THE FLORIDA BAR

Health Law Section Newsletter

Vol. XV, No. 4 www.flabarhls.org July 2009

INSIDE:

The Stark Law: Compensation Arrangements - Payment of Overall Profits and Productivity Bonuses

by David L. Schick, Esq., Orlando, FL; Troy A. Kishbaugh, Esq., Orlando, FL

I. Stark Law Summary

Stark Law governs physician self-referral for Medicare and Medicaid[1] patients. Physician self-referral is the practice of a physician referring a patient to a medical facility in which he or she has a financial interest, be it ownership, investment, or a structured compensation arrangement. Stark Law provides that neither a physician nor his immediate family members may make a referral to an entity, for designated health services ("DHS") under Medicare, if such physician or family member has a direct or indirect "financial relationship" with the entity.[2] DHS consists of the following services: clinical laboratory services; physical therapy, occupational therapy, and speech-language pathology services (as of July 1, 2009 these services will include outpatient speech-language pathology services); radiology and certain imaging services; radiation therapy and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services.[3] Stark only applies to DHS payable, in whole or in part, by Medicare or Medicaid.[4]

A. Group Practice Definition and In-Office Ancillary Services Exception

1. Group Practice Definition

The determination of whether an organiza-

See "Stark Law" page 13

Message from the Chair

by Jeanne E. Helton, Esq., Jacksonville, FL

The Health Law Section has had a great year thanks to the dedicated work of a number of Section members and the Executive Council. This year, our Section placed an increased emphasis on practical value for Section members. In an effort to gain a better understanding of the needs of the members, the Section is distributing a survey to the membership to learn what we can do better to meet the needs of our members. In light of the effects of the economic downturn, we intend to offer more teleconferences and our first Webinar this fall as additional opportunities to permit our membership to obtain timely information on new legal issues as well as continuing education credits.

In January of 2009, the Executive Council authorized the Section to publish a Journal publication designed to provide an in-depth analysis of healthcare issues facing providers and their counsel. James "Chet" Barclay has undertaken to lead the efforts to publish the first Journal, anticipated to be released in November, 2009. The process is well underway so look for this new publication in the Fall.

See "Message From the Chair," page 2

MESSAGE FROM THE CHAIR

from previous page

Our CLE Committee Chair, Charmaine Chiu, was exceptionally busy this year and, by all accounts, does a wonderful job. In January, at the mid-year meeting, the Section, together with the Tax Section, sponsored the popular CLE, Representing the Physician 2009, co-chaired by Lester Perling and Alan Gassman. In March, 2009, the Section presented its annual Advanced Health Law Topics and Certification Review 2009, co-chaired by Sandra Greenblatt and James "Chet" Barclay. Our June "Health Law Hot Topics" CLE program, scheduled in connection with the Annual Meeting, is always well attended, and this year will feature lectures on the Obama Administration's plans for health care, the *Wyeth* decision by the U.S. Supreme Court, and our update on health care legislation during the 2009 Florida Legislative Session. In the Fall of 2009, the Section is making plans to present the first Florida Bar Health Law Fundamentals Program that is designed to introduce new lawyers, or lawyers new to health law, to the basics of health law with a focus on Florida law. James "Chet" Barclay and Lisa Barclay are co-chairing this program, and it is shaping up to be a wonderful program. With the establishment of this program, our Section will offer comprehensive courses at varying levels of expertise.

The Section also is publishing a 2009 edition of the Health Law Handbook, co-edited by John Buchanan and Jeanne Helton, and should be available at the Annual Meeting and thereafter. Historically, the Handbook has been a best seller in terms of publications and serves as a wonderful desk reference guide. The 2009 edition promises to be equally as useful as prior editions.

Another useful tool that has benefited the Section membership is the publication of a newsletter approximately three times a year. Tom Clark is the new Editor of the newsletter with Bernabe Icaza, prior Editor, offering assistance in a secondary role. We invite anyone who has an article of interest to submit it for review.

In terms of significant events, the Section was saddened to learn of the death of a longtime member and contributor, Barbara Ropes Pankau. Barbara leaves a legacy of service and commitment and the entire section has benefited from her efforts. She will be missed but certainly not forgotten. Also, the Section owes a debt of gratitude to Valerie Yarbrough, our former Section Administrator from The Florida Bar, for all of her efforts. We also welcome Christina Sykes, our new Section Administrator and look forward to working with her. We also accepted the resignation of Spencer Levine from the Executive Council in mid-April. Spencer was appointed as a Judge on the Fourth District Court of Appeals. Congratulations to the Honorable Spencer Levine!

The Health Law Section continues its efforts to increase the interest in health law among law students. As part of this effort, the Section has an organized program to host pizza luncheons at law schools around the state, ideally on an annual basis. The luncheons pair area lawyers with students at the law school so students can get a sense of the variety of work under the umbrella of healthcare and to hopefully inspire some to join the practice area. Also, in the vein of academic updates, the Section previously endowed a professorship at the Florida State University School of Law. Due to the relocation of a health law professor, the position was vacant for some time. Chet Barclay agreed to begin teaching a health law course in January 2009, while continuing in his private practice. We can already see evidences of the increase in interest among students.

This year, we made an extra effort to reach out to the Section and request new volunteers to consider putting their names in for consideration to possibly serve on the Executive Council. There were over twenty individuals that responded but we have only four vacancies coming up this year. However, we are thrilled with the interest expressed by everyone and are certain that we can channel this renewed interest into areas that will be beneficial to the Section. Fresh ideas and perspective are vital to any organization. Come to the meetings in person if possible, and participate by phone if not. Volunteer to work on a committee. If you have expertise in an area, volunteer to speak at a program or author a piece in the newsletter. Your efforts will make your own practice enjoyable and you will become a better lawyer.

As we move toward the annual meeting in June 2009, I am preparing to pass the chair's gavel to our incoming Chair for 2009-2010, Troy Kishbaugh, Esq. He is ready to lead the Section and make the coming year the best yet!

In closing, I want to thank everyone for all of the encouragement and support that made my year as Chair exciting and enjoyable. Special thanks to each member of the Executive Council, each of our officers, and each person who volunteered to serve on a committee. It has been a complete privilege to serve alongside each of you!

Editor's Note

by Bernabe A. Icaza, Esq., Ft.Lauderdale, FL

Welcome to the latest edition of the Florida Bar Health Law Section Newsletter.

We once again thank those authors who submitted articles for publication.

The new concerns over a swine flu epidemic last month reminded us of the importance of public health as it relates to our practice and every day life. Many of us who interact each day with hospitals, clinics and other health care providers have to remain alert over new developments as it relates to this new national emergency. I would like to remind you that the Florida Bar Health Law Section last year formed the Public Health Law Committee to help keep you informed about such important public health matters. Anyone wishing to participate or get involved should feel free to contact the co-chairs, Rod Johnson (*Rodney_Johnson@doh.state.fl.us*) and Walter Carfora (wcarfora@carforahealthlaw.com).

I have enjoyed serving as Editor of the Health Law Section Newsletter since 2006. During this period over forty authors have prepared and submitted articles for publication. This newsletter would not be possible without the work, dedication and commitment of each of these authors and the dedication and commitment of the executive council members and bar staff who have devoted significant time and attention to this newsletter. Tom Clarke, Esq., will be taking over the role of Editor. I invite you to submit articles to him for publication at *thomas.clark@henlaw.com.*

Incoming Editor's Note

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

I was recently asked to assume Bernabe Icaza's responsibilities as the Editor of the Health Law Section E-Newsletter. As many of you know, Bernabe has served as the Editor of the newsletter since its first publication in September 2006. Under Bernabe's supervision, and with the help and support of the various authors and staff members of the Florida Bar, the newsletter has grown in quality and substance.

To maintain the newsletter as an informative and useful publication, we need your help. So, if you are interested in submitting articles for publication, please submit them to me at thomas.clark@henlaw.com. I look forward to working with you.

Thank you again Bernabe for all of your hard work.

Thomas P. Clark, Esq., is a shareholder with the law firm of Henderson, Franklin, Starnes & Holt, P.A., located at 1715 Monroe Street, Fort Myers, Florida 33902. Mr. Clark is a Member of the Health Law Section and Tax Section of The Florida Bar. Mr. Clark is Board Certified by the Florida Bar in Health Law and Tax Law. Mr. Clark may be reached at (239) 344-1178 or thomas.clark@henlaw.com

Introduction to Recovery Audit Program (RAC)

by John D. Buchanan, Jr., Esq., Tallahassee, FL

Medical overpayments have been a problem. In early 2003, the Department of Health and Human Services under Congressional Act began a three-year demonstration program to determine whether RACs would be cost effective. The three demo states were California, Florida and New York. The demonstration program ended in 2008. While the demonstration program was in full swing, CMS expanded the program. Other states were added to the demonstration program. The demonstration program was a success. The program was to be expanded nation-wide by 2010.

In 2005, the program became permanent ("RAC program"). All states will have RAC programs beginning 2009 or 2010.

Under the RAC program, compensation is paid to the RAC's private contractors and is on a contingency basis. In 2007, the RAC program collected $371 million in improper Medicare payments, with only 5 percent overturned on appeal.

The Recovery Audit Program (RACs)

Florida was among the first of the pilot projects. The Florida RAC program started October 1, 2008. The Center for Medical Services ("CMS") determined that the RAC program was practical. As a result, there were independent contractors selected for various states based on regions. Florida is in Region C, which includes South Carolina, Colorado and New Mexico. The contractor for CMS Florida is Conley Associates, Inc., of Wilton, Connecticut. Viant is the subcontractor for Florida. Viant will do the complex reviews on hospital claims.

Focus

The focus generally will be on hospitals, home health agencies, durable medical equipment suppliers (DMEs), and later doctors, which would include clinics.

Theory Behind the RAC

While CMS has always had the authority to recoup from providers (hospitals, doctors, clinics, etc.), this process has been cumbersome. The pilot projects, which included Florida, found that if CMS contracted with contractors on a contingency basis, the success ratio for recouping overpayments worked. This is very similar to where insurance carriers involve various outside organizations to question legal fees.

The Review Process-How it Works

The RAC conducts two types of review. The first is called the "automated review," and the second is the "complex review." An automated review is a review of claims data *without a review of Medicare records*, and it is only conducted in cases where there is certainty that a claim includes an overpayment. A complex review consists of a review of medical or other records, and the possibility of overpayment.

These reviews certainly are not unbridled reviews. The RAC contractor must abide by the federal statutory regulations and manuals. The RAC review can look back three years as far back as October 1, 2007. According to the Florida Hospital Association ("FHA"), records review will start late April or early May 2009 (FHA report).

The big concern for providers in the overpayment process by RACs is at what stage can CMS as the Medicare payor withhold payments or if certain appeal processes are going on can Medicare include interest for a pending claim. There are certain points along the appeal line that a provider must make certain decisions regarding how to approach the overpayment claim asserted by a RAC.

The process from the beginning to where the RAC has a preliminary stage is called a rebuttal, according to just furnished information.

DISCUSSION

Stage One

An intermediary conducts the inquiry for payment. First Coast, which is the contractor and intermediary ("F.I.") and a subsidiary of Blue Cross/Blue Shield, located in Jacksonville, Florida, is the contractor determining payments of Medicare in Florida. After the F.I. determines and renders an unfavorable initial determination and finds an overpayment to exist then there is issued a demand letter and withholding starts the 41st day following the demand letter. The provider can request a "redetermination" within 120 days from the date of the initial demand letter from the F.I.

If the provider files the request for re-determination, Medicare will cease its withholding activities, but interest will continue to accrue on the claim. The provider must request a re-determination within 120 days from the date of the initial demand letter from the F.I.

The re-determination decision can result in full or partial affirmation of the over-payment. The F.I. has 60 days to decide whether RAC was correct or not. If correct, the F.I. will request full payment. If denied, the F.I. will submit a letter of explanation for denial of the claim conducted by RAC. (Please note

See "Recovery Audit Program" page 16

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

Defending Unlicensed Practice of Medicine and Unlicensed Practice of Health Care Professions Prosecutions

by Kevin J. Darken, Esq., Tampa, FL

A. Introduction

Increasingly, Florida Department of Health investigators are bringing criminal charges against electrologists and cosmetologists for unlicensed practice of medicine or unlicensed practice of health care professions for such conduct as performing laser hair removal without a physician being present, removing skin tags, or performing laser tattoo removal without a physician being present. My firm has defended four such cases in Hillsborough, Pinellas and Pasco Counties in the last two years. Each time we were able to resolve the case with a pretrial intervention agreement under which the criminal charges will be dropped upon completion of the pretrial intervention program. Although the facts of each case obviously differ, here is an outline of arguments potentially available for use in such cases.

B. Elements of the Offenses

Florida Statute § 458.327(1)(a) makes "[t]he practice of medicine or an attempt to practice medicine without a license to practice in Florida" a felony of the third degree. Florida Statute § 458.303(1)(a) provides that Section 458.327 "shall have no application to . . . other duly licensed health care practitioners acting within their scope of practice authorized by statute."

Florida Statute § 458.305(3) defines "practice of medicine" as "the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition."

Florida Statute § 456.065(2)(d)(1) provides that "[i]t is a felony of the third degree . . . to practice, attempt to practice, or offer to practice a health care profession without an active, valid Florida license to practice that profession." Attempting or offering to practice a profession is defined as including "[a]pplying for employment for a position that requires a license without notifying the employer that the person does not currently possess a valid, active license to practice that profession..."

Neither the unlicensed practice of medicine crime nor the unlicensed practice of health care profession crime by their statutory language contain any mental state element at all.

C. The Problem

Both the unlicensed practice of medicine and unlicensed practice of health care professions crimes are classified as Level 7 offenses under the Criminal Punishment Code in Florida Statute § 921.0022. Under the Criminal Punishment Code worksheet computations in Florida Statute § 921.0024 the lowest permissible sentence for a Level 7 offense committed by a defendant with no prior record, no victim injury, and no other aggravating factors is 21 months imprisonment.

D. Arguments

I. The Defendant Did Not Practice or Attempt to Practice Medicine or a Health Care Profession

In one case we defended in Pasco County, the defendant electrologist was charged with unlicensed practice of medicine for performing laser tattoo removal. We argued to the State Attorney's Office that nothing in Florida Statute § 458.305(3) says anything about the practice of medicine including tattoo removal. Moreover, a tattoo is not a disease, a pain, an injury, a deformity, a physical condition, or a mental condition. Similarly, removing a tattoo is not a diagnosis, an operation, a prescription, or a treatment because there is nothing medically wrong with the skin underlying the tattoo. Just as taking a person's blood pressure is not the practice of medicine because "blood pressure is not a disease", so too tattoo removal is not the practice of medicine because a tattoo is not a disease either.[1]

As further support, we noted that research had located no case in any state holding that tattoo removal constitutes the practice of medicine. Furthermore, we observed that Florida Statute § 877.04 permits tattooing, as opposed to tattoo removal, to be done under a physician's general supervision without requiring a physician's presence during the tattooing procedure. We argued that since tattooing does not have to be performed by a physician, and does not even have to be performed in the presence of a doctor, how can tattoo removal constitute the practice of medicine?

In another case we defended in Pinellas County, the defendant electrologist/cosmetologist was charged with unlicensed practice of a health care profession for offering to remove skin tags from an undercover detective with an electrolysis instrument. First, we argued to the State Attorney's Office that the defendant had not "offered" to remove skin tags from the detective, she had merely quoted a price.[2] Second, we argued that removal of skin tags by an electrolysis instrument did not constitute the practice of a health care profession which the defendant was not licensed to practice. As a licensed electrologist, the defendant was permitted to practice electrology, which is defined in Florida Statute § 478.42(5) as "the permanent removal of hair by destroying the hair-producing cells of the skin and vascular system ...." Applying an electrology instrument to skin tags, we asserted, would have destroyed the hair-producing cells of the skin and vascular system on the skin tag. As support for that argument, we downloaded internet sites of electrologists around the country to show that it is commonplace for electrologists to use electrolysis to remove skin tags.

In two cases we defended in Hillsborough County, the defendant electrologists were charged with unlicensed practice of a health care profession for performing laser hair removal while not being under a physician's direct supervision and responsibility. We argued to the State Attorney's Office that the key term "direct supervision and responsibility" is not defined in either Florida Statutes or the Florida Administrative Code.[3] We pointed out that "direct supervision and responsibility" is a

continued, next page

combination of two definitions formerly contained in FAC Section 64B8-2.001 prior to its amendment in 2001. That section defined "direct supervision and control" as requiring "the physical presence of the supervising physician on the premises so that the supervising physician is immediately available when needed." However, that same section also defined "direct responsibility" as meaning "that the responsible physician need not be physically present on the premises but must be within close physical proximity and easily accessible." The key term "direct supervision and responsibility" is thus a combination of two conflicting definitions, one of which requires the physical presence of the supervising physician and one of which does not. As further support, we provided minutes from four meetings of the Florida Electrolysis Council in 2006-2007 demonstrating that even this body did not agree that that a supervising physician was required to be on the premises when laser hair removal was done by a licensed electrologist.

II. No Constitutionally Required Fair Warning Was Provided to the Defendant that the Alleged Conduct Constituted the Practice of Medicine or the Practice of a Health Care Profession

The Due Process Clauses of both the Florida Constitution and the United States Constitution are designed in part "to insure that no individual is convicted unless 'a fair warning [has first been] given to the world in language that the common world will understand, of what the law intends to do if a certain line is passed.'"[4] In the Pasco County tattoo removal case, we argued that no constitutionally required fair notice was provided in either Florida Statutes or the Florida Administrative Code that a non-physician who performs laser tattoo removal was committing the felony crime of unlicensed practice of medicine. In the Hillsborough County laser hair removal cases, we argued that the ambiguity of the key term "direct supervision and responsibility" precluded the constitutionally required fair warning.

III. The Defendant Did Not Know His or Her Conduct Was Illegal

As stated above, neither the unlicensed practice of medicine crime nor the unlicensed practice of health care profession crime contains a mental state element. Moreover, the Florida Supreme Court has stated that "under the Medical Practice Act the state is required to prove only the elements of the crime charged: that defendant is not a licensed physician, but that he practices medicine within the statutory definition."[5] However, both Florida courts and the United States Supreme Court have held that even criminal statutes which do not explicitly require proof that the defendant knew he or she was acting illegally in fact implicitly require proof that the defendant knew his or her conduct fell within the statutory prohibition.[6] Because both the unlicensed practice of medicine crime and the unlicensed practice of health care profession crimes are third degree felonies punishable by up to five years imprisonment, those statutes must be interpreted as requiring that the defendant knew his or her conduct was illegal in order for those statutes to be constitutional.[7]

Proof that the defendant did not know his or her conduct was illegal is likely too easily available. In some cases, defendants openly advertise the charged conduct. In other cases, defendants have relied on web sites which advise that direct physician supervision is not required for laser hair removal by electrologists in Florida. In still other cases, the defendant's transaction with an undercover detective may be recorded and the defendant may display no indications that he or she thinks the charged conduct is illegal or even wrong.

E. Conclusion

Criminal unlicensed practice of medicine and unlicensed practice of health care profession prosecutions are high stakes cases for the defendants because of both the mandatory prison sentence which will follow a conviction and because of the effect a conviction will have on the defendant's license to practice electrology, cosmetology or another profession. Yet there are arguments available for skilled defense counsel to make which may well persuade a prosecutor to either drop the case or else resolve the case through a pretrial intervention program.

Kevin Darken, Esq., *practices white collar criminal defense, False Claims Act and qui tam litigation, and health care litigation at Cohen & Foster in*

See "Defending Unlicensed" page 17

HITECH Impact on Florida HealthCare Providers

by Rodney M. Johnson, Esq., Pensacola, FL

On Tuesday, February 17, 2009, the President of the United States signed into law HITECH beginning at page 113 of the American Recovery and Reinvestment Act of 2009 Stimulus Package.[1] HITECH stands for Health Information Technology for Economic and Clinical Health. HITECH emphasizes development of health information networks. Overall the Act bodes well for implementation of (HIPAA) Health Insurance Portability and Accountability Act goals of national health information network with easy access by healthcare providers. Most in the healthcare industry look forward to the lessening of unnecessary repeat of medical tests and more complete access to the records of a patient's prior care that is the promise of HIPAA. However, HIPAA also imposes some requirements on how information is handled by healthcare providers. HITECH makes some substantial changes short of earth shattering, unless you are a business associate. Business associates will be held accountable to the same civil and criminal standards as covered entities.[2] This change will make business associates responsible not only to the involved covered entity but now to enforcement authorities to the same extent as a covered entity.

The biggest change facing healthcare practitioners and facilities is the requirement to accept and honor a patient's restriction on disclosure of their information. Prior to this, healthcare practitioners often rejected patient restrictions on healthcare information so that all records would be handled the same way. Not anymore. The change is not as drastic as it appears at first blush. A patient may limit disclosure for payment or healthcare operations only if the services have been paid in full prior to the restriction. No restriction is permitted on disclosures for treatment.[3]

When a patient is to be notified of a breach is now specified. Previously the HIPAA Privacy Rule gave no guidance on when a patient was to be notified of an unauthorized disclosure of their information. Now, clarity has been provided. The term 'breach' has been introduced for the unauthorized acquisition, access, use, or disclosure of a patient's health information. Excepted from the broad definition of 'breach' is unintentional access or use by an employee or agent of the covered entity or business associate.[4] The end result is expected to be a regulation requiring patient notification when the breach has a reasonable possibility of harm and not for unintentional in-house disclosures.

HITECH also introduces the new concept of a (PHR) personal health record. This is a record controlled primarily by the individual. Google, Microsoft, and others have been offering a PHR service. HITECH provides needed accountability for operation of PHR services.[5]

The Secretary of (HHS) Health and Human Services has eighteen (18) months to promulgate regulations to implement the above changes.[6]

All in all, healthcare providers in Florida will continue pretty much the same. The need to obtain consent to disclose patient information for payment or operation still exists due to the more stringent Practitioner and Hospital Confidentiality laws of Florida. [7]

Though HITECH limits disclosure log presentations to three (3) years, instead of the previous six (6) years, Florida's Practitioner Confidentiality laws still require the log to cover all disclosures and not just those for purposes other than treatment, payment, or operations.[8]

HITECH promises construction of a National Information Network. The federal funds made available are truly impressive and stimulating. Starting in 2011, ten federal dollars are available for every state dollar.[9] The language of the law indicates that an even smaller state match may be adequate for those able to act in 2009 or 2010.[10] We should have functioning health information networks up and running nationwide in the very near future.

****

Rodney M. Johnson, Esq., *is Florida Bar Board Certified in Health Law and State and Federal Government and Administrative Practice, is Chief Legal Counsel of the Northwest Law Office of the Florida Department of Health, 1295 West Fairfield Drive Pensacola, Florida 32501, (850) 595-6517. He was the Department's Privacy Officer from 2004-2009. The views expressed in this article are his alone and are not ascribable to any other entity.*

Endnotes:

1 The American Recovery and Reinvestment Act contains within it the Health Information Technology for Economic and Clinical Health (HITECH) Act at page 113 through 165.

2 Title XIII Health Information Technology Subtitle D Privacy - Section 13401-1341.

3 Title XIII Health Information Technology Subtitle D Privacy - Section 13405(a).

continued, next page

HITECH

from previous page

4 Title XIII Health Information Technology Subtitle D Privacy – Section 13400(1) Breach (A) In General - The term "breach" means the unauthorized acquisition, access, use, or disclosure of protected health information which compromises the security or privacy of such information, except where an unauthorized person to whom such information is disclosed would not reasonably have been able to retain such information. (B) Exceptions – The term "breach" does not include (i) any unintentional acquisition, access, or use of protected health information by any employee or individual acting under the authority of a covered entity or business associate if – (I) such acquisition, access, or use was made in good faith and within the course and scope of the employment or professional relationship of such employee or individual, respectively, with the covered entity or business associate; and (II) such information is not further acquired, accessed, used, or disclosed by any person; or (ii) any inadvertent disclosure from an individual who is otherwise authorized to access protected health information at a facility operated by a covered entity or business associate to another similarly situated individual at same facility; and (iii) any such information received as a result of such disclosure is not further acquired, accessed, used, or disclosed without authorization by any person.

5 Title XIII Health Information Technology Subtitle D Privacy – Section 13400(11) page 145.

6 Title XIII Health Information Technology page 158 - Section 13410(b)(2) GAO Report – Not later than 18 months after the date of the enactment of this title, the Comptroller General shall submit to the Secretary a report including recommendations for a methodology under which an individual who is harmed by an act that constitutes an offense referred to in paragraph (1) may receive a percentage of any civil monetary penalty or monetary settlement collected with respect to such offense.

7 Sections 456.057, 395.3025, Florida Statutes.

8 Section 456.057(12), Florida Statute, and 45 CFR 164.528(a)(1).

9 Title XII Health Information Technology Subtitle B Incentives for the Use of Health Information Technology – Section 3013(i) Required Match (1) In General - For a fiscal year (beginning with fiscal year 2011), the Secretary may not make a grant under this section to a State unless the State agrees to make available non-Federal contributions (which may include in-kind contributions) toward the costs of a grant awarded under subsection (c) in an amount equal to (A) for fiscal year 2011, not less than $1 for each $10 of Federal funds provided under the grant; (B) for fiscal year 2012, not less than $1 for each $7 of Federal funds provided under the grant; and (C) for fiscal year 2013 and each subsequent fiscal year, not less than $1 for each $3 of Federal funds provided under the grant. (2) Authority to Required State Match for Fiscal Years Before Fiscal Year 2011 – For any fiscal year during the grant program under this section before fiscal year 2011, the Secretary may determine the extent to which there shall be required a non-Federal contribution from a State receiving a grant under this section.

10 Title XII Health Information Technology Subtitle B Incentives for the Use of Health Information Technology – Section 3013(i)(2).

Practice Pointer: Providers Inability to Produce Irretrievable Medical Records May Not Be Fatal To Medicare Overpayment Appeal

by Harold E. Kaplan, ESQ., Coral Springs, FL

What should a physician do when he or she must produce medical records for a Medicare overpayment review and those records were destroyed in a storm or other catastrophe? If a hurricane or other disaster, natural or man-made caused the records' destruction, a 2006 update to the Medicare Program Integrity Manual (the "Program Integrity Manual")[1] may provide a basis to excuse non-production of medical records in order to claim reimbursement for professional services in a post payment review.

Although there is a paucity of reported decisions regarding lost or destroyed medical records, *in the case of Samuel Nigro, M.D.,*[2] the Department of Health & Human Services, Departmental Appeals Board, Medicare Appeals Council (the "Council"), gave the physician the "benefit of the doubt" when he could not provide copies of missing skilled nursing facility ("SNF") records. In its decision, the Council acknowledged that the provider was not the custodian of SNF records and ordered the removal of those missing records (and their related claims denials) from the overpayment extrapolation since the provider was unable to obtain those records from the SNF stating:

"Generally, it is the obligation of a physician or other supplier to maintain documentation of Medicare services provided. However, when medical services are provided in a nursing home, the medical records are maintained by and remain in the custody of the nursing home rather than the physician. For this reason, we are giving the appellant the benefit of the doubt and have recalculated the overpayment dropping these beneficiaries from the sample on which the overpayment is calculated."[3]

In the case of Unihealth, Inc.,[4] a recent unpublished decision, the Council applied section 3.2.2 of the Medicare Program Integrity Manual (the "Program Integrity Manual"), to reverse the overpayment determination based on irretrievably lost medical records.[5] Section 3.2.2 of the Program Integrity Manual is a relatively new provision, and provides in pertinent part that "[i]n the case of complete destruction of medical records where no backup records exist, [Medicare] contractors must accept an attestation that no medical records exist and consider the services covered and correctly coded."[6]

In *Unihealth,* the provider was not the custodian of missing SNF records which it could not provide to Medicare for review and which were destroyed by a disaster. Nevertheless, the Administrative Law Judge ("ALJ") refused to apply or follow section 3.2.2 of the Program Integrity Manual, stating that he was not bound by the provisions in the manuals issued by the Centers for Medicare and Medicaid Services. Instead, the ALJ reasoned that "[w]ithout supporting records, medical necessity…. cannot be determined."

The Council did not agree with the ALJ's ruling, and pointed out in its decision that although the ALJ recognized that the medical records were stored offsite and under the control of the SNF, the ALJ still considered the provider to be "at fault" for the loss of the records. Importantly, the ALJ never discussed the evidence proffered by the provider. That evidence included an affidavit of the provider's senior officer stating that he personally made repeated requests to the SNF for the missing records. The provider also gave the ALJ its attestation that it was advised by the SNF that medical records were destroyed in a hurricane. The provider also submitted evidence from the records storage facility that reported that the records storage facility was damaged by a hurricane and a letter from the SNF's administrator responding to the provider's request for

See "Practice Pointer" page 18

Recent Developments in Florida Law Regarding Due Process Rights for Physicians Whose Medical Staff Privileges are Impacted by a Hospital's Decision to Enter into an Exclusive Contract Relationship with a Provider Group

by Justin C. Fineberg, Esq., Fort Lauderdale, FL and Lorelei J. Van Wey, Esq., Miami, FL

Florida courts continue to grapple with the question of due process rights to be afforded a physician whose medical staff privileges are impacted by a hospital's decision to enter into an exclusive contract relationship with a provider group. Three recent Florida appellate and trial courts decisions have confronted the issues under varying factual scenarios and have reached different conclusions. As a result, some areas of consensus are developing, while other areas of significant divergence are also emerging.

A. Recent Cases

I. *Naples Community Hospital, Inc. v. Hussey,* 918 So. 2d 323 (Fla. 2d DCA 2006)

In *Hussey,* the Second DCA addressed the question of a physician's due process rights when the hospital denied the physician's request for reappointment of his clinical privileges based solely upon its decision to enter into an exclusive provider contract with a separate group.

Dr. Hussey was granted clinical privileges (including in pain management) for a two-year term. In the middle of the two-year term, the hospital's parent company entered into an exclusive contract with another medical provider to provide pain management services. Upon expiration of Dr. Hussey's clinical privileges, the hospital denied his application for reappointment without a hearing.

The hospital's medical staff bylaws discussed the reappointment procedure, which generally involved considerations of the physician's quality of care. Under the bylaws, if an initial recommendation was to deny the application based on quality of care considerations, the affected physician would be afforded a hearing. The bylaws did not specifically address the issue raised by Dr. Hussey's situation – whether a staff member who is reapplying for clinical privileges in a newly closed practice area now under an exclusive contract would be afforded the same process. However, the bylaws expressly provided that the purpose of a hearing was to recommend a course of action to the hospital's governing body.

After his reappointment was denied, Dr. Hussey sued the hospital, claiming that the bylaws required that the hospital afford him a hearing upon its refusal to reappoint him with the same clinical privileges. The trial court agreed with Dr. Hussey, granting injunctive relief and requiring the Hospital to give Dr. Hussey a hearing and to allow Dr. Hussey to exercise his privileges until the hearing.

On appeal, the appellate court reversed, finding that a hearing was not required under these circumstances. In determining that a hearing process would be an exercise in futility, the Second DCA found:

> [B]ecause the Hospital would be denying renewal of such clinical privileges based on a business decision to enter into an exclusive contract, and not because of recommendations from department chairpersons, it would seem like a futile process. In fact, the entire hearing process, described in [the bylaws] is based on the premise that a doctor's competence is called into question and his or her reputation is at stake. The notice of hearing includes "a proposed list of witnesses who will give testimony or evidence in support of the Credentials Committee or the Board at the hearing" and "shall contain a concise statement of the practitioner's alleged acts or omissions, a list by number of specific patient records in question, and any other reasons or subject matter which form the basis for the adverse recommendation.

We cannot imagine how Dr. Hussey's hearing, if he were to get one, would proceed. There would be no statement of acts or omissions, no patient records, and no testimony casting doubt on his skill-no accusations against which to defend himself. Ultimately, the decision of reappointment would fall to the Board of Directors, the very body that made the business decision that adversely affected Dr. Hussey's clinical privileges at the Hospital.

The court went on to find that because those acting for the corporation had already entered the exclusive contract, the hearing process would be pointless. Ultimately, the court held that the hearing process clearly did not apply when a staff member is denied reappointment because of a hospital's business decision to enter into an exclusive contract with another provider.

II. *Valdes v. Lifemark Hospitals of Florida, Inc.,* No. 01-19521 CA 10, 2006 WL 6218178 (Fla. 11th Cir. Ct., July 21, 2006)

In this case, a Florida trial court addressed the issue of whether physicians who practiced as part of an exclusive group were entitled a hearing when they were unable to exercise their clinical privileges after voluntarily leaving the exclusive group.

In *Valdes,* the plaintiff-physicians were members of a physician group which had an exclusive contract to provide neonatology services to the hospital. The plaintiff-physicians had applied for, and received, medical staff privileges in neonatology.

Following an internal dispute within the physicians' group, the physician-

continued, next page

plaintiffs voluntarily left the group to form their own separate practice. The plaintiff-physicians then voluntarily stopped practicing at the hospital, but maintained their staff privileges.

Nearly a year-and-a-half after splitting with the exclusive group, the plaintiff-physicians attempted to return to practicing at the hospital as members of the new group. However, the hospital still had an exclusive contract with the former group. Accordingly, the hospital rejected these attempts, informing the plaintiff-physicians that because of the exclusive provider contract, and because the plaintiff-physicians were no longer part of the exclusive group, the plaintiff-physicians could not exercise their privileges in neonatology. The hospital's decision was purely administrative and had nothing to do with the clinical competence of the plaintiff-physicians. The hospital did not provide the plaintiff-physicians with a hearing.

Like the bylaws in *Hussey,* the hospital's medical staff bylaws provided for a notice of hearing that contemplated quality of care considerations. The bylaws did not address the question of whether a physician is entitled to a hearing when the physician cannot exercise his or her privileges based upon the physician's voluntary decision to leave a group holding the exclusive contract for those services at the hospital.

The plaintiff-physicians then sued the hospital, asserting claims for breach of the bylaws and for injunctive relief in failing to grant the physician-plaintiffs a hearing. In rejecting the plaintiff-physicians' claims, the trial court relied upon the *Hussey* opinion. The trial court found that like *Hussey,* the plaintiff-physicians were no longer able to exercise their privileges because of the hospital's administrative business decision to enter into an exclusive contract with another practice group. There was no question of clinical competency and the bylaws contained provisions for notice and a hearing only on questions of competency.

In addition to those similarities, the trial court further concluded that the facts presented were even more compelling than in *Hussey:*

> Plaintiffs voluntarily left the practice group holding the exclusive contract for neonatology services with [the hospital]. Plaintiffs sought to return to practicing at [the hospital] after an absence of a year-and-a-half despite the fact that they had left the exclusive contract group and that an exclusive contract was in place. Having enjoyed the benefits of working under an exclusive contract while practicing at [the hospital], Plaintiffs now sought to have the hospital act in derogation of its exclusive contract with Plaintiffs' former partner/employers, with whom Plaintiffs were now in direct competition. Moreover, the Hospital continued to grant Plaintiffs reappointment to the Medical Staff with privileges and allowed Plaintiffs to exercise any privileges they held other than neonatology. Plaintiffs also continue to hold their neonatology privileges, putting them in the position of seeking to become the exclusive provider or even to exercise their privileges in the event the exclusive contract with their competitors is terminated.

To further support its conclusion, the trial court looked to cases outside of Florida. The court concluded that its decision was consistent with the majority view in other states that the hearing rights under the medical staff bylaws are not implicated when a provider cannot exercise his or her privileges resulting from the hospital's decision to enter into an exclusive contract.[1] The trial court also found that its decision was consistent with other Florida courts, which had indicated that they would follow this majority view.[2]

III. *University Community Hospital, Inc. v. Wilson*, 1 So. 3d 206 (Fla. 2d DCA 2008)

In Wilson, the Second DCA confronted the similar issue of due process rights afforded to a physician whose privileges were impacted by the hospital's decision to terminate the exclusive contract with the physician's group.

The hospital had an exclusive contract with the plaintiff-physicians to provide radiology services. The hospital gave the plaintiff-physicians timely notice of its intent to terminate the exclusive contract effective November 2001. However, the hospital had previously granted the individual plaintiff-physicians clinical privileges for terms that extended beyond the contract termination date. Notwithstanding, the hospital notified the plaintiff-physicians of the decision to change contract providers and to continue to maintain the provision of radiology services on an exclusive basis. The decision was not based on quality of clinical services, and the hospital took the position that the decision did not trigger the hearing process under the medical staff bylaws, which was generally triggered by quality-of-care issues.

Nevertheless, the hospital offered a hearing to the plaintiff-physicians, after which the hospital reaffirmed its decision. The plaintiff-physicians were thereafter not allowed to exercise their clinical privileges.

The plaintiff-physicians then sued the hospital, claiming that the hospital had violated the bylaws by terminating or restricting their privileges despite not finding any quality-of-care issues. At trial, the parties submitted cross motions for summary judgment based upon a joint stipulation of undisputed facts. The hospital argued that it did not terminate, revoke, suspend, curtain or restrict the physician's privileges, but only advised the physicians that they could not exercise their privileges. The trial court rejected this contention, finding that the hospital had terminated the medical staff privileges by virtue of entering into an exclusive provider contract with other physicians and by no longer allowing the physicians to exercise their privileges.

On appeal, the Second DCA affirmed this decision. Importantly, the appellate court affirmed the trial court's ruling which rejected the hospital's argument distinguishing between the granting of privileges and the exercise of those privileges, finding it to be a "distinction without a difference." This key finding, made without discussion or citation to authority, was the underpinning of the balance of the court's opinion.

The appellate court found that once privileges are granted, the hospital bylaws become a binding and enforceable contract between a hospital and its medical staff. The appellate court then found that once privileges are granted, those privileges either expire at the conclusion of the awarded term or in accordance with the bylaws or rules established by the hospital. Because the hospital found no quality-of

continued, next page

DUE PROCESS RIGHTS

from previous page

care issues, the court found that the bylaws did not allow the hospital to use its award of a new exclusive provider contract as a basis to "prematurely terminate the physician's clinical privileges contract."

The appellate court further addressed the hospital's contention that the bylaws allowed it to impact the physician's existing privileges by reason of an administrative decision to contract with another exclusive group. The relevant portion of the bylaws provided in part that "[w]ith the exception of actions of an administrative nature, privileges may not be revoked, revised or renewed without the consideration of quality of care." In rejecting this argument, the appellate court stated:

The Bylaws, i.e., the privileges contracts, clearly demonstrate that a physician's clinical privileges cannot be terminated during the term of those privileges without proper consideration of the physician's quality of care, unless it is due to administrative action. The phrase "with the exception of actions of an administrative nature" separates quality of care concerns from actions that the governing board of [the hospital] may take in overall management of the hospital, but does not excuse the hospital from following the due process safeguards accorded the physicians in each's privileges contract. Such general management decisions by the hospital's governing board "would have nothing to do with the practitioner's competence to practice." *Palm Springs Gen. Hosp. Inc. v. Valdes,* 784 So.2d 1151, 1155 (Fla. 3d DCA 2001) (Schwartz, C.J., dissenting). But neither do they mean that due process rights in the Bylaws should be disregarded. (Footnote omitted)

The appellate court distinguished the case from *Hussey,* finding that if the same circumstance had occurred when the physician's privileges were due for review at the end of the privilege term, *Hussey* would have controlled. Ultimately, the appellate court found that the hospital made a decision to favor the exclusive provider contract over its obligations to the physicians under the bylaws. The court remanded the case for a proper determination of the damages suffered by the plaintiff-physicians

continued, next page

for a damage period from the date of that the hospital's breach of the bylaws through the date of the expiration of the physician's privileges.

B. Lessons Learned

From these three cases, certain areas of consensus are beginning to emerge under Florida law. One, these decisions are uniform in determining that hospital decisions to enter into exclusive contracts are administrative decisions that do not necessarily implicate quality of care concerns. Thus, the courts have given the hospital deference regarding these decisions and have not questioned the underlying merits of the decisions themselves.

Two, the decisions consistently found that the hospital's medical staff bylaws form a contract between the physician and the hospital. Consequently, courts interpreting bylaws will employ standards applicable to other contracts to determine the parties' intent. The courts have not deferred to the hospital's construction of the bylaws, but have rather indicated that they are applying the terms as drafted.

Despite these areas of agreement, there are significant areas of divergence. Most importantly, the decisions have differed regarding whether there is a distinction between the granting of clinical privileges and the right to exercise those privileges. As the trial court in Valdes found, the majority view is that a hospital's grant of staff privileges reflects only upon a physician's qualifications and competency and does not equate to the physician's right to utilize the hospital's facilities. Accordingly, most courts around the country have held that the due process rights embodied in the medical staff bylaws are not implicated when an exclusive contract incidentally limits a physician's use of the hospital facilities.

Courts have not been uniform in their treatment of exclusive contracts and the impact they have upon existing practitioners. By its decision in *Wilson,* the Second DCA, without discussion, followed the minority view that a physician's due process rights are implicated by virtue of the hospital's entry into an exclusive contract which impinge upon the ability to exercise privileges.[3]

However, the *Wilson* decision leaves many questions unanswered. In its decision, the Second DCA was the first Florida appellate court to address the question of whether Florida law will recognize a distinction between the granting of clinical privileges and the exercise thereof. The *Wilson* court did not address or discuss the logic of the *Valdes* opinion or of the other decisions from other courts finding a distinction.

Interestingly, the *Wilson* court relies on a dissenting decision from Judge Schwarz in the earlier (but unrelated) *Valdes* decision from the Third DCA. In that dissent, Judge Schwartz cited favorably to several appellate decisions from other jurisdictions which have found that there is a material difference between the granting of clinical privileges and the exercise thereof. Regardless of the apparent inconsistency, the Wilson decision may be controlling on other Florida trial courts until either a conflicting decision is rendered by another Florida appellate court or the Florida Supreme Court.

The lack of discussion of the reasoning behind the Wilson decision raises other questions. While the appellate court found the hospital liable for its administrative decision to "favor" the exclusive contract over the medical staff bylaws, it is not clear whether all administrative decisions that impact a physician's privileges will similarly place the hospital at risk. For example, under the logic of Wilson, a hospital could potentially be liable for an administrative decision to close a department or to stop offering a service line. It is not clear how far and to what extent courts will potentially impose liability on a hospital for such administrative decisions.

C. Conclusion

As a result, Florida physicians and hospitals must be aware of the implications of the decisions to enter into exclusive provider contracts and the impact those decisions may have on physicians with existing privileges. Each situation must be carefully analyzed under the specific facts and circumstances. In particular, the timing of when to enter into exclusive contracts may need to be timed with a hospital's reappointment cycle for the affected privileges. The medical staff bylaws and other contract language must be carefully reviewed to determine how to address the specific situations until Florida's courts more firmly adopt the majority view or clarify Florida's position on physician hearing rights.

****

Justin C. Fineberg *is a partner with Lash & Goldberg LLP, where he practices in commercial and civil litigation, with a focus on complex healthcare litigation, as well as commercial transactions. Mr. Fineberg represents publicly traded for-profit hospital chains, individual teaching and non-profit hospitals, provider networks and other multi-specialty healthcare providers in a variety of complex litigation matters, arbitrations, and transactions. He can be reached at: 2500 Weston Road, Suite 317, Fort Lauderdale, FL 33331, (954) 384-2500, and jfineberg@lashgoldberg.com.*

Lorelei J. Van Wey *is a partner with Lash & Goldberg LLP, where she practices complex civil and commercial litigation. Ms. Van Wey represents various corporate and individual clients in state and federal court as well as in commercial arbitrations. Before becoming a lawyer, she worked for 14 years in journalism, primarily with Knight-Ridder Inc. as an editor at the Detroit Free Press and* The Miami Herald. *Her last position at* The Miami Herald *was as the Daily Business News Editor. She also previously worked at Knight-Ridder's on-line information service, Viewtron. She can be reached at: 100 S.E. 2d Street, Suite 1200, Miami, FL 33131, (305) 347-4040,* Lvanwey@lashgoldberg.com.

Endnotes:

1 *Engelstad v. Virginia Mun. Hosp.,* 718 F.2d 262, 268 (8th Cir. 1983); *Harron v. United Hosp. Ctr. Inc.,* 522 F.2d 1133 (4th Cir. 1975); *Bloom v. Hennepin County,* 783 F.Supp. 418, 433 (D. Minn. 1992); *Rockland Physician Assocs., P.C. v. Grodin,* 616 F. Supp. 945, 950 (S.D.N.Y. 1985); *Radiation Therapy Oncology, P.C. v. Providence Hospital,* 906 So. 2d 904, 911 (Ala. 2005); *Tomlinson v. Humana, Inc.,* 495 So. 2d 630 (Ala. 1986); *Redding v. St. Francis Medical Ctr.,* 208 Cal. App. 3d 98 (Cal. Ct. App. 1989); *Hutton v. Memorial Hosp.,* 824 P.2d 61, 64 (Colo. App. 1991); *Dutta v. St. Francis Reg'l Medical Ctr., Inc.,* 850 P.2d 928, 934 (Ct. App. Kan. 1993); *Bartley v. Eastern Maine Medical Center,* 617 A.2d 1020, 1023 (Me. 1992); *Anne Arundel Gen. Hosp. v. O'Brien,* 432 A.2d 488, 489-91 (Md. App. 1981); *Vakil v. Anesthesiology Assocs. of Taunton, Inc.,* 744 N.E.2d 651, 658 (Mass. App. 2001); *Holt v. Good Samaritan Hosp. and Health Ctr.,* 590 N.E.2d 1318, 1323 (Ohio App. 1990); *Adler v. Montefiore Hosp. Asson of W. Pa.,* 311 A.2d 634 (Pa. 1973); *Van Valkenburg v. Paracelsus Healthcare Corp.,* 606 N.W.2d 908 (S.D. 2000); *Lister v. Methodist Medical Ctr.,* 1993 WL 481402 (Tenn. Ct. App.

continued, next page

DUE PROCESS RIGHTS

from previous page

1993); *East Texas Med. Ctr. Cancer Inst. v. Anderson,* 991 S.W.2d 55, 63 (Tex. App. 1998); and *Gonzalez v. San Jacinto Methodist Hosp.,* 880 S.W.2d 436, 440 (Tex. App. 1994).

2 *See, e.g., J. Sternberg v. Hospital Corp. of America,* 571 So. 2d 1334, 1335 (Fla. 4th DCA 1989) (affirming denial of temporary injunction where hospital claimed that physicians had no right to a hearing to challenge hospital's decision to enter into an exclusive contract). *See also Hager v. Venice Hosp., Inc.,* 944 F. Supp. 1530, 1534 (M.D. Fla. 1996) (granting summary judgment for hospital where physician's clinical privileges were deemed affected "only as an incidental consequence of the exclusive contract"); *Gould v. Sacred Heart Hosp. of Pensacola,* 1998 WL 995313 (N.D. Fla. 1988) (state administrative regulations pertaining to terminations of staff privileges apply only to dismissals relating to a physician's ability to practice medicine and do not apply where the hospital intends to terminate staff privileges for contractual reasons).

3 *See, e.g., Vakharia v. Little Company of Mary Hospital,* 917 F.Supp. 1282, 1302 (N.D. Ill. 1996) (holding that regardless of the hospital's right to enter exclusive provider agreements, hospitals may not breach contracts already accorded to physicians under bylaws); *Lewisburg Community Hospital, Inc. v. Alfredson,* 805 S.W.2d 756 (Tenn. 1991) (finding that hospital breached its bylaws by not affording radiologist a hearing when he was denied access to the hospital's facilities upon termination of his exclusive contract).

STARK LAW

from page 1

tion qualifies as a group practice is critical for several exceptions to the Stark Law, particularly the in-office ancillary services exception, which provides flexibility in compensating physicians in the group. As a general principle, in order to qualify as a group practice, the group must: (a) be a single legal entity; (b) have at least two members (employees or owners); (c) provide the full range of patient care services; (d) with certain exceptions, ensure that members provide at least 75% of their patient care services through the group; (e) have predetermined methods for distribution and income; (f) be a unified business; (g) not allow members to directly or indirectly receive compensation based on the volume or value of referrals (except as provided in the special rules for compensation described herein); and (h) have its members conduct no less than 75% of the physician-patient encounters.[5] If all the conditions are met, the group will constitute a group practice, which will enable its members to take advantage of the in-office ancillary services exception.[6]

2. In-Office Ancillary Services Exception

The in-office ancillary services exception allows physicians in a group practice to furnish ancillary services (e.g. x-ray, lab, ultrasound, physical therapy and other DHS) in their practices and utilize certain flexible physician compensation arrangements. In order to satisfy the in-office ancillary services exception, there are three restrictions covering: a) who may furnish the DHS; b) where the DHS must be provided; and c) how the DHS must be billed.[7] If all three restrictions are met, the DHS will not be prohibited referrals under Stark and the group practice may distribute the generated revenue from the DHS as provided herein.

2.1. Who May Furnish DHS

The DHS must be furnished by the referring physician, a physician who is in the same group practice as the referring physician, an individual who is supervised by the referring physician, or an individual who is supervised by another physician in the same group practice.[8]

2.2. Where Must the DHS be Provided

The Stark Law provides two options for "where" DHS must be provided for purposes of compliance with the in-office ancillary services exception. The DHS may be provided in the "same building" or in a "centralized building."

2.2.1 Same Building

DHS services may be provided in the "same building," but not necessarily in the same space or part of the building, where the group practice physician furnishes substantial physician services, without regard to whether such substantial services are DHS and without regard to whether such substantial services are paid by Medicare, Medicaid or any other payer.[9] The same building must be composed of a structure, or combination of structures, that share a single street address as assigned by the U.S. Postal Service.[10] However, the same building does not include exterior spaces, interior loading docks or parking garages, nor does it include mobile vehicles, vans or trailers.[11]

In addition to the above, and in order to qualify as a same building for purposes of the Stark Law, the group practice must satisfy certain office hour time frame requirements, and provide some physician services that are unrelated to the furnishing of DHS payable not only by Medicare, but also any other federal health care payer or a private payer, even though such physician's services may lead to the ordering of DHS.[12] The office hour time frame and physician services requirements can be satisfied if:

2.2.1.1 The referring physician or his or her group practice (if any) has an office that is normally open to the physician's or group's patients for medical services at least 35 hours per week; **and** the referring physician or one or more members of the referring physician's group practice regularly practices medicine and furnishes physician services to patients at least 30 hours per week in such office. The 30 hours must include some physician services that are unrelated to the furnishing of DHS as outlined above in Section 2.2.1;[13] **or**

2.2.1.2 The patient receiving the DHS usually receives physician services from the referring physician or members of the referring physician's group practice (if any); the referring physician or the referring physician's group practice owns or rents an office that is normally open to the physician's or group's patients for medical services at least 8 hours per week; **and** the referring physician regularly practices medicine and furnishes physician services to patients at least 6 hours per week in such office. The 6 hours must include some physician services that are unrelated to the furnishing of DHS as outlined above in Section 2.2.1;[14] **or**

2.2.1.3 The referring physician is present and orders the DHS during a

continued, next page

patient visit on the premises described in this Section 2.2.1.3, or the referring physician or a member of the referring physician's group practice (if any) is present while the DHS is furnished; the referring physician or the referring physician's group practice owns or rents an office that is normally open to the physician's or group's patients for medical services at least 8 hours per week; **and** the referring physician or one or more members of the referring physician's group practice regularly practices medicine and furnishes physician services to patients at least 6 hours per week in such office. The 6 hours must include some physician services that are unrelated to the furnishing of DHS as outlined above in Section 2.2.1.[15]

2.2.2 Centralized Building

DHS also may be provided in a "centralized building" (including a mobile vehicle, van or trailer) that is used by the group practice for some or all of the group practice's DHS.[16] The centralized building (including a mobile vehicle, van or trailer) must be owned or leased on a full time basis (that is, twenty-four hours per day, seven days per week, for a term of not less than six months) by the group practice and used exclusively by the group practice. Space in a building (including a mobile vehicle, van or trailer) that is shared by more than one group practice, by a group practice and one or more solo practitioners, or by a group practice and another provider/supplier, is not considered a "centralized building" for Stark purposes.[17] Please note, however, that a group practice can have more than one centralized building and still comply with the Stark Law.[18]

2.3. How Must the DHS be Billed

The in-office ancillary exception provides five options with respect to how DHS must be billed. DHS must be billed either by:

2.3.1 the physician performing or supervising the services;

2.3.2 the group practice of which the performing or supervising physician is a member under a billing number assigned to the group practice;

2.3.3 the group practice if the supervising physician is a "physician in the group practice"[19] under a billing number assigned to the group practice;

2.3.4 an entity that is wholly owned by the performing or supervising physician or by that physician's group practice under the entity's own billing number or under a billing number assigned to the physician or group practice; or

2.3.5 an independent third party billing company acting as an agent of the physician, the group practice, or an entity under a billing number assigned to such physician, group practice, or entity.[20]

B. Financial Relationships (Compensation)

Stark Law defines financial relationships to include direct and indirect ownership and investment interests, and direct and indirect compensation arrangements between referring physicians and DHS entities.[21] The Stark Law is triggered by the existence of a financial relationship between the referring physician (or an immediate family member) and the entity furnishing DHS. A physician practice may not compensate a physician, who is a "member of a group practice,"[22] directly or indirectly, based on the volume or value of referrals by the physician (the "Compensation Test").[23]

1. Compensation, Overall Profits and Productivity Bonuses

Compensation. The Compensation Test provides that no physician, who is a member of the group practice, may, directly or indirectly, receive compensation based on the volume or value of such physician's referrals, except through the use of "overall profit sharing" or "productivity bonuses."[24] Accordingly, a group practice may distribute revenues, income, or profits from DHS referrals via "overall profit sharing," "productivity bonuses" or both.

Overall Profit Sharing. A group practice may pay a physician in the group practice a share of overall profits of the group, provided that share is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician.[25] "Overall profits" means the group's entire profits derived from DHS payable by Medicare or Medicaid or the profits derived from DHS payable by Medicare or Medicaid of any component of the group practice that consists of at least five physicians.[26]

Productivity Bonuses. A group practice also may pay a physician in the group practice a productivity bonus based on services the physician has personally performed, services "incident to" such personally performed services, or both; provided that the bonus is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician.[27] The bonus must be calculated in a reasonable and verifiable manner.[28] A physician's productivity bonus will not be considered directly related to the volume or value of referrals of DHS if: (1) the bonus is based on the physician's total patient encounters or RVUs (relative value units); (2) the bonus is based on the allocation of the physician's compensation attributable to services that are not DHS; or (3) the group practice's DHS revenues constitute less than five percent of the group's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes five percent or less of such physician's total compensation from the group practice.[29]

2. Group Component Consisting of at Least Five Physicians

Stark Law requires the use of "overall profit sharing" or "productivity bonus" methodologies in order to distribute income, profits or revenues from DHS in a group practice;[30] and the employed method must be calculated in a reasonable and verifiable manner.[31] When profit sharing exists, a group practice must distribute a share of the overall DHS profits to the entire group or to a component of the group that consists of at least five physicians.[32] This rule allows profit center accounting for pools of five or more physicians.[33]

Any grouping of five or more physicians within the group constitutes an acceptable pool ("cost center"), so long as the compensation does not directly or indirectly reward volume or value of referrals.[34] Group practices can create subpractices or cost centers of five or more physicians for the distribution of

continued, next page

ancillary income, profits or revenues based on reasonable factors.[35] For example, the cost centers may be aggregated by location or specialty so long as the compensation does not directly reward volume or value of referrals.[36] For compensation purposes, a group practice or cost center of five or more physicians (within the group practice) can divide DHS income, profits or revenues: equally among its physicians; based on the distribution of revenues attributed to services that are not DHS; or via any distribution methodology so long as the revenues derived from DHS constitutes less than five percent of the group practice's total revenues, and the allocated revenues constitute five percent or less of such physician's total compensation from the group practice.[37]

II. Conclusion

Arguably, a group practice consisting of fifteen physicians, with three satellite offices (A, B and C) and five physicians practicing out of each of such offices could use profit center accounting for each office for purposes of distributing DHS income, profits or revenues. The profit center accounting concept can be broken down by, for example, region or specialty.

Office A could distribute the DHS income, profits or revenues generated by the Office A physicians equally among such physicians. Office B could distribute the DHS income, profits or revenues generated by the Office B physicians based on each Office B physician's total patient encounters or RVUs. Office C could distribute the DHS income, profits or revenues generated by the Office C physicians based on the Office C physician's relative non-DHS revenue. Alternatively, the DHS income, profits or revenues generated by Offices A, B and C together could be distributed equally among the physicians, based on each physician's total patient encounters or RVUs, or based on the physicians' relative non-DHS revenue.[38]

****

David L. Schick, Esq., *is a Partner with the law firm of GrayRobinson, P.A. David is a corporate, tax and healthcare attorney practicing out of the firm's Miami, Naples and Orlando offices. David has been with GrayRobinson, P.A. for over 20 years. David can be contacted at the following:*
Email: david.schick.@gray-robinson.com
Phone: 407.244.5618
Fax: 407.244.5690

Troy A. Kishbaugh, Esq., *is Of Counsel with the law firm of GrayRobinson, P.A. Troy is a corporate and healthcare attorney practicing out of the firm's Fort Lauderdale and Orlando offices. Troy is the current Chair-Elect for The Florida Bar Health Law Section and will assume the Chair office following the June 25, 2009 Florida Bar annual meeting. Troy can be reached at the following:*
Email: troy.kishbaugh@gray-robinson.com
Phone: 407.244.5626
Fax: 407.244.5690

GrayRobinson, P.A.*, is a full-service corporate law firm with over 200 attorneys throughout 10 offices across Florida. The firm provides legal services for Fortune 500 companies, emerging businesses, lending institutions, local and state governments, developers, entrepreneurs and individuals across Florida, the nation and the world.*

Endnotes:

1 It should be noted that the Stark Law, generally, only applies to Medicare. However, the Centers for Medicare and Medicaid Services have been debating whether (and how) to extend the Stark Law to include Medicaid (as outlined in the Stark II, Phase III preamble – 69 Fed. Reg. 16054, 16055 (March 26, 2004)). Nonetheless, and some may disagree, 42 USC Section 1396b(s) appears to expand denial of payment by Medicaid for violations of the Stark Law.

2 42 C.F.R. § 411.353(a)-(b).

3 42 C.F.R. § 411.351.

4 *Id.*

5 42 C.F.R. § 411.352.

6 Note: The Stark Law is a strict liability statute, so, absolute compliance with the requirements of its terms (including definitions and exceptions) is mandatory to avoid a violation. Significant penalties attach for violating the Stark Law, including, monetary penalties, exclusion from federal health care programs, and potential exposure under the Federal Anti-Kickback Statute and False Claims Act.

7 42 C.F.R. § 411.355(b).

8 *Id.* at § 411.355(b)(1).

9 *Id.* at § 411.355(b)(2)(i).

10 42 C.F.R. § 411.351.

11 *Id.*

12 42 C.F.R. § 411.355(b)(2)(i).

13 *Id.* at § 411.355(b)(2)(i)(A).

14 *Id.* at § 411.355(b)(2)(i)(B).

15 *Id.* at § 411.355(b)(2)(i)(C).

16 *Id. at* § 411.355(b)(2)(ii)-(iii).

17 42 C.F.R. § 411.351.

18 *Id.*

19 *Id.* "Physician in the group practice" means a "member of the group practice" (as defined below), as well as an independent contractor physician during the time he/she is furnishing "patient care services" (as defined by Stark) for the group practice pursuant to a contract directly with the group to provide services to the group's patients in the group's facilities.

20 42 C.F.R. § 411.355(b)(3).

21 42 C.F.R. § 411.354(a).

22 *Id.* "Member of a group practice" means a direct or indirect physician owner of a group practice (including a physician whose interest is held by his/her professional corporation or by another entity), a physician employee of the group practice (including a physician employed by his/her professional corporation that has an equity interest in the group practice), a locum te-

continued, next page

STARK LAW

from previous page

nens physician (as defined by Stark) or an on-call physician while that physician is providing on-call services for members of the group practice.

23 42 C.F.R. § 411.352(g).

24 42 C.F.R. § 411.352(g).

25 *Id.* at § 411.352(i)(1).

26 *Id.* at § 411.352(i).

27 *Id.* at § 411.352(i)(1).

28 *Id.* at § 411.352(i)(3).

29 Note: Supporting documentation verifying the method used to calculate the profit share or productivity bonus, and the resulting amount of compensation, must be made available to the Secretary of the Department of Health and Human Services upon request. *Id.* at § 411.352(i)(4).

30 Bruce A. Johnson, JD, MPA & Deborah Walker Keegan, PhD, FACMPE, *Physician Compensation Plans: State of the Art Strategies* 159 (Medical Group Management Association 1st ed. 2006).

31 42 C.F.R. § 411.352(i)(1).

32 *Id.* at § 411.352(i)(1)-(2).

33 *Id.* at § 411.352(i)(2)-(3).

34 Medicare Program; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships, 69 Fed. Reg. at 16080 (Mar.26, 2004).

35 Bruce A. Johnson, JD, MPA & Deborah Walker Keegan, PhD, FACMPE, *Physician Compensation Plans: State of the Art Strategies* 238 (Medical Group Management Association 1st ed. 2006).

36 42 C.F.R. § 411.352(i)(1); 66 Fed. Reg. 856, 9008-909 (January 4, 2001); and 69 Fed. Reg. 16054, 16080-16081.

37 *Id.* at § 411.352(i)(2).

38 42 C.F.R. § 411.353(a)-(b).

RECOVERY AUDIT PROGRAM

from page 4

that the time of the request for a re-consideration cannot start the recoupment process). There is a period of time in which withholding the funds becomes critical, but this is where the analysis should begin.

Stage Two

The provider has 180 days from the date of the re-determination decision to file for a re-consideration with the qualified independent contractor (RAC). (Standard CMS form or the re-consideration request form included in the F.I. letter of redetermination.) If the provider goes to re-consideration, the intermediary like First Coast can withhold funds, after 61 days after re-determination, even though the provider has 180 days. This becomes a business decision as to when the provider should file a reconsideration. This is a strategic point as to appeal. Withholding can occur until the re-determination is filed. Recoupment is stopped based on the valid re-consideration as filed.

The re-consideration request is also a very critical time. It's like a trial court where the provider must present all of the evidence at that time because any subsequent process (appeals) upward the provider must have been put into evidence at the re-consideration request at stage 2. As the appeal process goes on, providers can't introduce new evidence.

Stage Three

If there is an unfavorable reconsideration decision against the provider the intermediary can get recoupment of the funds regardless of whether the provider, in this case the hospital or doctor, goes to the third stage, which is a hearing before an administrative law judge. Please remember that interest is still accruing, which goes back to how quickly does the provider wants to appeal, and does the provider have all the evidence that the provider needs to proceed at an earlier funding date. In the Medicare appeals process, the re-determination must be in writing within 120 calendar days preceding the notice of initial determination.

The re-determination decision

The provider files a request for reconsideration. This is within 180 calendar days of receiving F.I. re-determination decision. Between the re-consideration and the re-determination, it is like preparing for a Section 120 Florida administrative hearing. The provider needs to allege the facts in dispute, as the basis for an administrative judge hearing. This request must be filed within 60 days following receipt of the re-consideration decision. The amount in controversy must exceed $120.00 and the hearing conducted by the administrative law judge can be held via videoconference, via telephone, or in person. Usually, the telephone is the way to have the hearing unless it is a huge amount of money, then the provider may want to request a hearing in person.

After the administrative law judge hearing, then there is what is known as the Medicare appeals council review. This must be filed within 60 days following receipt of the administrative law judge's decision, and this is very similar to an appellate process, where the provider must identify the administrative law judge's improper actions in the proceedings below. The Medicare appeal council limits its review to what is in the record. The final stage is a Federal District Court, which documents must be filed within 60 days of the receipt of the Medicare Appeals Counsel review decision. This amount must be at least $1,180.00. The federal district court, like a District Court of Appeal in Florida, bases the decision of the administrative law judge's decision but findings of fact, are deemed conclusive if supported by substantial evidence.

It may be that the Provider will want a judicial review in lieu of an administrative law judge's hearing or MAC. This judicial entity is composed of three reviewers or administrative law judges, or the administrative judge certifies the Medicare appeals council review does not have authority, or there is a question of law or regulation, and no material facts are in dispute, this method could expedite the appeals process, particularly if the provider has a large amount in controversy.

Procedure to be Followed by a Provider as to Legal Defenses

What should providers do? For one thing, like analyzing any case, the Provider wants to draft a paper outlining both the factual arguments and legal arguments, particularly for large amounts before starting any process. Some decisions have favored the expert hired by the reviewing authority as to a final determination of medical necessity over the treating physician. It becomes a factual dispute similar to a medical

continued, next page

RECOVERY AUDIT PROGRAM

from previous page

malpractice case for the administrative law judge to determine whether medical necessity existed or not.

Waiver of Liability as a Defense. The Treating Doctor Defense

There are certain other defenses that a provider can raise. One of them is the waiver of liability. The provider is without fault because on previous audits this type of service had been approved. Another defense is the treating physician rule that the treating physician who has examined the patient and is familiar with the patient's condition, is in the best position to make the "medical necessity determination". This legal defense has been recognized in Medicare cases, not Medicaid cases. This becomes tricky in that a physician reviewer, or even a nurse reviewer, can pick out in the record certain gaps, which may indicate that medical necessity did not exist for the number of days that the treating physician indicated the patient needed the required service.

The "medical necessity" determination. This is the process in which is there a medical basis for extending the length of stay (LOS) ten days rather than six, and what documentation supports that decision. Again, medical judgment plays an important part in this determination, and that is why from the Medicare side one can use the treating physician rule, who may be in a better position to observe the patient, but there must be sufficient documentation to support the provider's claim.

The next area is corporate compliance, which all hospitals now do. For non-hospital providers, which include doctors and clinics, the provider wants to have in place a compliance program for proper documentation and coding education. Coding clerks usually go to a coding seminar but mistakes do happen. Doctors who return from a hospital visit scribble something and the coding clerk is expected to decipher that and apply the proper code for service. This is where the provider gets into the overpayment problems.

The bottom line is that this process can be time consuming and expensive.

Summary

The RAC program is in a state of flux but the predictions are that some form of RAC will continue because the Government under the demonstration programs did recover huge sums of money and determined that the bounty or the contingent fee they had to pay out to RACS was well worth what Medicare recovered.

****

John D. Buchanan, Jr., Esq., *is the senior shareholder with Henry, Buchanan, Hudson, Suber & Carter, P.A., in Tallahassee, FL. He can be reached at (850) 222-2920 or by email at* JBuchanan@henryblaw.com.

DEFENDING UNLICENSED

from page 6

Tampa, Florida. He is a former federal prosecutor, the author of Defending and Preventing Health Care Fraud Cases: An Attorney's Guide (CCH Aspen: 10th ed. 2008), and a 1986 graduate of Harvard Law School.

Endnotes:

1 *L. W. Lambert v. State*, 77 So. 2d 869, 871 (Fla. 1955) ("One who takes blood pressure tests only, announces the result without giving advice or prescribing treatment, is not a medical practitioner... It seems to be recognized that blood pressure is not a disease but is one of the symptoms or factors which aids the physician in diagnosing the physical condition of the patient").

2 In *Scullock v. State*, 377 So.2d 682, 683 (Fla. 1979), the Florida Supreme Court defined the verb "offer" as "to make a proposal to" and "to try to begin or exert."

3 Florida Administrative Code Section 64B-56.002(2)(d) and (4)(a) provide that licensed electrologists may use laser hair removal devices only if they "are operating under the direct supervision and responsibility of a physician" and do so pursuant to written protocols. Similarly, Florida Statute Section 458.348(3) provides that protocols for electrologists using laser hair removal devices shall require electrologists to work "only under the direct supervision and responsibility of a physician..."

4 *Hermanson v. State*, 604 So.2d 775, 782 (Fla. 1992), quoting *Mourning v. Family Publications Service, Inc.*, 411 U.S. 356, 375 (1973).

5 *Reams v. State,* 279 So.2d 839, 843 (Fla. 1973).

6 *State v. Giorgetti,* 868 So.2d 512, 520-521 (Fla. 2004) (state must prove defendant was aware of the registration requirement and therefore knew his conduct was illegal in order to convict defendant of failing to register as a sex offender*); Chicone v. State*, 684 So.2d 736, 744 (Fla. 1996) (to convict a defendant of possession of controlled substances, the state is required to prove that the defendant knew of the illicit nature of the items in his possession and thereby knew his conduct was illegal*); Cohen v. State*, 125 So.2d 560, 563 (Fla. 1960) (statute prohibiting sale of obscene material required that state prove defendant's knowledge of the obscene nature of the material and thereby knew his conduct was illegal*); Siplin v. State*, 972 So.2d 982, 989-90 n.9 (Fla. 5th DCA 2007) (holding that F.S. § 106.15(3) must contain an implied knowledge element so that a candidate for public office cannot be convicted of "us[ing] the services of any state, county, municipal, or district officer or employee during working hours" without proof that the defendant did so knowingly and thereby knew his conduct was illegal*); Staples v. United States*, 511 U.S. 600, 619 (1994) (to convict a defendant of possessing an unregistered machine gun, the government must prove beyond a reasonable doubt that the defendant knew the weapon he possessed had characteristics that brought it within the statutory definition of machine gun and thereby knew his possession was illegal*); Liparota v. United States*, 471 U.S. 419, 426 (1985) (to convict a defendant of unauthorized acquisition or possession of food stamps, the government must prove beyond a reasonable doubt that the defendant knew his possession of food stamps was unauthorized and thereby knew his conduct was illegal*); United States v. X-Citement Video, Inc.*, 513 U.S. 64, 77 (1994) (federal child pornography statute required that a defendant have knowledge that the performer was a minor and thereby knew his conduct was illegal).

7 *State v. Giorgetti*, 868 So.2d 512, 518-519 (Fla. 2004) (holding that the third degree felony penalties for the crime of failure to register as a sex offender required the state to prove that the defendant was aware of the sex offender registration requirement*); Chicone v. State*, 684 So.2d 736, 742-43 (Fla. 1996) ("The penalties imposed for violating [controlled substance statutes] are incongruous with crimes that require no mens rea. For example, a defendant convicted of possession of a controlled substance can receive up to five years imprisonment....*"); Staples v. United States*, 511 U.S. 600, 617 (1994) (holding that the "potentially harsh penalty" of up to 10 years imprisonment for possession of an unregistered firearm is a factor supporting "the usual presumption that a defendant must know the facts that make his conduct illegal").

the records stating "we regret to inform you that some of our medical records, in the storage area, from 2003, were severely damaged during last year's hurricane season [and the records you requested] are most likely among those damaged by the storm last year."

The Council acknowledged that the proffered evidence did not prove that a specific medical record was irretrievable. The Council also stated, however, that the Program Integrity Manual "does not require documentation of specific efforts made to trace individual records. Instead, it instructs [Medicare] contractors to accept an attestation that the records no longer exist and that no backup copies are available." The Council then concluded that all of the conditions stated in section 3.2.2 of the Program Integrity Manual were satisfied for acceptance of a claim based on attestation and ordered that the appealed claims be paid and the overpayment extrapolation revised.

For health law practitioners, it is important to note that *Nigro* and *Unihealth* are instructive for several reasons. First, most importantly, argue everything even if there is no specific law which supports the argument. As we now see, section 3.2.2 of the Program Integrity Manual adopted what the Council decided five (5) years earlier in *Nigro*. Second, an ALJ may misapply the law. Therefore, appealing an ALJ decision should be considered when evaluating various types of cases, where appeal includes an ALJ component. Third, given the high probably that there will be more hurricanes in the future, without a doubt, there may be medical records irretrievably damaged. Fourth, disaster is very broadly defined in the section 3.2.2. of the Program Integrity Manual. Fifth, section 3.2.2. of the Program Integrity Manual is not limited to post payment review where medical records are irretrievable, and that section contains a variety of provisions, all designed to facilitate payment and review when there is a disaster. Finally, health law practitioners should remember not to overlook reported decisions of the various agencies, such as the Council. Besides being instructive, they may also be cited when appealing on your client's behalf.

Harold E. Kaplan, Esq. *is a Board Certified Health Law Attorney and former Chair of the Health Law Section. His office is in Coral Springs, Florida where he principally represents physicians and other health care providers for a broad range of matters.*

Endnotes:

1 Medicare Program Integrity Manual (CMS Pub. 100-8).

2 *In the Case of Samuel Nigro, M.D.*, HHS Departmental Appeals Board, Medicare Appeals Council, CCH ¶ 120,371 (April 30, 2001).

3 *Id* at 14.

4 *In the case of Unihealth, Inc.*, HHS Departmental Appeals Board, Medicare Appeals Council (March 19, 2009) (an unpublished decision).

5 Medicare Program Integrity Manual (CMS Pub. 100-8), Chapter 3, § 3.2.2, Administrative Relief from Medical Review in the Presence of a Disaster.

Medicare Program Integrity Manual (CMS Pub. 100-8), Chapter 3, § 3.2.2, Administrative Relief from Medical Review in the Presence of a Disaster. §3.2.2 - Administrative Relief from Medical Review in the Presence of a Disaster

(Rev.174, Issued: 11-17-06, Effective: 10-01-06, Implementation: 10-06-06).

When a disaster occurs, whether natural or man-made, contractors should anticipate both an increased demand for emergency and other health care services, and a corresponding disruption to normal health care service delivery systems and networks. In disaster situations, contractors should do whatever they can to assure that all Medicare beneficiaries have access to the emergency or urgent care they need. Contractors should let providers know (via website, responses to provider calls, etc.) that the provider's first responsibility, as in any emergency, is to provide the needed emergency or urgent service or treatment. Contractors should assure providers that they will work with providers to ensure that they receive payment for all covered services. The administrative flexibility available to contractors is discussed below. These actions will prevent most inappropriate denials and subsequent appeals.

A. Definition of Disaster

"Disaster" is defined as any natural or man-made catastrophe (such as hurricane, tornado, earthquake, volcanic eruption, mudslide, snowstorm, tsunami, terrorist attack, bombing, fire, flood, or explosion) which causes damage of sufficient severity and magnitude to:

1. Partially or completely destroy medical records and associated documentation that may be requested by the contractor in the course of a Medicare medical review audit,

2. Interrupt normal mail service (including US Postal delivery, overnight parcel delivery services etc.), or

3. Otherwise significantly limit the provider's daily operations.

A disaster may be widespread and impact multiple structures (e.g., a regional flood) or isolated and impact a single site only (e.g., water main failure). The fact that a provider is located in an area designated as a disaster by the Federal Emergency Management Act (FEMA) is not sufficient in itself to justify administrative relief, as not all structures in the disaster area may have been subject to the same amount of damage. Damage must be of sufficient severity and extent to compromise retrieval of medical documentation.

B. Basis for Providing Administrative Relief

In the event of a disaster, contractors may grant temporary administrative relief to any affected providers for up to 6 months (or longer with good cause). Administrative relief is to be granted to these providers on a case-by-case basis in accord with the following guidelines:

Contractors must make every effort to be responsive to providers who are victims of the disaster and whose medical record documentation may be partially or completely destroyed.

Providers must maintain and, upon contractor request, submit verification that (1) a disaster has occurred and (2) medical record loss resulted from this disaster to the point where administrative relief from medical review requirements is necessary to allow the provider sufficient time to obtain duplicates of lost records, or reconstruct partially destroyed records.

Verification of the disaster and the resultant damage may include but is not limited to: (1) copies of claims filed by the provider with his/her insurance and liability company, (2) copies of police reports filed to report the damage, (3) copies of claims submitted to FEMA for financial assistance, (4) copies of tax reports filed to report the losses, or (5) photographs of damage. Contractors should not routinely request providers to submit verification of damage or loss of medical record documentation.

C. Types of Relief
Providers Directly Impacted By Disaster

When a provider who has been selected for complex pre or post pay review is directly

continued, next page

PRACTICE POINTER
from previous page

affected by a disaster, the contractor should consider shifting the time period of the claims being reviewed to a later time period (e.g. 6 months later). Additional Documentation Requests (ADRs) should be stopped for providers who have been directly affected for at least 60 days. These claims should not be denied as noncovered and may be tagged for later postpay review. Contractors should consult with their regional office prior to shifting the time period of review or suspend ADRs for certain providers.

Contractors should allow up to an additional 6 months beyond the original due date for the submission of requested records. Requests for extensions beyond this date may be granted with good cause at the discretion of the contractor.

In the case of complete destruction of medical records where backup records exist, contractors must accept reproduced medical record copies from microfiched, microfilmed, or optical disk systems that may be available in larger facilities, in lieu of the original document. In the case of complete destruction of medical records where no backup records exist, contractors must accept an attestation that no medical records exist and consider the services covered and correctly coded. In the case of partial destruction, contractors should instruct providers to reconstruct the records as best they can with whatever original records can be salvaged. Providers should note on the face sheet of the completely or partially reconstructed medical record: "This record was reconstructed because of disaster."

Providers Indirectly Impacted By Disaster

For providers that are indirectly affected by a disaster (e.g., an interruption of mail service caused by a grounding of US commercial air flights), contractors must take the following actions:

For prepay or postpay documentation requests, extend the parameter that triggers denial for non-receipt of medical records from 45 days to 90 days. ADR letters must reflect that the response is due in 90 days rather than 45 days. This action will prevent most inappropriate denials and unnecessary increases in appeals workload.

If a contractor receives the requested documentation after a denial has been issued but within a reasonable number of days beyond the denial date, the contractor should reopen the claim and make a medical review determination. Many contractors believe that 15 days is a reasonable number of days although contractors should make these decisions on a case-by-case basis. The workload, costs and savings associated with this activity should be allocated to the appropriate MR activity code (e.g., prepay complex or postpay complex review). Contractors should conduct these reopenings retroactively back to the date of the disaster.

D. Impact on Data Analysis

Contractors' data analysis should take into consideration the expected increase in certain services in disaster areas.

E. Impact on Contractor Performance Evaluation (CPE)

During CPE and SAS-70 reviews, CMS will consider a waiver to all contractor MR requirements, as necessary, to allow contractors the flexibility where required to handle issues that arise in the presence of disaster. Examples of such requirements include workload targets and any other MR administrative rules. Contractors must retain documentation of how their MR operations were affected during the disaster and make it available to CPE and SAS-70 review teams, CCMO staff, and local regional office staff, upon request.

6 Medicare Program Integrity Manual (CMS Pub. 100-8), Chapter 3, § 3.2.2 (C).