervise more than 100 medical students and residents at Kosair.

Furthermore, the court rejected plaintiffs' contentions that compensation provided to the defendant doctors exceeded fair market value (FMV) and was determined in a manner that took into account the volume and value of referrals. As an initial matter, the court refused to adopt the plaintiffs' theory that the FMV determination of a physician's compensation paid by the AMC should take into account the physician's income derived from his or her private practice, in addition to his or her faculty salary. Finding that the defendant doctors' salaries were in line with national salary data, the court further rejected the plaintiffs' argument that the salaries failed to meet the safe harbor

because they do not fall within the Phase II methodologies for calculating FMV, which had been explicitly rejected in Phase III as both "impractical" and "infeasible." Addressing specifically the salary provided to Kosair's chief of staff, which was near or above the high-end range for neonatologists, the court found that the salary was appropriate in light of the chief's duties and responsibilities at the Medical School and that he is arguably at or near the top of his profession. To compare with ordinary neonatologists, the court held, would be to compare "apples and oranges."

> *"The Villafane court takes a common-sense approach to applying the elements of the AMC exception, focusing more on the purpose of the AMC exception and its elements, and rejecting the "hyper-technical" arguments set forth by the plaintiffs."*

Next, the court considered whether compensation to faculty physicians took into account the volume or value of the referrals. Plaintiffs argued that payments made by Kosair to the Foundation reflected the volume or value of referrals because, according to the plaintiffs, Kosair would not have contributed to the Foundation if such payments did not fund physician referrals to Kosair. The court found the plaintiffs' argument "contrary to the clear statutory and regulatory purpose" of the AMC exception and concluded that, because the physicians' salaries were fixed at FMV and did not vary during a given fiscal year based on referrals, the salaries do not reflect the volume or value of referrals. The court again specifically analyzed payments made to the chief of staff at Kosair, whose salary was substantially higher than other physicians and who also generated substantially more revenue for Kosair than other physicians. Again, the court noted that his salary was "hardly surprising" given his greater responsibilities at the Medical School and did not reflect the volume or value of referrals.

The court considered several other arguments presented by the plaintiffs contending that the defendants did not meet the AMC exception. Of note, the plaintiffs argued that the relationship between Kosair and the Medical School was not sufficiently memorialized by one or more written agreements or other documents. The court found that, although there was no lengthy, detailed contract between the two parties, the parties presented sufficient documentary evidence of their relationship dating back to 1962. This evidence included, among other things, documents that the two parties approved annually memorializing the amount of support provided by Kosair to the Foundation. The court noted that "[n]o authority requires a specific type of documentation to memorialize the relationship between the AMC components."

In addition to the foregoing, the court found that the relationship did not run afoul of the antikickback statute. As part of its analysis, the court expressly declined to adopt the "one purpose" test established in *U.S. v. Greber*, 760 F.2d 68, 71 (3d. Cir. 1985). The "one purpose" test, which has been adopted in other circuits, generally holds that the intent element of the antikickback statute can be met if payments to physicians are to any extent motivated to induce referrals. Instead, the court found that the plaintiffs here presented no specific evidence or facts to support their general allegation that the arrangement at issue violates the antikickback statute. Because the defendants' arrangement fell within the AMC exception to the Stark law and no violation of the antikickback statute was found, the court dismissed the FCA allegations in the plaintiffs' complaint. In addition, the court dismissed freestanding allegations under Stark and the antikickback statute because of the lack of a private cause of action under those provisions.

The court's decision in *U.S. ex rel. Villafane v. Solinger* is significant because it is the first published opinion that provides a detailed discussion of the AMC exception to the Stark law. Additionally, *Villafane* provides a common-sense approach to applying the elements of the AMC exception. The court's approach focused more on the purpose of the AMC exception and its elements, and rejected the "hyper-technical" arguments set forth by the plaintiffs. ■

Congratulations

Sandy Teplitzky *received the American Health Lawyers Association's prestigious David J. Greenburg Service Award.*

Presented annually, the award is given to those lawyers who have made significant contributions to the AHLA over the course of their careers. Only eighteen attorneys have been selected for the award to date. Mr. Teplitzky becomes the third Ober|Kaler attorney to receive this lifetime achievement award, joining past honorees Leonard C. Homer and Thomas K. Hyatt.

Mr. Teplitzky has been a member of AHLA (and its predecessor organization, National Health Lawyers Association) for more than thirty years. He served on the Board of Directors from 1986 to 1995 and as President from 1993 to 1994. He was named a Founding Fellow in 2005 and is currently the Chair of the AHLA Fellows Program.

FCA

Allison Engine: A "Less Friendly" Environment for Qui Tam Plaintiffs—But How Much So?

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When the Supreme Court handed down its opinion in *Allison Engine Co. v. United States ex rel. Sanders*, 128 S. Ct. 2123 (2008), last year, it addressed a split in the circuits over the meaning of the "presentment" requirement of § 3729(a)(2) of the False Claims Act and examined "the relationship" between the making of a "false record or statement," and the payment of the ultimate "false or fraudulent claim… by the government." *Id.* at 2126. Did claims have to be presented directly *to* the government and must payment be made directly *by* the government? Did there have to be a nexus between the falsity and the reimbursement? Or, under the Act could a *qui tam* plaintiff meet his burden simply by establishing that government money was eventually used to pay any "false or fraudulent" claim?

The Court's consideration of the issue was immediately seen as having significant reach. Within a month of publication, the Sixth Circuit observed in *U.S. v. Ford Motor*, 532 F.3d 496, 509 (6th Cir. 2008) "[I]n light of the Supreme Court's recent decision in *Allison Engine*… the law in this Circuit is now less friendly to *qui tam* plaintiffs than it was prior to that decision." It is too early to tell how much less friendly the legal environment will become for relators, or whether the case will give rise to a legislative response, but the courts have begun the process of interpreting the holding and an examination of the case and the early returns is certainly worthwhile.

The Facts of *Allison Engine*

The defendants in *Allison Engine*, a declined *qui tam*, were alleged to have submitted false claims for generator sets that were not manufactured in accordance with the Navy's baseline drawings or with military standards — both of which were incorporated into the defendant's subcontracts. The relator alleged that the invoices for the generator sets were fraudulent because 1) they were defective; 2) they did not meet military standards though the Certificates of Conformance falsely claimed they did; and 3) the defendants knew that the generator sets were defective and failed to meet military standards.

> *"It is too early to tell how much less friendly the legal environment will become for relators, or whether the case will give rise to a legislative response, but the courts have begun the process of interpreting the holding."*

At the conclusion of the trial, but before a verdict was rendered, the defendants moved to dismiss, asserting the plaintiff had failed to prove that the claims had been presented to the government, and that such a failure was fatal as a matter of law. The trial court agreed and dismissed the action, but a divided panel of the Sixth Circuit reversed, holding that the intent to cause a false

claim to ultimately be paid with government funds was sufficient. This holding was in conflict with *United States ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488 (C.A. DC 2004), written by Chief Justice Roberts when he was still sitting as a Circuit Judge, and the Supreme Court granted certiorari to resolve the conflict.

The Supreme Court's Analysis

Not surprisingly, the Court sided with *Totten*. The unanimous opinion held that it was "insufficient" for a plaintiff to "show merely" that a false statement's use either resulted "in obtaining or getting payment or approval of the claim," or that "government money was used to pay the false or fraudulent claim," *Allison Engine* at 2126. The court rejected the view that it is enough to show that government funds will ultimately be involved, stating "[P]aid by the government" is not the same as getting a claim paid by someone simply using government funds; a defendant must intend that "the Government itself pay the claim." *Id.* at 2128. To eliminate this element would, the Court said, expand the FCA well beyond its intended role of combating "fraud against the Government." *Id.*

The Court went on to hold that while the claim itself has to be paid by the government, it doesn't have to be made to the government as long as it is submitted for the purpose of getting "a false or fraudulent claim paid or approved by the Government." *Id.* This distinction is important where subcontractors' claims are passed on directly to the government by the prime, or in health care cases where claims are made through intermediaries and carriers, but the Court held that where a subcontractor makes a false statement to a private entity without the intent to have the Government rely upon it, such a claim would not be made with the purpose of inducing payment of a false claim "by the Government."

Importantly, the Court also addressed the relationship between statement or record and the claim itself, creating what would appear to be a two-part test. Not only must the false record or statement be made with the intent "to get" a false or fraudulent claim "paid or approved by the Government," but a plaintiff must also allege and prove that "the defendant intended that the false record or statement be material to the Government's decision to pay or approve the false claim." *Allison Engine* at 2125. "Materiality" is an issue in almost every health care FCA case, as the line between the alleged falsity and the payment is often very hazy and unclear. However, it is noted that the Court stopped short of also holding that the false record or statement actually be material to the payment determination itself by the government. Finally, the Court further held that it was insufficient in a conspiracy claim to show that the conspirators had a general scheme to defraud the government, and that it must be shown that "conspirators agreed to make use of the false record or statement" to have a "material effect" on the government's decision to pay. *Id.* at 2126.

Reaction by the Lower Courts

The initial reaction by the lower courts has focused on the materiality and intent in several different contexts. One district court reversed itself and dismissed a crop insurance fraud case because the "direct link between the false statements and the government decision to pay is too attenuated to establish liability" (*United States v. Hawley*, citing page 6 of *Allison*). The Fifth Circuit recently used it in an unpublished opinion to affirm summary judgment for a lack of intent to prove materiality saying "The FCA is … not an appropriate vehicle for policing regulatory compliance." *U.S. ex rel. Gudur v. Deloitte & Touche.* And several other courts have applied *Allison Engine* to support dismissals under Motions to Dismiss under both 12(b) as well as 9(b).

> *"We are beginning to see the response to* Allison Engine*, but its impact in health care false claims cases won't be known for some time."*

Another potential extension of the reasoning in *Allison Engine* is that it can be used as the basis for finding that Medicaid claims are not "claims to the government" and, therefore, are inapplicable under the FCA. This has been raised in a number of cases as well as in a November 6, 2008, report released by the Congressional Reporting Service (CRS), but to date no court has taken such an action and at least two courts have declined to do so. While this is an issue which must be considered ripe under a literal reading of the case, if it is successful, the CRS report suggests that such a ruling would likely be vulnerable to a legislative fix.

Conclusion

We are beginning to see the response to *Allison Engine*, but its impact in health care false claims cases won't be known for some time. At the least, the courts appear willing to enforce the more vigorous materiality requirement in motion practice, and that alone will create a less friendly atmosphere for *qui tam* plaintiffs, but the jury is out on just how far that will go — or whether larger changes may take place. ■

FCA

Fighting Back Against Whistleblowers

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Widespread media attention has been given to successful "whistleblower" lawsuits filed under the False Claims Act (FCA). The steady reports of large settlements in whistleblower lawsuits are enough to make many health care providers feel powerless to stop aggressive whistleblowers from inflicting significant damage to a provider's bottom line and reputation. That sense of powerlessness has driven many providers to conclude that it is better to settle a suit quickly than to muster a defense. That course has rewarded whistleblowers and their lawyers, creating a cycle of suits, settlements, and more suits.

Two recent court decisions, however, give providers encouragement that it is possible to fight back against meritless whistleblower lawsuits. In cases where whistleblowers were forced to defend the validity of their legal claims, the whistleblowers could not meet the challenge.

U.S. ex rel. Duxbury v. Ortho Biotech Products

In *U.S. ex rel. Duxbury v. Ortho Biotech Products*, L.P., 551 F. Supp. 2d 100 (D. Mass. 2008), two whistleblowers formerly employed by Ortho asserted violations of the FCA based on two theories. First, they alleged that Ortho had given kickbacks to providers to induce them to prescribe Ortho's drug, Procrit®. The alleged kickbacks were in the form of free samples, discounts, rebates, consulting fees, educational grants and honoraria. These kickbacks allegedly caused the providers receiving them to submit false claims for Medicare payment. Second, they alleged that Ortho promoted off-label dosing of Procrit (above the level approved by the FDA) in order to obtain excessive Medicare reimbursement.

Ortho filed a motion to dismiss those legal claims. Ortho requested the dismissal of the kickback claim based, in part, on the whistleblowers' failure to plead their allegations with particularity. When alleging a violation of the FCA, a whistleblower cannot stand on vague allegations of "fraud" that smear the defendant but lack the detail necessary to advise the defendant of the specific misconduct that it is accused of committing.

In this case, the court agreed with Ortho that the whistleblowers had failed to plead the details of the alleged false claims and, therefore, the court rejected their kickback theory of liability. Although the whistleblowers had alleged a variety of kickback schemes involving Procrit, they were unable to allege any specific instance in which a kickback resulted in the submission of a false claim to the Medicare program. The court was unwilling to assume that the allegation of a kickback, standing alone, necessarily entailed a false claim in violation of the FCA. Thus, it is not enough for a whistleblower to hurl vague accusations of "kickbacks." A whistleblower must tie alleged kickbacks to a false claim for the payment of federal funds.

Ortho also filed a motion to dismiss the off-label marketing claims based on the FCA's "first-to-file" rule. The FCA includes a provision designed to prevent "copy cat" litigation, i.e., lawsuits based on similar facts previously alleged by another whistleblower. Only the first whistleblower is allowed to proceed with his or her case.

In this case, filed in Massachusetts, the court analyzed whether the whistleblower's allegations were derived from similar allegations in a Colorado lawsuit. The Colorado lawsuit was actually filed *after* the Massachusetts suit, but

the initial complaint filed in the Massachusetts court did *not* include detailed allegations about an off-label marketing scheme involving Procrit. The first allegations concerning that scheme were made in the Colorado case. Thereafter, the Massachusetts whistleblowers amended their complaint to include similar allegations regarding the off-label marketing of Procrit. Based on that sequence of events, the court concluded that the off-label marketing claims asserted by the Massachusetts whistleblowers were prohibited by the first-to-file rule.

Copy-cat lawsuits are a real phenomenon in FCA litigation, as whistleblowers sometimes try to take advantage of false claim theories already asserted in another forum. Thus, it is incumbent upon defendants in FCA lawsuits to determine whether the whistleblower filing suit is deriving his legal claim from another whistleblower's case.

U.S. ex rel. El-Amin v. George Washington University

In *U.S. ex rel. El-Amin v. George Washington University*, 533 F. Supp. 2d 12 (D.D.C. 2008), four whistleblowers formerly employed as certified registered nurse anesthetists (CRNAs) at George Washington University Hospital (GW) asserted that GW submitted false claims for anesthesia services to the Medicare program. They alleged that GW had misrepresented to Medicare that the services were provided by anesthesiologists when, in fact, the services were provided by CRNAs or residents. GW filed a motion to dismiss the lawsuit, which was denied by the court, and the case was scheduled for trial.

Undeterred, GW later filed several motions to prohibit the whistleblowers from offering various types of evidence at trial. The court granted those motions, making it substantially more difficult for the whistleblowers to present their case at trial.

For example, GW requested the court to preclude the whistleblowers from testifying regarding anesthesia procedures in which they were not involved. The whistleblowers countered that even though they were not involved in every anesthesia procedure, they should be allowed to testify about GW's routine practices applicable to all anesthesia procedures. The court sided with GW, finding that the whistleblowers could not testify about anesthesia procedures in which they were not involved, and finding that they had failed to establish that GW had routine anesthesia procedures that could substitute for testimony about each specific procedure at GW. The court's ruling impaired the whistleblowers' ability to seek a financial recovery based on every anesthesia procedure provided to a Medicare patient at GW.

In addition, GW requested the court to preclude the whistleblowers from offering evidence about anesthesia procedures that did not lead to an alleged false claim to Medicare. Because FCA liability is based on false claims involving federal funds, evidence regarding anesthesia procedures that did not entail Medicare payment was irrelevant to the issue of whether GW violated the FCA. The court's ruling precluded the whistleblowers from magnifying the scope of GW's alleged misconduct.

GW also requested the court to preclude the whistleblowers from testifying about GW's billing procedures because they had no personal knowledge of those procedures. The court agreed that the CRNAs were not involved in GW's billing and, therefore, they had no basis to testify regarding GW's billing practices. The court's ruling had the effect of forcing the whistleblowers to search for another witness with firsthand knowledge of GW's billing practices.

> *"The* El-Amin *case demonstrates that even if a whistleblower's claim survives a motion to dismiss, providers still are able to defend themselves successfully by strategically blocking the whistleblower from using irrelevant, but inflammatory evidence at trial."*

Furthermore, GW also requested the court to preclude the whistleblowers from offering evidence that patients were harmed as a result of anesthesia procedures. Because the FCA is designed to remedy false claims that threaten the federal treasury, and is not a tort law for remedying personal injuries, the court agreed that evidence of patient harm was irrelevant and must be excluded at the trial. The court's ruling prevented the whistleblowers from offering evidence that would have inflamed a jury.

The *El-Amin* case demonstrates that even if a whistleblower's claim survives a motion to dismiss, providers still are able to defend themselves successfully by strategically blocking the whistleblower from using irrelevant, but inflammatory evidence at trial.

Conclusion

The whistleblower lawsuit remains a threat for providers. However, in appropriate cases, providers have a variety of tools at their disposal to fight back against whistleblowers and level the playing field. It is critical for providers that are subjected to whistleblower suits to consult with counsel regarding all available defense strategies. ■

LITIGATION/ADR

The Rise and Fall of Medicare Secondary Payer Litigation

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More than two years ago, celebrity litigant Erin Brockovich began filing a series of lawsuits against health care providers, asserting violations of the Medicare Secondary Payer Act (MSP), 42 U.S.C. § 1395y(b). Brockovich and another plaintiff, Douglas Stalley, filed dozens of MSP lawsuits throughout the United States, asserting virtually identical claims. The lawsuits asserted that Medicare had paid providers for treating injuries allegedly caused by the providers themselves during the course of delivering other services to Medicare beneficiaries. Furthermore, the lawsuits asserted that private parties, such as Brockovich, were entitled to sue for the recovery of those Medicare payments on behalf of the federal government. Although the lawsuits did not specify the amount of recovery sought, hundreds of millions of dollars were potentially at stake.

After an ambitious start, however, the MSP lawsuits have fizzled. Most of the lawsuits were dismissed by trial courts and the dismissals were affirmed on appeal. Brockovich and Stalley recently agreed to drop appeals in two other courts in the wake of a decision by the United States Court of Appeals for the Sixth Circuit that the novel legal theory serving as the foundation for the MSP lawsuits was "frivolous."

It was undisputed that Brockovich and Stalley were not Medicare beneficiaries, they were not patients of the health care providers they sued, and they had not suffered any injury. Thus, they lacked a clear basis to file a lawsuit. However, Brockovich and Stalley asserted that the MSP created a *qui tam* cause of action that authorized private parties to sue for injuries allegedly sustained by the federal government. Another federal statute familiar to many providers — the False Claims Act — creates a *qui tam* cause of action in which a private person is authorized to sue on behalf of the government. Brockovich and Stalley asserted that the MSP created a similar right to file a *qui tam* lawsuit, but that theory was soundly rejected by every trial court in which Brockovich and Stalley had filed suit. After their MSP suits were dismissed at the trial court level, Brockovich and Stalley appealed those dismissals in several federal appellate courts.

In one of those appeals, *Stalley v. Methodist Healthcare*, 517 F.3d 911 (6th Cir. 2008), the Sixth Circuit affirmed the lower court's ruling that the MSP does *not* create a *qui tam* cause of action and, therefore, Stalley lacked any basis to assert his claim. The court noted that "Stalley has presented this same argument before several different tribunals, all of which have held that the MSP is not a *qui tam* statute and that Stalley does not have standing to sue on behalf of the United States." *Id.* at 919.

The Sixth Circuit proceeded to consider sanctions against Stalley:

> Rather than acting as a private attorney general to benefit the United States, Stalley proceeds in these cases as a "self-appointed bounty hunter" . . . whose goal, apparently, is to profit at the expense of Appellees. . . . He literally has no support whatsoever for his argument. Moreover, Stalley — along with his partner in litigation, Erin Brockovich — has made the exact same claims numerous times in other jurisdictions and been unanimously turned away. . . . Stalley's claims before this court are utterly frivolous, and we are troubled that any attorney would elect to advance them.

Id. at 919-20, *quoting Stalley v. Sumner Regional Health Systems, Inc.* No. 06-0074, 2007 WL 173686, *1 (M.D. Tenn. Jan. 18, 2007). Based on the frivolous litigation, the court awarded sanctions in the amount of $172,823 against Stalley and his lawyers.

Consistent with the Sixth Circuit, several other circuits have concluded that the MSP does not create a *qui tam* cause of action authorizing private parties to seek the recovery of Medicare funds on behalf of the federal government. *See Stalley v. Orlando Regional Healthcare System, Inc.*, 524 F.3d 1229, 1234 (11th Cir. 2008); *Stalley v. Catholic Health Initiatives*, 509 F.3d 517, 519 (8th Cir. 2007); *United Seniors Ass'n v. Phillip Morris USA*, 500 F.3d 19, 25-26 (1st Cir. 2007), *cert. denied*, 128 S. Ct. 1125 (2008).

Following the rejection of the MSP *qui tam* theory by the First, Sixth, Eighth and Eleventh Circuits, Brockovich voluntarily dismissed her appeal in the Ninth Circuit and Stalley voluntarily dismissed his appeal in the Third Circuit, thereby bringing their MSP litigation to a close. It remains to be seen whether the sanctions order issued by the Sixth Circuit will discourage others from filing lawsuits under the MSP. ■

BUSINESS

Single Member LLCs—Not Always the Vehicle of Choice

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More than one half of the states now permit the use of single member LLCs ("SMLLC"). This legal option has become the planning vehicle for choice for many hospitals for owned medical practices and other ancillary businesses, as the model offers the advantages of corporate protection, and pass through federal tax treatment. As a "disregarded entity," the SMLLC's economic activity is both accounted for and taxed as a component of the exempt hospital member. This avoids the need for a federal tax exemption application; whether the activity will be unrelated or related business income of the member will depend on the exact nature of the activity.

The SMLLC offers flexible governance. It can be managed by its managers (often the choice where the health system is comfortable that the governance of the entity can be properly delegated to management) or the hospital member itself—acting through it board or a delegated representative. This choice is largely a function of the size and importance of the ancillary activity being conducted, and the oversight required.

Other advantages include the following. In the event that the SMLLC has employees (for example in the case of a hospital owned medical practice), the hospital has the choice of treating either the hospital itself or the SMLLC as the actual employer. In the case of the former, such treatment creates an opportunity for compensation incentives based on achieving legitimate hospital goals—as opposed just to quality or economic parameters of the medical practice itself. And as pay for performance becomes more widespread, aligning physician economic incentives with hospital quality goals becomes increasingly important.

Donations to a SMLLC where an exempt hospital or system parent is the sole member are tax deductible. This opens up additional giving opportunities to systems where discrete care centers (e.g., a cancer center) may be likely magnets for charitable giving.

Again, in the medical practice context, a SMLLC can take advantage of the "own use" exemption to Robinson-Patman pricing limitations. Thus, either the exempt hospital parent can make protected, discounted purchases for the SMLLC, or, alternatively, the SMLLC can purchase on its own account and qualify for permitted discounts based on its own nonprofit status.

Perhaps the single most important disadvantage of this form of entity, however, is the fact that judgment creditors can indirectly defeat its corporate "separateness." This is not due to the fact that the entity is a SMLLC. Rather the concern is one of potential execution on assets. More specifically, suppose a nonprofit entity tried to isolate assets in a SMLLC, thinking that the corporate separateness would shield such assets from the member's creditors. Missing in this analysis is the fact that the assets of the nonprofit include the membership interest of the SMLLC (just as with stock in a subsidiary corporation). As such, judgment creditors of the SMLLC member could execute on the membership interest, essentially gaining control of the SMLLC and all of its assets. This produces just the opposite result of what was intended.

SMLLCs offer several advantages for business planning. However, when selecting such a model, make sure that all of its disadvantages have been thoroughly explored. ■

Stark Changes… FROM PAGE 21

ment, the financial relationship does not necessarily end on the date the agreement terminates. In this scenario, CMS is concerned that prior excess payments may have been paid for future referrals after the contract's termination.

Burden of Proof/Persuasion and Burden of Production

CMS adopts a burden of *proof* (burden of persuasion) rule that places the burden on the provider-claimant (not the government) when a provider administratively appeals a Stark claim denial. CMS notes that this rule is not intended to apply to civil money penalty actions or false claims act appeals. In addition, CMS acknowledges that while the burden of *production* is initially on the claimant, that burden may shift to the government to prove that the requirement of an exception was not met. ■

INTELLECTUAL PROPERTY

An Ounce of Prevention — IP Audits Are Good Medicine

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As information technology and other innovations have become more pervasive, companies in the health care field have come to appreciate the critical importance of their intellectual property in maintaining a competitive edge. Companies engaged in research and development, joint ventures, and licensing activities understand well the importance of capturing, assessing and protecting the intellectual property they create. Too often such assessments are pursued on a reactive basis, as opportunities or risks come into view. The reactive approach is often remedial in nature, undertaken too late to avoid the risk or capture the opportunity that precipitated the review. Clearly, a proactive approach to evaluating and managing a company's IP assets is preferable, and best accomplished through an initial intellectual property audit.

Comparable in some respects to the due diligence investigation of IP assets in a commercial transaction, the intellectual property audit goes beyond simply inventorying intellectual property. The audit report provides recommendations, tailored to help the company establish priorities and set policies for protecting, maintaining and maximizing its IP assets.

The intellectual property audit begins with a comprehensive assessment of a company's patents, copyrights, trademarks (including domain names), trade secrets, website, and other intellectual property, as well as third-party rights used under license. The audit report provides recommendations for preventing losses due to failure to make required governmental filings or to maintain adequate internal controls. The report includes recommendations of best practices for capturing newly developed IP and maximizing the value of the company's existing intellectual property. The IP audit report will include a review of the company's employment, disclosure and independent contractor policies, and suggest changes where appropriate to ensure that the company acquires and protects its intellectual property assets as they are developed. ■

Mr. Johnson is Chair of Ober|Kaler's intellectual property practice and is resident in the firm's Baltimore office.

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- Notice of reopening for an "own motion" reopening not involving fraud or similar fault must be mailed no later than three years after the date of the determination.
- Requests to reopen not involving fraud or similar fault must be received within three years after the date of the determination.
- CMS or an intermediary may reopen a determination that is pending before the PRRB or Administrator. An intermediary also may reopen a determination for which no appeal has been taken if the deadline for filing an appeal has not yet passed.
- The intermediary or reviewing entity must notify the parties of a reopening and allow the parties to present additional evidence.
- Any matter considered in a reopening, but not revised, is not appealable through the revised determination.

Many of the new regulations appear one-sided, restricting providers' rights to pursue appeals before the PRRB, so as not to overburden CMS and the intermediaries and in order to reduce the PRRB's caseload. It is likely some of these new regulations will ultimately be challenged in court as impermissibly restricting a provider's statutory right to appeal and the PRRB's statutory scope of jurisdiction. In the meantime, however, providers must be sure to include the costs they wish to appeal on their cost reports either as claimed costs or amounts in protest. Providers must further identify all of the potential issues they wish to appeal and include them in the appeal of the determination, since adding issues at a later time will be severely restricted. Finally, providers must be sure to closely abide by the requirements for filing appeals, to avoid the risk of the appeal being dismissed with prejudice for failure to include all of the requisite information and documentation in the initial appeal letter. ■

The PRRB's new rules are available on CMS's website at www.cms.hhs.gov/PRRBReview/DownloadsPRRBRules2008.pdf.

The revised CMS regulations are available at http://edocket.access.gpo.gov/2008/pdf/E8-11227.pdf.

PEER REVIEW

Credentialing, Peer Review Files Producible in Federal Tort Actions

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On March 27, 2008, a federal district court ruled that state and federal peer review laws do not preclude production of a physician's credentialing file or a hospital's peer review data sought by plaintiffs in a lawsuit brought under the Federal Tort Claims Act. *Vezina v. United States* (W.D. La., No. 07-cv-904). The ruling was in the context of a Motion to Quash in connection with the Federal Tort Claims Action, 20 U.S.C. § 1346(b) (2671-2680), brought by plaintiffs for personal injury suffered when she was treated by a physician employee of the Department of Health and Human Resources working at a Louisiana hospital in March 2004. The plaintiffs requested the documents concerning the physician's file, credentials, and peer review data from the hospital.

> *"The court ruled that, while both the Health Care Quality Improvement Act and HIPAA created privileges that protect peer review and credentialing files from disclosure, it is also clear that the federal acts do not categorically prohibit production."*

The hospital maintained that a number of the documents requested were subject to privileges under the Health Care Quality Improvement Act, 42 C.F.R. § 11101, La. R.S. 13:3715.3, and/or HIPAA. The hospital also maintained that the documents included privileged information concerning the Credentials Committee peer review data and patient information. The hospital consequently filed a Motion to Quash.

Because this suit was filed under the Federal Tort Claims Act, the court ruled that principals of federal law applied to privilege issues in this case and that the Louisiana privilege law, La. R.S. 13:3715.3, concerning the production of patient information, physician files, credentials and peer review did not apply. Moreover, the court said there was no federal law prohibiting the production of such information. The court ruled that, while both the Health Care Quality Improvement Act and HIPAA created privileges that protect the requested information from disclosure, it is also clear that the federal acts do not categorically prohibit production. Thus, patient information is entitled to the protection of a court protective order; however, it is not prohibited from being produced. Similarly, the court ruled that the Health Care Quality Improvement Act does not create a federal statutory privilege prohibiting the disclosure of peer review materials. The court noted that "there is no historical or statutory basis for a peer review materials privilege, the federal Health Care Quality Improvement Act of 1986, 42 U.S.C. § 11101 *et seq*., provides qualified immunity for persons providing information to a professional review body regarding the competence or professional conduct of the physician. 42 U.S.C. § 11111(a). This Act also established confidentiality for information reported under it but did not establish confidentiality for peer review records or protect peer review records and materials from discovery and court subpoena.

The absence of such privilege in the statute is evidence that Congress did not intend these records to have the level of confidentiality and protection advanced by the hospitals and provided in the state statute. The court did note, however, that although there are no federal privileges, it is clear that peer review materials are sensitive and inherently confidential. The court nevertheless ruled that the information was not prohibited from being disclosed. It conducted an in-camera review and ruled that the relevant documents should be produced with limitations, placed under a stipulated protective order, and marked "extremely confidential," which prohibited any disclosure to any person other than the party, attorney and staff, stenographers taking depositions, experts, and the court. Moreover, because some of the documents include the patients' identities, the court concluded that all reference to patients' names and other patient identifying information must be redacted from the records by the hospital prior to production.

It is important to be aware that when specific state statutes do not apply, the federal laws governing patient information and physician peer review material may not preclude the discovery and the appropriately "limited" production of relevant physician files, credentialing and peer review documents. ■

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