Acknowledgement of Editors

California Health Law News wishes to thank the following Publications Committee Members for their editorial work on the articles included in this issue:

Outpatient Dialysis Fraud and Abuse Risks
by Francis J. LaPallo, Esq.
Edited by Terri D. Keville, Esq.

Topical Reports
Prepared by:
Sarah G. Benator, Esq., Patricia M. Kosich, Esq., Jeffrey R. Bates, Esq., and Lauren R. Polak, Esq.
Edited by Sarah G. Benator

CALIFORNIA SOCIETY FOR HEALTHCARE ATTORNEYS
1215 K Street, Suite 800
Sacramento, CA 95814
916.552.7605
www.csha.info

C A L I F O R N I A
Health Law News

Volume XXIV, Issue 2 • Fall 2005/Winter 2006

Members are invited to contribute articles and ideas. Send to:

Bruce John Shih
Chair and Editor in-Chief
c/o CSHA
1215 K Street, Suite 800
Sacramento, CA 95814

BOARD OF EDITORS

Sarah Benator
Foley & Lardner LLP
Los Angeles

Kathryn Coburn
WellPoint
Woodland Hills

Elspeth Delaney
Hooper, Lundy & Bookman, Inc.
Los Angeles

Marc E. Jacobowitz
Davis Wright Tremaine LLP
Los Angeles

David Kalifon, M.D.
Jeffer, Mangels, Butler & Marmaro
Los Angeles

Terri D. Keville
Manatt, Phelps & Phillips LLP
Los Angeles

Raja Sekaran
Catholic Healthcare West
Pasadena

Daniel Settelmayer
Latham & Watkins LLP
Los Angeles

NEW MEMBERS....3

ANNOUNCEMENTS....4

FEATURE ARTICLE....5

Outpatient Dialysis Fraud and Abuse Risks
By Francis J. LaPallo, Esq.
Manatt Phelps & Phillips LLP

TOPICAL REPORTS....19

Anti-SLAPP....19
Arbitration....20
Confidentiality....22
Denti-Cal....23
Health Plan Unfair Competition....24
Hospital Lien Act....25
Lanterman-Petris-Short Act....25
Medicaid....26
Medical Board....28
Medical Staff....28
Professional Liability....31

ACKNOWLEDGEMENT OF EDITORS....32

© 2006 The California Society for Healthcare Attorneys (www.csha.info)

C A L I F O R N I A
Health Law News

Chair and Editor-in-Chief
Bruce John Shih
c/o CSHA

BOARD OF EDITORS

Sarah Benator
Foley & Lardner, LLP Los Angeles

Kathryn Coburn
WellPoint, Woodland Hills

Elspeth Delaney
Hooper, Lundy & Bookman, Inc.
Los Angeles

Marc E. Jacobowitz
Davis Wright Tremaine LLP
Los Angeles

David R. Kalifon, M.D.
Jeffer, Mangels, Butler & Marmaro
Los Angeles

Terri D. Keville
Manatt, Phelps & Phillips, LLP
Los Angeles

Raja Sekaran
Catholic Healthcare West
Pasadena

Daniel Settelmayer
Latham & Watkins LLP
Los Angeles

BOARD OF DIRECTORS

PRESIDENT
Bruce J. Shih
c/o CSHA
1215 K Street, Suite 800
Sacramento, CA 95814
bjshihwork@yahoo.com

PRESIDENT-ELECT
Shelley Hubner
Blue Shield of California
50 Beale Street, Law Department
San Francisco, CA 94105-5817
(415) 229-5817
shelley.hubner@blueshieldca.com

CHIEF FINANCIAL OFFICER
Robyn Meinhardt
Foley & Lardner LLP
1942 Broadway, Suite 404
Boulder, CO 80302
(303) 294-4400
rmeinhardt@foleylaw.com

IMMEDIATE PAST PRESIDENT
Terri D. Keville
Manatt, Phelps & Phillips LLP
11355 West Olympic Boulevard
Los Angeles, CA 90067
(310) 312-4183
tkeville@manatt.com

DIRECTORS
Greg Abrams
California Medical Association
P.O. Box 7690
San Francisco, CA 94120-7690
(415) 882-3350
gabrams@cmanet.org

Brent Barnhart
Kaiser Foundation Health Plan, Inc.
1 Kaiser Plaza, Floor 27
Oakland, CA 94612
(510) 271-2320
brent.barnhart@kp.org

Derek Covert
Catholic Healthcare West
185 Berry Street, Suite 300
San Francisco, CA 94107
(415) 438-5616
dcovert@chw.edu

Marc E. Jacobowitz
Davis, Wright, Tremaine LLP
865 S. Figueroa Street, Suite 2400
Los Angeles, CA 90017-2566
(213) 633-6800
marcjacobowitz@dwt.com

David Kalifon, M.D.
Jeffer, Mangels, Butler & Marmaro
1900 Avenue of the Stars, 7th Floor
Los Angeles, CA 90067-4308
(310) 785-5311
drk@jmbm.com

Carlisle C. (Ky) Lewis, III
Sharp Healthcare
8695 Spectrum Center Blvd.
San Diego, CA 92123
(858) 499-3026
ky.lewis@sharp.com

Beverly Tiffany
Paul, Hastings, Janofsky
& Walker LLP
515 S. Flower Street, 25th Floor
Los Angeles, CA 90071-2228
(213) 683-6167
beverlytiffany@paulhastings.com

Robert Valencia
Catholic Healthcare West
251 South Lake Avenue, 8th Floor
Pasadena, CA 91101-4842
(626) 744-2285
robert.valencia@chw.edu

EXECUTIVE DIRECTOR
Lois Richardson
Vice President & Legal Counsel
California Hospital Association
1215 K Street, Suite 800
Sacramento, CA 95814
(916) 552-7611
lrichardson@calhealth.org

EXECUTIVE ASSISTANT
Susan Gill
(916) 552-7605
sgill@calhealth.org

only to qualified physicians. The Court held that this reasonable restriction did not permit Anaheim Memorial to further restrict physicians on the basis of race. Therefore, Dr. Payne had standing under the Unruh Act. The Court of Appeal reversed the trial court's judgment and remanded the case.

PROFESSIONAL LIABILITY

MICRA's statute of limitations governs claims for negligent failure by healthcare providers to report suspected child abuse.

David M. v. Beverly Hospital, 131 Cal. App. 4th 1272 (2nd Dist. 2005).

In October 1992, when he was four months old, David M. was examined by Dr. Rodney Cotner at Beverly Hospital ("Beverly"). David M. had marks on his body which he alleged should have created a reasonable suspicion of child abuse that Dr. Cotner and Beverly employees had a duty to report pursuant to Penal Code Sections 11165.7 and 11166(a). Dr. Cotner and the Beverly employees, however, did not report suspected abuse. After returning home from the examination, David M.'s father severely abused him, causing a serious and permanent medical condition. In August 2003, when he was 11 years old, David M. filed a complaint against Dr. Cotner and Beverly, alleging three general negligence causes of action. The first action alleged that but for the negligent failure by Dr. Cotner to report the suspected child abuse, David M. would not have suffered subsequent abuse by his father and the severe injuries that resulted. The remaining two actions were directed against Beverly. These included David M.'s claim that (1) the nurses and other health care practitioners employed by Beverly failed to fulfill their statutory duty to report suspected child abuse, and (2) Beverly failed in its duty to ensure its health care practitioners comply with the mandatory requirement to report suspected child abuse.

At the trial court level, both Dr. Cotner and Beverly demurred to the complaint, arguing that the statute of limitations under Code of Civil Procedure Section 340.5, part of the Medical Injury Compensation Reform Act ("MICRA"), controlled the action. MICRA requires that suits for professional negligence be filed either three years from the date of injury, or prior to the child's eighth birthday, whichever period is longer. The trial court sustained the demurrers without leave to amend, and dismissed the complaint as to both Dr. Cotner and Beverly. David M. appealed.

The California Court of Appeal held that allegations that Dr. Cotner and Beverly employees negligently failed to report suspected child abuse constituted a claim for professional negligence within the meaning of MICRA. Therefore, the MICRA statute of limitations applies and defendants were relieved from liability. Before the Court, David M. contended that under Code of Civil Procedure Section 338(a), which governs actions alleging violations of Penal Code Sections 11165.7 and 11166(a), the applicable statute of limitations is three years, but that the statute of limitations is tolled during the period of minority pursuant to Code of Civil Procedure Section 352(a). The Court disagreed, stating David M.'s action alleged professional negligence, and nothing more. The Court noted that MICRA specifically defines professional negligence as "a negligent act or omission to act by a health care provider in the rendering of professional services, which act or omission is the proximate cause of a personal injury or wrongful death." MICRA's restrictive statute of limitations does not apply to intentional torts; here, however, David M. did not allege that Dr. Cotner intentionally failed to act or concealed his failure to act. The Court held that because David M.'s causes of action were limited to professional negligence claims, MICRA's statute of limitations applies. The Court supported its holding by highlighting the well-settled principle that a more specific and more recent statute controls over a more general and earlier one. The Court emphasized that one reason MICRA was enacted in 1970 was to specifically address tort claims against healthcare providers by restricting drawn out tolling provisions in malpractice claims. By contrast, Sections 338 and 352 date back to the 1850s, are more general and don't specifically contemplate healthcare related claims as does MICRA. The Court also held that allegations of failure by Beverly, as a healthcare provider, to exercise its duty to use reasonable care and diligence in safeguarding a patient committed to its charge also amounted to a pure professional negligence claim. Accordingly, MICRA's shorter statue of limitations also governed both claims against Beverly. The California Court of Appeal affirmed the trial court's dismissal of the complaint as to both Dr. Cotner and Beverly.

given Dr. Mileikowsky's repeated disruptions, his repeated refusals to comply with the hearing officer's rulings, and the multiple lesser sanctions imposed upon him prior to termination. The Court of Appeal affirmed the trial court's denial of the writ of mandate.

Physician was not required to exhaust medical staff administrative procedures prior to pursuing damages claim alleging racist conduct because medical staff bylaws did not provide applicable administrative procedures.

Payne v. Anaheim Memorial Medical Center, 130 Cal. App. 4th 729 (4th Dist. 2005).

Dr. David H. Payne, an African-American, alleged that certain surgical staff and other members of the Anaheim Memorial Medical Center ("Anaheim Memorial") medical staff provided a lower standard of care to minority patients and interfered with his ability to care for minority patients. Dr. Payne also alleged that when he reported a perceived racial slur to the chief of radiology, it was dismissed as a "personality conflict," and Dr. Payne was advised to take it up with the chief of the medical staff. Before he was able to do so, however, the chief of staff ordered Dr. Payne to report to a Physician Well-Being Committee to respond to allegations against Dr. Payne concerning unprofessional behavior and slander of another physician. Dr. Payne claimed that although he was assured of a thorough and independent investigation of his allegations of racial discrimination, nothing further was done. Dr. Payne filed a complaint alleging causes of action for violation of the Unruh Act, which prohibits arbitrary discrimination by businesses based on classifications such as race and gender. Anaheim Memorial filed a motion for a judgment on the pleadings, stating that Dr. Payne failed to exhaust his administrative remedies under the medical staff bylaws and lacked standing under the Unruh Act because he was not a "customer, client or patron" of the hospital. The trial court granted Anaheim Memorial's motion, and Dr. Payne appealed.

The California Court of Appeal held that because administrative remedies were unavailable, Dr. Payne (1) was not required to exhaust administrative remedies prior to bringing a lawsuit, (2) was not obligated to file a writ of mandate prior to proceeding with his claim for damages, and (3) had standing to assert a civil rights claim against the hospital. The Court noted that the grievance procedures under the medical staff bylaws did not provide Dr. Payne with a right to a hearing or to present evidence in this circumstance. Because Dr. Payne's privileges were not formally impacted, he had no right to any administrative process to air his grievances. Although the chief of staff could appoint an ad hoc committee to review such complaints, that committee was not required to interview the physician against whom the claim was made or to issue a written report. Moreover, a complaining physician had no right to be heard or present evidence to the ad hoc committee, and there was no procedural remedy for a physician who felt his or her complaints were improperly dismissed. The Court noted that simple internal grievance procedures may be inadequate to address and resolve complicated issues. The allegations in Dr. Payne's case involved complex issues, including a pattern of racially discriminatory conduct which provided minority patients with a lower standard of care and which also interfered with his ability to care for his patients. The Court held that because there was no opportunity for Dr. Payne to provide testimony or evidence and no "quasi-judicial remedy" for him to pursue, there were no administrative remedies for him to exhaust.

The Court also rejected Anaheim Memorial's claim that even if Dr. Payne had exhausted all administrative remedies, he was still required to file a writ of mandate before proceeding with a claim for damages. Reasoning instead that because Anaheim Memorial did not provide Dr. Payne with any rights to seek administrative redress of his grievances, the Court found that he was not required to seek writ relief prior to pursing his damages claim.

The Court also found Dr. Payne had standing under the Unruh Act. The Court noted that the Unruh Act is intended to be liberally construed, and rejected Anaheim Memorial's contention that the Unruh Act applies only to businesses or public facilities that offer their wares or services to everyone. Conversely, the Court found that Anaheim Memorial was not exempt from the Unruh Act merely because it limits medical staff membership

NEW MEMBERS

Amanda S. Abbott
Hooper, Lundy & Bookman, Inc.
101 W. Broadway, Suite 1105
San Diego, CA 92104

Erin Elizabeth Abood
Ropes & Gray LLP
One Embarcadero Center,
Suite 2200
San Francisco, CA 94111

Mary Anderson
Aetna, Inc.
2625 Shadelands Drive
Walnut Creek, CA 94596

Marcia L. Augsberger
McDonough Holland & Allen
555 Capitol Mall, 9th Floor
Sacramento, CA 95814

John C. J. Barnes
McDonough Holland & Allen
555 Capitol Mall, 9th Floor
Sacramento, CA 95814

Thomas R. Bradford
Peterson & Bradford, LLP
100 North First Street, Suite 300
Burbank, CA 91502-1845

Tara Brewer
St. Joseph Health System
500 S. Main Street, Suite 400
Orange, CA 92868-4515

Kristine Cerro
Saint Agnes Medical Center
1303 E. Herndon Avenue
Fresno, CA 93720

Brian Fields
WellPoint, Inc.
1 Wellpoint Way
Thousand Oaks, CA 91362

Stephen L. Goff
McDonough Holland & Allen
555 Capitol Mall, 9th Floor
Sacramento, CA 95814

Brian Hagadorn
Children's Hospital of
Orange County
455 South Main Street
Orange, CA 92868

Melinda Hayes
Paul, Hastings, Janofsky &
Walker LLP
515 South Flower Street, 25th Floor
Los Angeles, CA 90071

Patricia M. Kosich
Foley & Lardner LLP
2029 Century Park East, #3500
Los Angeles, CA 90067-3021

David Lerman
Kaiser Permanente
393 E. Walnut Street, 2nd Floor
Pasadena, CA 91188

David Levine
U.C. Davis Health System
2315 Stockton Blvd.
Sherman Bldg., #3900
Sacramento, CA 95817

Jesse D. Miller
Law Offices of Jesse D. Miller
865 Greenridge Drive
La Canada, CA 91011

Geoffrey Goodman Murphy
Austin Adams Schoenfeld LLP
1000 G Street, Third Floor
Sacramento, CA 95814

Leslie C. Murphy
McDonough Holland & Allen
555 Capitol Mall, 9th Floor
Sacramento, CA 95814

Eric Tuckman
Advisory Health Management
Group
1148 Manhattan Avenue, Suite 5
Manhattan Beach, CA 90266

ANNOUNCEMENTS

CSHA 2006 ANNUAL MEETING & SPRING SEMINAR

Plans are underway for CSHA's 2006 Annual Meeting and Spring Seminar, being held May 5-7, 2006, at the beautiful Resort at Squaw Creek (Olympic Valley), at Lake Tahoe.

New this year is a three-hour Contracting Workshop on Friday morning. Healthcare contracts are unique, and yet there are few resource materials available. This workshop will provide a solid overview for new professionals as well as numerous insights for seasoned veterans.

The workshop is being offered in lieu of the Society's traditional offering,"Back to Basics," and a separate registration fee is required.

Program highlights include: a perspective on the changing world of healthcare and the in-house practice of law; updates on workers' compensation and Medi-Cal redesign (two California government programs that have undergone extensive changes); an insider's overview of the California law making system; a presentation on healthcare fraud defense from a former federal defender; and separate presentations on healthcare finance, tax-exempt issues, community clinics, senior care facilities, and physician compensation.

In keeping with tradition, a variety of social gatherings are planned to strike a balance between continuing education and collegiality.

FRIDAY EVENING WELCOME RECEPTION

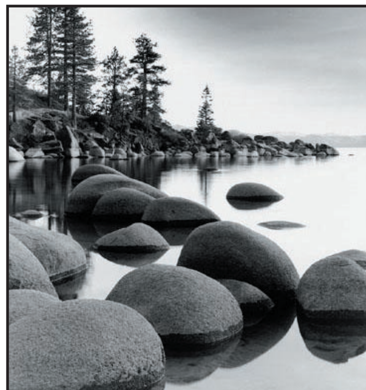
The Society wishes to thank the following law firms for their generous sponsorship of this year's Friday Welcome Reception:

- *Epstein Becker & Green PC*
- *Foley and Lardner LLP*
- *Hanson, Bridgett, Marcus, Vlahos & Rudy LLP*
- *Hooper Lundy & Bookman, Inc.*
- *Latham & Watkins*
- *Manatt Phelps & Phillips LLP*
- *McDonough Holland & Allen PC*
- *Nossaman, Guthner, Knox & Elliott LLP*
- *Paul Hastings Janofsky & Walker LLP*

On Saturday evening, we are pleased to offer our traditional Annual Dinner, open to attendees and their guest. A special guest speaker makes this an annual dinner you won't want to miss.

Early registration and hotel reservations are strongly advised. Please contact the hotel directly at (800) 403-4434 and identify yourself as a CSHA 2006 Annual Meeting and Spring Seminar participant to reserve your desired accomodations at the corresponding group rate. The deadline to make your reservations and receive the group rate is April 14, 2006.

Further details and registration materials are available on our website at www.csha.info.



CSHA MENTOR PROGRAM

CSHA is pleased to announce the commencement of its new Mentor Program.

The program was developed by Robert Valencia, Senior Counsel for Catholic Healthcare West and Chairman of the CSHA Membership Committee. Mr. Valencia is a CSHA board member and the chair of the CSHA membership committee.

The primary goal for the Mentor Program is to increase awareness of the career opportunities awaiting new attorneys specializing in healthcare law, to assist students in career planning, and to provide practical resources to achieve their career objectives.

Initially, the Mentor Program is underway at four law schools: Boalt, Loyola, Stanford, and USC.

If you are a CSHA member interested in becoming a mentor, or know a law student interested in finding a mentor, please contact Robert Valencia via e-mail at: *robert.valencia@chw.edu*.

are generally invoked when irreparable harm would occur or the administrative remedy is unavailable or inadequate. The Court rejected Dr. Dennis's assertion that irreparable harm would result as the harm—her termination from the group—already had occurred.

Moreover, the Court found that Dr. Dennis was not entitled to due process under the state and federal constitutions because the Hospital and TPMG were private institutions, not state actors. Dr. Dennis instead was entitled to a fair process as governed by statute. The Court found that, given the preservation of her basic procedural protections, Dr. Dennis was not deprived of a fair process because of the delay. Had Dr. Dennis wanted to compel the Hospital to start the hearing within the 60-day period, she could have sought a writ of mandate from the superior court directing the Hospital to begin the hearing, rather than applying for declaratory relief. She chose not to do so. On the question of hearing officer bias, the Court similarly found that Dr. Dennis was afforded procedural protections as she had the right to challenge the impartiality of the hearing officer. Finally, the Court rejected Dr. Dennis's contention that the exhaustion doctrine applies only to some of the causes of action she alleged, but not others. The Court found that the exhaustion of administrative remedies doctrine applied to all causes of action arising from or related to the summary suspension and termination. The Court of Appeal granted the Hospital's petition for a writ of mandate and directed the trial court to vacate its orders regarding the motions for declaratory relief.

A hearing officer has the authority to terminate a proceeding in egregious circumstances when such sanctions are appropriate.

Mileikowsky v. Tenet Healthsystem, 128 Cal. App. 4th 531 (2nd Dist. 2005).

Encino-Tarzana Regional Medical Center ("Medical Center") suspended Dr. Gil Mileikowsky's medical staff privileges on the grounds that he engaged in abusive, disruptive and unprofessional conduct. The Medical Center also recommended that Dr. Mileikowsky not be reappointed to the medical staff. Shortly thereafter, a hearing was convened at Dr. Mileikowsky's request to challenge the Medical Center's action and recommendation. As a result of Dr. Mileikowsky's continued disruptive behavior and persistent refusal to comply with the hearing officer's rulings during proceedings – including failing to comply with discovery rulings, inappropriately submitting documents to the judicial review committee, and exhibiting disruptive behavior during the hearing – the hearing officer asked the parties to submit briefs regarding the hearing officer's authority to declare a default and Dr. Mileikowsky's abandonment of his defense. After the submission of the briefs, the hearing officer terminated the proceeding, finding that Dr. Mileikowsky's conduct had so prejudiced the hearing that it was impossible to complete it consistent with fair-procedure requirements. After exhausting all administrative remedies, Dr. Mileikowsky filed a petition for a writ of mandate in the superior court. The trial court denied the petition and Dr. Mileikowsky appealed.

The Court of Appeal affirmed the trial court's judgment and held both that the hearing officer had the authority to terminate the proceedings, and that such authority was exercised with appropriate discretion under the circumstances. The Court found that the authority of the hearing officer to terminate a proceeding is inferred from Business and Professions Code Section 809.2, which provides for a presiding officer who "may impose any safeguards the protection of the peer review process and justice requires." In addition, the statute contemplates that hospitals will supplement the statutory requirements in the medical staff bylaws. Together, the statute and the Medical Center's Bylaws support the hearing officer's conclusion that he had authority to suspend the hearing. Moreover, the Court found that even if the authority to terminate a procedure was not inferred from the statute, hearing officers must have the power to control the parties to a proceeding to prevent disruption, delay, and abuse. The Court rejected Dr. Mileikowsky's assertion that the hearing committee, rather than the hearing officer, should be charged with the decision to terminate a proceeding as unsupported by the statute and unworkable as a solution. Although the Court recognized that physicians may be concerned about the concentration of power in the hearing officer, it concluded that the power to terminate a hearing will be checked by internal and judicial reviews of the propriety of such an action. After determining that the hearing officer had the authority to terminate the hearing, the Court found that, in this case, the hearing officer did not abuse his discretion in terminating the hearing. Although courts are hesitant to impose termination as a sanction in a hearing, they will do so when it is clear that no

was not arbitrary or capricious. Rather, Life Care failed to meet its burden of showing that CalOptima's policy was arbitrary or capricious. Life Care's attempts to compare CalOptima's policies with other COHS's policies were not helpful because Life Care did not provide any evidence that these agencies operated under the same statutory scheme, or were in any way similar to CalOptima. The Court therefore rejected all of Life Care's arguments, and found that CalOptima was entitled to judgment. The Court of Appeal reversed the trial court orders denying CalOptima's motion for judgment and granting Life Care's petition for peremptory writ and granting attorney's fees, and ordered the trial court to enter judgment on the writ petition in favor of CalOptima.

MEDICAL BOARD

Medical Board of California is statutorily required to post information online regarding licensee's completion of probation.

Szold v. Medical Board of California, 127 Cal.App.4th 591 (4th Dist. 2005).

The Medical Board of California ("Board") alleged that Dr. Philip D. Szold committed various improper acts in connection with his treatment of a patient, and placed him on probation for a period of five years. When Dr. Szold's probation ended, the Board posted information on its website pertaining to his completion of probation. Dr. Szold filed a petition for writ of mandamus asking the trial court to order the Board to remove from its website any references to the probation. The trial court denied his petition, and Dr. Szold appealed.

The California Court of Appeal rejected Dr. Szold's claim that the Medical Board of California is prohibited from posting on its website information pertaining to a licensee's completion of probation. The Court noted that Business & Professions Code Section 803.1 ("Section 803.1") mandates that the Board disclose to the public certain information regarding licensees, including information on probations. Moreover, Business & Professions Code Section 2027 mandates that the Board post on its website "any information required to be disclosed pursuant to Section 803.1." The Court found that the plain language and legislative history of these statutes supported the conclusion that the Board was required to post on the internet information pertaining to Dr. Szold's probation. The Court of Appeal affirmed the trial court's decision denying Dr. Szold's petition for writ of mandamus.

MEDICAL STAFF

The failure of a hospital to begin a peer review hearing within 60 days does not excuse a physician from exhausting administrative remedies.

Kaiser v. Sacramento County Superior Court, 128 Cal. App. 4th 85 (3rd Dist. 2005).

After Kaiser Foundation Hospital-Sacramento/Roseville (the "Hospital") summarily suspended Dr. Debbie Dennis-Johnson's ("Dr. Dennis") gynecological surgery privileges, The Permanente Medical Group ("TPMG") terminated Dr. Dennis's employment with the group. Shortly thereafter, Dr. Dennis was notified of her right to a consolidated hearing on the subject of her suspension and termination within 60 days before a neutral panel and hearing officer. Dr. Dennis availed herself of this right and requested a hearing. Disagreements between the Hospital and Dr. Dennis regarding the selection of the hearing officer resulted in the hearing's commencement being delayed. Dr. Dennis filed suit in superior court seeking, among other relief, a judicial declaration that she was excused from exhausting the hearing process on the grounds that the process would deny her a fair hearing before a neutral and unbiased decision maker, and that she did not receive a hearing within 60 days as required by statute and due process. The Hospital filed a motion seeking a judicial declaration that Dr. Dennis was required to exhaust the hearing process before seeking a remedy with the courts. The trial court granted Dr. Dennis's motion and denied the Hospital's motion. The Hospital sought a writ of mandate.

The California Court of Appeal reversed the trial court and held that the failure of a hospital to begin a hearing within the 60-day period provided by California Business and Professions Code Section 809.2(h) does not excuse a physician who is subject to peer review from completing the process, nor does it permit the physician to bring an immediate action for tort damages in superior court. The Court found nothing within the applicable statute to support the assertion that a physician is exempted from exhausting an administrative process because of mere delay. The Court reasoned that if the Legislature had intended such a result, such language could have been specified within the statute. Nor did the Court find traditional exceptions to exhaustion to be applicable, as such exceptions

FEATURE ARTICLE

Outpatient Dialysis Fraud and Abuse Risks

By Francis J. LaPallo, Esq.
Manatt, Phelps & Phillips LLP

INTRODUCTION

Recently the outpatient dialysis industry has experienced noteworthy federal fraud and abuse enforcement actions. At the end of 2004, Gambro Healthcare agreed to a settlement with the U.S. Department of Justice ("DOJ") and the Office of Inspector General ("OIG") of the Department of Health and Human Services, under which a Gambro subsidiary agreed to plead guilty to criminal charges, pay over $323 million, and be permanently excluded from the Medicare Program. Subsequently, Gambro announced its departure from the U.S. dialysis market through the sale of its U.S. operations to DaVita, Inc. That transaction closed in October 2005 and included the spin-off of 70 facilities to a new market participant, RenalAmerica. Shortly before that transaction closed, Gambro announced a multi-state settlement of charges that it improperly billed Medicaid programs, agreeing to pay $37.5 million. In March 2005, DaVita announced that it had received a subpoena from the U.S. Attorney for the Eastern District of Missouri seeking information on pharmaceutical services, financial relationships with physicians and joint ventures. In April 2005, Fresenius Medical Care AG disclosed that it had received a subpoena from the U.S. Attorney for Eastern District of Missouri to produce records about medical director compensation, physician relations and other aspects of its business. Fresenius later announced an agreement to acquire Renal Care Group, Inc., another large dialysis chain. In August 2005, Renal Care Group too announced a subpoena from the U.S. Attorney for Eastern District of Missouri to produce records including those concerning relationships with pharmaceutical companies and physicians and medical director compensation and joint ventures with physicians.

All healthcare industry participants, large or small, including dialysis providers, face the increasing threat of *qui tam* "whistle blower" actions for violations and alleged violations of federal fraud and abuse laws. In light of these developments, this article outlines the basics of Medicare reimbursement methods for end stage renal disease ("ESRD") treatments and explores the main areas of federal[1] fraud and abuse exposure for dialysis clinic operators and the physicians who treat dialysis patients.

MEDICARE REIMBURSEMENT FOR OUTPATIENT TREATMENT OF END STAGE RENAL DISEASE

ESRD affects approximately 390,000 Americans, around 300,000 of whom receive dialysis treatment in the United States. This life-sustaining procedure, and the extensive infrastructure for ESRD that supports it, are made possible by the fact that the Medicare program covers both the technical component and the professional component of treatment for ESRD regardless of the patient's age. In 2003, the Medicare program expended approximately $6.36 billion on outpatient dialysis and related treatments.

Facility/Technical Component

Most ESRD patients undergo hemodialysis[2], a procedure in which the patient's blood is circulated through a machine and filtered, three or four times per week on

1 This article does not address in detail potential fraud and abuse risks arising from California law, such as anti-kickback statutes (*e.g.*, Bus. & Prof. Code § 650 (physicians)); Welfare & Inst. Code § 14107.2 (Medi-Cal anti-kickback statute); physician financial relationship statutes (*e.g.*, Bus. & Prof. Code §§ 650.01 and 650.02); physician financial interest disclosure obligations (*e.g.*, Bus. & Prof. Code § 654.1); and false claims (*e.g.*, Government Code § 12650).

2 ESRD patients who qualify medically may receive kidney transplants, also covered by Medicare. Medicare Benefit Policy Manual, Pub. 100-02, ch. 11, § 140, *available at* http://www.cms.hhs.gov/manuals/102_policy/bp102index.asp [hereinafter Medicare Benefit Policy Manual]

an outpatient basis.[3] Medicare reimburses for such treatments on a prospectively determined "composite rate" per treatment basis. Prior to April 1, 2005, this "composite rate" for free-standing outpatient dialysis facilities compensated facilities for all elements of dialysis care except for separate reimbursements for bad debts and certain specified items and services, including certain drugs – notably including erythropoietin ("EPO"), a drug that stimulates bone marrow to produce red blood cells.

An alternative method of outpatient treatment is peritoneal dialysis, an ambulatory procedure employing an osmotic process in the patient's peritoneum. It can be performed by a trained patient generally without assistance except for periodic check-ups. Both peritoneal dialysis and home hemodialysis, in which the blood filtering process is performed by a machine installed at the patient's home, are covered by Medicare. An outpatient dialysis facility receives the same reimbursement regardless of treatment modality.[4] Because self-dialysis procedures (peritoneal and home hemodialysis) impose lower costs on outpatient dialysis facilities, such facilities are incentivized to encourage patients to utilize those modalities.

Under the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA"),[5] a case-mix adjusted prospective reimbursement system has been implemented. As of April 1, 2005 the average per-treatment payments to an individual outpatient dialysis facility depends on the facility's case-mix. The case-mix determination considers patient age, body mass index ("BMI") and body surface area ("BSA"), with a special adjustment for patients under age 18.[6] Certain drugs and biologicals, including EPO, are reimbursed separately based upon rates determined by CMS.[7] The case-mix adjusted reimbursement system imposes on facilities an obligation to include data on patient age, BMI and BSA as part of the claims process.[8] The composite rate for both the current and previous payment methodology includes routine laboratory testing performed on patients undergoing dialysis.[9]

Physicians

Medicare provides two methods to reimburse physicians (typically nephrologists) for routine physician services provided to ESRD patients: through the dialysis facility,[10] and as a direct capitated

---

3 Hospital inpatient dialysis services are reimbursed under hospital reimbursement rules. Dialysis services provided by any participating Medicare hospital are covered if the inpatient stay is medically necessary and the primary reason for the admission is not maintenance dialysis. Reimbursement for such dialysis is included in the PPS reimbursement for the Diagnostic Related Group ("DRG") that represents care for the actual reason for admission. Medicare Benefit Policy Manual, ch. 11, § 130.

4 Ctrs. For Medicare & Medicaid Servs., Dep't. of Health & Human Servs., Medicare Claims Processing Manual, Pub. 100-04, ch. 8, § 10.1, *available at* http://www.cms.hhs.gov/manuals/pub151/PUB_15_1.asp [hereinafter Medicare Claims Processing Manual]. ("The facility's composite rate is a comprehensive payment for all modes of in-facility dialysis, hemofiltration, and home dialysis except for bad debts, physicians' patient care services, and certain laboratory services and drugs that are separately billable.")

5 Pub. Law. No. 108-173, 117 Stat. 2066.

6 Ctrs. For Medicare & Medicaid Servs., Dep't. of Health & Human Servs., Change Request 3720, Transmittal 477, Pub. 100-04 (Feb. 18, 2005), *available at* http://www.cms.hhs.gov/manuals/transmittals/comm_date_dsc.asp.

7 *See* 42 C.F.R. § 413.174.

8 *Id*. It remains to be seen whether the reimbursement adjustment resulting from reporting of such data will provide an incentive for alleged abuse.

9 Ctrs. For Medicare & Medicaid Servs., Dep't. of Health & Human Servs., Provider Reimbursement Manual, Pub. 15-I, Part I, § 2712.

10 *See* 42 C.F.R. § 414.313.

expenditures as under a state plan for some purposes and not for others, and called this case "the latest in a series of case in which the Secretary has refused to implement the DSH provision in conformity with the intent behind the statute." The Court held that the entire low-income population actually served by the Hospitals, including Section 1115 expansion populations, must be regarded as "eligible" for medical assistance under a state Medicaid plan and accounted for in the DSH calculation. The Ninth Circuit affirmed the district court's decision granting summary judgment for the Hospitals.

County Organized Health System's adoption and application of a timeliness submission requirement as part of its utilization controls is permissible.

Life Care Centers of America v. CalOptima, 133 Cal. App. 4th 1169 (4th Dist. 2005).

The California Department of Health Services ("DHS") is permitted by statute to administer Medi-Cal through managed care models. One legislatively authorized model is a county organized health system ("COHS"), which gets paid on a capitated basis. The COHS then pays the health service providers. Defendant CalOptima, under contract with DHS, is the COHS for Orange County, and provides services through contracts with various health care providers. CalOptima required long-term care providers to submit a treatment authorization request ("TAR") within 21 days of the patient's admission in order for CalOptima to authorize and pay for the patient's treatment retrospective to the date of admission. If CalOptima receives the TAR after the 21-day deadline, reimbursement is made only to the date of receipt.

Plaintiff Life Care Centers of America dba La Habra Convalescent Hospital ("Life Care") submitted six TARs after the 21-day deadline, ranging from 26 to 205 days after admission. As a result of the late submissions, CalOptima denied a portion of the requested reimbursement for each TAR. Life Care filed a petition for a peremptory writ of mandate, asking the court to order CalOptima to make the full payment on each of the TARs. The trial court denied CalOptima's motion for judgment on the orders, granted Life Care's petition, and awarded Life Care attorney's fees. CalOptima appealed.

The California Court of Appeal reversed the trial court, holding that county organized health systems such as CalOptima have been granted flexibility in how they provide services to Medi-Cal beneficiaries. Therefore, because CalOptima's contract with the state does not prohibit claim submission deadlines, CalOptima may, as part of its utilization controls, adopt and enforce a timeliness requirement for treatment authorization requests. The Court rejected Life Care's argument that Welfare and Institutions Code Section 14133.05 ("Section 14133.05") limits the review of TARs by a COHS only to determine whether medical necessity exists. The Court noted that an existing Attorney General opinion and existing DHS interpretations of Section 14133.05 have found that the statute only limits DHS' review of TARs, not a COHS's review. The Court recognized that a COHS operates under a statutory scheme different from DHS, and through a negotiated contract that, among other terms, requires the COHS to develop, implement, and maintain utilization controls. Therefore, unless the contract expressly forbids it, a COHS can set deadlines for the submission of TARs as part of its utilization controls.

The Court also rejected Life Care's argument that different rules and policies by different COHS's would produce absurd variances in reimbursement from county to county. The Court instead found that the purpose of the various models is to develop innovative and cost-effective health care delivery systems. To further this goal, the Legislature granted COHS's the authority to negotiate payment terms with health care providers. Therefore, absent intervention by DHS, a COHS can negotiate TARs deadlines with providers. The Court found Life Care's reliance on precedent unpersuasive, noting that the cases that required reimbursement despite untimely TARs had been abrogated by the passage of Welfare and Institutions Code Section 14018.5, which specifically limited the application of certain remedies to Medi-Cal reimbursement questions. Because the Legislature had demonstrated disapproval of judicial efforts to circumvent management controls on Medi-Cal reimbursement, the Court refused to extend the equitable principle of quantum meruit to the present case.

Finally, the Court rejected Life Care's claim that CalOptima's requirement that TARs be submitted within 21 days of admission was arbitrary and capricious. The Court disapproved of Life Care's, and the trial court's, attempt to reverse the burden of proof by requiring CalOptima to show that its policy

Plaintiffs appealed.

The California Court of Appeal upheld the trial court's decision and found that Dr. Sievert was immune from liability. Section 5154(a) grants immunity to psychiatrists from civil or criminal liability for any action by a person released early from 72-hour detention "if the provisions of [Welfare & Institutions Code] Section 5152 have been met." Section 5152, which is part of the same statutory scheme as Welfare & Institutions Code Sections 5150 and 5154, lists certain requirements as part of a 72-hour hold, including requirements for the evaluation and treatment of a person subject to the hold. Section 5152 also provides that a person may be released from a 72-hour hold early only if "the psychiatrist directly responsible for the person's treatment believes, as a result of his or her personal observations, that the person no longer requires evaluation or treatment." Plaintiffs argued that Section 5154's immunities apply only if all of Section 5152's provisions are met, including those involving evaluation and treatment. They alleged that Mr. Coburn did not receive appropriate evaluation and treatment, and that Dr. Sievert's belief that Mr. Coburn no longer needed treatment was not in good faith. Therefore, Plaintiffs contended, Section 5154's immunities were inapplicable.

The Court rejected Plaintiffs' argument that Section 5154's immunities applied only if all the provisions of Section 5152 were met. Instead, after an extensive examination of the statutory construction and legislative history of the section, the Court concluded the phrase in Section 5154, "if the provisions of Section 5152 have been met," must be construed to mean only those provisions relating to early release. Therefore, allegations regarding whether the evaluation and treatment required under Section 5152 were provided to Mr. Coburn were not relevant to the application of the immunity under Section 5154. The Court then evaluated Plaintiffs' assertion that Dr. Sievert's belief that Mr. Coburn no longer needed treatment was not made in good faith. The Court determined that the Section 5152 does not support the conclusion that the psychiatrist's belief must be reasonable. Instead, the issue is whether or not the psychiatrist actually held the belief, reasonable or not. Plaintiffs did not allege facts that would undermine the existence of an honest, no matter how negligent, belief by Dr. Sievert that Mr. Coburn no longer needed treatment. Therefore, Dr. Sievert was entitled to immunity under Section 5154. The Court declined to rule on whether Section 5154 would immunize a psychiatrist from liability for injuries that result from negligent treatment during detention. The Court of Appeal affirmed the trial court's judgment.

MEDICAID

Hospitals were entitled to Disproportionate Share Hospital payments from federal agency for providing services to expansion population.

Portland Adventist Medical Center v. Thompson, 399 F.3d 1091 (9th Cir. 2005).

A number of Oregon hospitals ("Hospitals") filed suit against the Secretary of the Department of Health and Human Services ("Secretary") alleging that the Secretary wrongly denied Disproportionate Share Hospital ("DSH") payments for services to low-income individuals receiving medical services under a demonstration project approved pursuant to a waiver under Section 1115 of the Social Security Act ("Section 1115"). The Secretary denied reimbursement to Hospitals by interpreting the Medicare statute to mean that patients eligible for DSH payments must have been eligible for medical assistance under a state Medicaid plan. Thus, according to the Secretary, Section 1115 patients, who receive assistance because the Department of Health and Human Services waived the state's compliance with general Medicaid requirements, were not eligible for DSH payments. The Hospitals brought an action alleging that the plain language of the DSH provision required the Secretary to treat expansion populations under Section 1115 as receiving medical assistance "under a state plan." The district court granted summary judgment in favor of the Hospitals, and the Secretary appealed.

The Ninth Circuit Court of Appeals held that the Secretary incorrectly denied reimbursement for services to certain low-income populations based on an erroneous interpretation of the Medicare statute's DSH calculation. The Court determined that the DSH provision is unambiguous, and that the plain language of the statute supported the Hospitals' argument. According to the Court, Congress clearly expressed its intent that expansion populations be included in DSH calculations. The Court rejected the Secretary's argument that language in Section 1115 gave him authority to determine the extent and period for which benefits provided under a demonstration project should be regarded as expenditures under a state plan. The Court also criticized the Secretary for characterizing

payment to the physician, referred to as the "monthly capitation payment ("MCP").[11] The MCP covers all physician services provided to the patient except for certain specified services, including services unrelated to the patient's renal condition.[12]

Medicare Secondary Payer Rule

Medicare "secondary payer" rules require that that for ESRD patients who are part of a group health plan, Medicare is the secondary payer (i.e., the other plan pays first) until a 30-month coordination period has ended. This provision applies to all Medicare covered items and services (not just for treatment of ESRD) furnished to beneficiaries who are in the coordination period.[13] Thus, for the first 30 months after a patient is eligible for dialysis treatments, the dialysis facility and the treating physician are required to seek payment in the first instance from the patient's group health insurer or HMO where such coverage is available.

The "Medical Director" Requirement

The Medicare conditions of participation ("COPs") for outpatient dialysis facilities are set forth in 42 C.F.R., Part 405, Subpart U. The COPs include a requirement that treatment at the dialysis facility "is under the general supervision of a director who is a physician."[14] The physician-director must be "either board eligible or board certified in internal medicine or pediatrics, and [have] at least 12 months of experience or training in the care of patients at ESRD facilities."[15]

11 *See* 42 C.F.R. § 414.314. Excepted from this rate are (1) administration of hepatitis B vaccine, (2) services furnished by another physician under certain circumstances, (3) inpatient hospital services (including inpatient dialysis services) provided by a physician who elects not to receive the MCP during the hospital stay, (4) surgical services (including declotting of shunts, but not including catheter insertions for patients on maintenance peritoneal dialysis who do not have indwelling catheters), and (5) physician services not related to the patient's renal condition or to a renal-related visit or session. 42 C.F.R. § 414.314(b). Physician services furnished to the ESRD patients that are excluded from the MCP are paid in accordance with the physician fee schedule and are described in the Medicare Claims Processing Manual, CMS Pub. 100-04, § 140.2.

12 *Id.*

13 Ctrs. For Medicare & Medicaid Servs., Dep't. of Health & Human Servs., Medicare Secondary Payer Manual, Pub. 100-05, § 20, *available at* http://www.cms.hhs.gov/manuals/105_msp/msp105index.asp.

14 42 C.F.R. § 405.2161. The complete section provides: Condition --Director of a renal dialysis facility or renal dialysis center Treatment is under the general supervision of a Director who is a physician. The physician-director need not devote full time as Director but is responsible for planning, organizing, conducting, and directing the professional ESRD services and must devote sufficient time to carrying out these responsibilities. The director may also serve as the Chief Executive Officer of the facility. (a) *Standard: qualifications* The director of a dialysis facility is a qualified physician-director. (*See* § 405.2102.) (b) *Standard: responsibilities* The responsibilities of the physician-director include but are not limited to the following: (1) Participating in the selection of a suitable treatment modality, i.e., transplantation or dialysis, and dialysis setting, for all patients; (2) Assuring adequate training of nurses and technicians in dialysis techniques; (3) Assuring adequate monitoring of the patient and the dialysis process, including, for self-dialysis patients, assuring periodic assessment of patient performance of dialysis tasks. (4) Assuring the development and availability of a patient care policy and procedures manual and its implementation. As a minimum, the manual describes the types of dialysis used in the facility and the procedures followed in performance of such dialysis; hepatitis prevention and procedures for handling an individual with hepatitis; and a disaster preparedness plan (*e.g.*, patient emergency, fire, flood); and (5) When self-dialysis training or home dialysis training is offered, assuring that patient teaching materials are available for the use of all trainees during training and at times other than during the dialysis procedure.

15 42 C.F.R. § 405.2102 sets forth the qualifications as follows: *Physician-director.* A physician who: (1) Is board eligible or board certified in internal medicine or pediatrics by a professional board, and has had at least 12 months of experience or training in the care of patients at ESRD facilities; or (2) During the 5-year period prior to September 1, 1976, served for at least 12 months as director of a dialysis or transplantation program. (3) In those areas where a physician who meets the definition in paragraph (1) or (2) of this definition is not available to direct a participating dialysis facility, another physician may direct the facility, subject to the approval of the Secretary.

Under the MCP system of reimbursement, no payment is made to the treating physician for "administrative services" furnished by physicians, including participation in management of the facility, advice on and procurement of facility equipment and supplies, supervision of staff, staff training, or staff conferences. Such services are deemed to be covered by the facility's composite rate, so it is the facility that is reimbursed for them.[16]

Thus, the applicable Medicare rules require a dialysis facility to provide for a physician director, who is required to perform specified services, and Medicare denies reimbursement to treating physicians for performing such services. Accordingly, to satisfy the physician director COP, operators of outpatient dialysis facilities enter into "medical director" agreements with physicians to obtain these required services. Often the medical director of the facility will be a nephrologist with a substantial number of his or her own patients receiving dialysis treatments at the facility. As discussed below, this arrangement can pose fraud and abuse exposure risks for the facility.

SOURCES OF POTENTIAL FRAUD AND ABUSE LIABILITY

Dialysis facility operators must consider the same laws traditionally applicable to other healthcare enterprises.

Medicare-Medicaid Anti-Kickback Statute

The Medicare-Medicaid Anti-Kickback Statute ("AKS")[17] generally prohibits offering or receiving remuneration in return for referral of Medicare or Medicaid business. Violation is a felony, subjecting the person convicted to fines and imprisonment. In addition, where a person commits an act described in the AKS, the OIG may initiate administrative proceedings to impose civil monetary penalties,[18] and also may initiate administrative proceedings to exclude the person from federal health care programs.[19] Further, as discussed below, some government settlements – and indeed some reported decisions – have used AKS violations as predicates for liability under the federal False Claims

16 Medicare Benefit Policy Manual, *supra* note 2, § 80.2, states as follows: "A component of the facility's cost or charge for dialysis is for (administrative services) furnished by physicians. Administrative services are differentiated from physicians' direct patient care services because they constitute supervision of staff or are not directly related to the care of an individual patient, but benefit all patients and the facility as a whole. The administrative type of physician's service are services that are supportive of the facility as a whole and have benefit to patients in general. Examples of such services include participation in management of the facility, advice on and procurement of facility equipment and supplies, supervision of staff, staff training, and staff conferences. The carrier will disallow all claims for these services with an explanation that such services are paid as part of the dialysis services that are included in the facility charge for dialysis."

17 42 U.S.C. § 1320a-7b(b) In pertinent part, the AKS provides: Illegal remunerations. (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind -- (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both. (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person -- (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

18 42 U.S.C. § 1320a-7a(7).

19 42 U.S.C. § 1320a-7(b)(7).

overruling the demurrer and fixing the time within which Blue Cross may answer, and (3) place the case on calendar for trial.

HOSPITAL LIEN ACT

A hospital may not assert a lien under the Hospital Lien Act absent an underlying debt from a patient.

Parnell v. Adventist Health System, 35 Cal. 4th 595 (2005).

Joel Parnell was injured in an automobile accident and received treatment for his injuries by a hospital owned by Adventist Health System (the "Hospital"). Mr. Parnell's health insurer reimbursed the Hospital for services rendered based on a provider agreement whereby the Hospital provided services at a discounted rate to the insured and accepted payment at such rate as "payment in full." Mr. Parnell later filed a lawsuit against the driver of the vehicle involved in the accident that caused his injuries. The Hospital filed a notice of lien against any judgment or settlement received by Mr. Parnell pursuant to Civil Code Section 3045.1, the Hospital Lien Act ("HLA"). Subsequently, Mr. Parnell filed suit against the Hospital alleging a number of claims, including breach of third party contract and unfair business practices. In response, the Hospital filed a motion for judgment on the pleadings. The trial court granted the motion in favor of the Hospital. Mr. Parnell appealed. The California Court of Appeal reversed, and the Hospital requested review by the Supreme Court of California.

The California Supreme Court granted review and held that in the absence of an underlying debt, a hospital may not assert a lien against any judgment or settlement received by a patient from a third party tortfeasor under the HLA. The Court affirmed the appellate court decision based on common law lien principles, the legislative history of the HLA, and the Court's interpretation of similar statutes. The Court found that the Legislature's use of the word "lien" implicated the typical statutory and common law definition of a lien, meaning that the HLA presupposes the existence of a debt. Moreover, the Court noted that the Legislature enacted the statute in response to uninsured patients who failed to pay portions of their hospital bills, despite recovering tort damages. The debt owed by the patient was therefore the underlying basis for the hospital lien on damages. The Hospital contended that the lien did not require a debt because it seeks to recoup losses from a third party tortfeasor, rather than the patient directly; however, the Court determined that such a distinction was irrelevant. The Court noted that similar lien statutes involving county governments had been interpreted to require a debt, even when collecting from a third party. In holding that a debt must be present, the Court expressly overruled the contrary holding in *Swanson v. St. John's Regional Medical Center*, 97 Cal. App. 4th 245 (2002).

Based on the foregoing, the Court ruled that the Hospital was not permitted to assert a lien against any judgment received by Mr. Parnell because the Hospital received payment for its services in the amount specified by the provider agreement and had accepted that amount as "payment in full." Therefore, no debt existed. The Court recognized that many hospitals faced with a financial crisis often use the HLA to recoup losses from discounted insurance rates, and that its ruling may result in significant financial hardship for many hospitals. The Court noted that hospitals can turn to the Legislature for relief from the plain language of the HLA, and that hospitals were free to contract with insurers for the right to recover the difference between usual and customary charges and the negotiated rate through a lien under the HLA. The Supreme Court of California affirmed the ruling of the appellate court denying the Hospital's motion for judgment on the pleadings.

LANTERMAN-PETRIS-SHORT ACT

Psychiatrist who released patient early from involuntary psychiatric commitment was immune from liability.

Coburn v. Sievert, 133 Cal.App.4th 1483 (5th Dist. 2005).

Dr. Dwight Sievert, a psychiatrist, treated and released Edward Coburn early from an involuntary 72-hour hold imposed under Welfare & Institutions Code Section 5150. The day after his release, Mr. Coburn had a violent outburst during an airplane trip home with his father. This resulted in further commitment and treatment of Mr. Coburn, along with criminal charges and civil lawsuits for property damage. Mr. Coburn and his father (collectively, "Plaintiffs") sued Dr. Sievert for damages arising from Mr. Coburn's violent outburst, claiming negligent treatment and premature release. The trial court granted Dr. Sievert's motion for summary judgment, on the basis that under Welfare & Institutions Code Section 5154 ("Section 5154"), he was entitled to immunity as the treating psychiatrist who authorized early release based on his personal observations.

met all of these conditions, and therefore, were excepted from the hearsay rule. First, Delta Dental employees acted as agents of DHS when they conducted various audit and payment duties, including the preparation of CDRs, on behalf of DHS. Second, because Delta Dental's payment of claims within three to eight weeks after services were rendered satisfied the statutory payment requirements for intermediaries, the timeframe between the transaction and Delta Dental's computer entry for payment met the timeliness requirement. Finally, Dr. Bhatt proffered no evidence to satisfy his burden to establish the CDRs' lack of trustworthiness. Therefore, the CDRs satisfied Section 1280's foundational requirements for trustworthiness and the Chief ALJ correctly admitted them under the exception.

The Court next examined and affirmed the trial court's holding that the dentist providing services to Denti-Cal beneficiaries must be enrolled in Denti-Cal at the time services are rendered in order to be reimbursed for such services. Dr. Bhatt claimed there was no statutory or other requirement that a dentist who is not the billing provider be enrolled in Denti-Cal to receive payments for services to beneficiaries. The Court rejected this argument. The Court highlighted that California Code of Regulations, title 22 ("Title 22"), Section 51458.1 requires DHS to recover overpayments made to any provider who does not meet the conditions of participation in the Medi-Cal program. Pursuant to Title 22, Section 51200, *et seq*., such conditions of participation require that each individual provider must complete a "Medi-Cal Physician Application/ Agreement." "Provider" is defined in California Welfare and Institutions Code Section 14043.1(e) to include any individual who directly or indirectly provides services to a Medi-Cal beneficiary. Finally, the Court emphasized that Welfare and Institutions Code Section 14043 explicitly requires that every applicant and every provider be subject to the requirements of that Provider Enrollment article. The Court of Appeal held that, when harmonized, the statutes and regulations provide that services provided to Denti-Cal beneficiaries may be billed only if the dentist providing the services is enrolled in Denti-Cal.

HEALTH PLAN UNFAIR COMPETITION

The Knox-Keene Act requires health care service plans to reimburse non-contracting providers of emergency services a reasonable amount.

Bell v. Blue Cross of California, 131 Cal. App. 4th 211 (2nd Dist. 2005).

Pursuant to Health and Safety Code Section 1317(b), Dr. Mark R. Bell, an emergency room physician, is obligated to treat all emergency room patients regardless of their insurance or ability to pay. Although he had not contracted with Blue Cross of California ("Blue Cross"), Blue Cross is required under Health and Safety Code Section 1371.4 to reimburse Dr. Bell for the emergency services he provides to Blue Cross patients. In a class action lawsuit, Dr. Bell alleged that Blue Cross' practice is to pay non-participating emergency care providers arbitrary amounts substantially below the cost, value, and common range of fees for services the providers render. The class sought relief and damages under Business and Professions Code Sections 17200 *et seq*., known as the Unfair Competition Law ("UCL"). In the alternative, the class sought reimbursement for the reasonable value of services rendered. Blue Cross filed a demurrer, which was sustained without leave to amend. Dr. Bell appealed.

The Court of Appeal held that (1) emergency room physicians had standing to seek reimbursement, and (2) Health and Safety Code Sections 1340 *et seq.* ("Knox-Keene Act") requires health care service plans to reimburse non-contracting providers at a reasonable rate for emergency medical services. The Court also found that the Knox-Keene Act leaves physicians free to pursue alternate theories to recover the reasonable value of services, and that the UCL claim does not infringe on the Department of Managed Health Care's jurisdiction. Under the Knox-Keene Act, the Court found that Health and Safety Code Section 1371.4 was enacted to impose a mandatory duty on health care plans to reimburse non-contracting providers for emergency services. The duty to reimburse arises out of the emergency care provider's duty to render services without regard to a patient's insurance status or ability to pay. Therefore, the Court reasoned, the duty to reimburse must be read as a duty to pay a reasonable and customary amount for the services rendered. Finally, the Court noted that to hold in favor of Blue Cross would be tantamount to requiring professionals to give away a portion of their income in violation of the California constitution. The Court of Appeal reversed the judgment and directed the trial court to (1) vacate its order sustaining the demurrer, (2) enter a new order

Act ("FCA"),[20] which can have additional serious consequences. The AKS provides for, and OIG has promulgated, "safe harbors" describing transactions that are deemed not to constitute illegal remuneration under the AKS.[21] To obtain the protections of a safe harbor, however, the subject transaction must satisfy all elements of the relevant safe harbor(s).[22]

In the outpatient dialysis context, nephrologists who manage the care of ESRD patients can strongly influence their patients' choices of dialysis facility. Thus, an operator of an outpatient dialysis facility may be tempted to reward nephrologists who have significant numbers of ESRD patients for their loyalty to the facility. The medical director agreement discussed above, as well as participation in ownership of the facility through a joint venture, are typical arrangements, and these have drawn the attention of enforcement authorities.

AKS: Medical Director Fees

Payments by a dialysis clinic operator to a nephrologist who refers patients to the facility create the potential for AKS liability. Under the "one purpose" test,[23] where one purpose of a payment to the nephrologist is to induce him or her to refer patients to the dialysis facility or keep them there, the AKS is violated. The AKS safe harbor rules generally do not provide protection in this context. With respect to the medical director agreement, the applicable safe harbor would be the personal services and management agreement.[24] An element of this safe harbor, however, is the requirement that, "[i]f the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals."[25] Because the medical director rarely performs duties in accordance with such a schedule, the medical director agreement cannot be made to conform to this requirement, and safe harbor protection would not be available.

Nevertheless, even if every element of a safe harbor cannot be satisfied, it is good practice to satisfy as many elements as the structure of the transaction permits. Of course, a key element of the

---

20 31 U.S.C. § 3729 *et seq.*

21 2 U.S.C. § 1320a-7b(b)(3)(E); *see* 42 C.F.R. § 1001.952 *et seq.*

22 42 C.F.R. § 1001.952 (*passim*).

23 The AKS has been interpreted to cover any arrangement where one purpose of the remuneration was to pay or obtain money for the referral of services or to induce further referrals. *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985).

24 This safe harbor provides as follows: Personal services and management contracts. As used in section 1128B of the Act, "remuneration" does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following seven standards are met -- (1) The agency agreement is set out in writing and signed by the parties. (2) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent. (3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals. (4) The term of the agreement is for not less than one year. (5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs. (6) The services performed under the agreement do not involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal law. (7) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services. For purposes of paragraph (d) of this section, an agent of a principal is any person, other than a bona fide employee of the principal, who has an agreement to perform services for, or on behalf of, the principal. 42 C.F.R. § 1001.952(d)

25 *Id.*

safe harbor, as well as related law,[26] is the requirement that the aggregate compensation paid to the physician over the term of the agreement is consistent with fair market value in arms-length transactions. Alleged departure from fair market value compensation has played a key part in publicly announced actions against dialysis providers.[27] The author's experience is that rates of compensation paid to dialysis facility medical directors vary widely, even within relatively small geographic areas. Facility operators may use numbers of patients receiving treatment at a facility as a proxy for the amount of "administrative services" work effort required of the medical director. This assumption may be a reasonable starting point for determining the medical director's fee. However, if the medical director is the treating physician for a significant proportion of the facility's patients, there is an obvious risk that the payments could be characterized as related to the number of the medical director's patients at the facility and thus "determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties." Payments to a referring physician measured by volume or value of referrals pose a substantial risk of being characterized as made "in return for" referrals of Medicare business and thus violative of the AKS.[28]

AKS: Joint Ventures

It is not uncommon for a dialysis facility operator to develop a new facility in partnership with one or more nephrologists. Because a patient base is essential for financial viability of such a facility, the physician partner(s) for such projects likely will be one or more nephrologists with a substantial number of patients on dialysis. Although the patients of the potential partner nephrologists usually are receiving dialysis treatment at one or more facilities unrelated to the partnering operator, in some cases the patients already may be undergoing treatment at the operator's facility. The motivation underlying the new development may be entirely benign; for example, the partnering nephrologist may desire to gain more influence over the patient care operations and quality of the facility at which his or her patients are treated. Or it may be less benign; for example, a nephrologist may threaten to move his or her patients to a competing facility unless given an opportunity to profit from the technical component of the care of his or her patients. The latter example poses the risk that the resulting joint venture relationship (or the returns on the nephrologist's investment) could be characterized as remuneration to the nephrologist for referral of patients to the joint venture facility, or indeed to any other facility in which the operator partner has an interest.[29]

Given the nature of ESRD (kidney failure that requires dialysis or transplantation for the patient to remain alive) it can be argued that the likelihood of excessive utilization of dialysis procedures is quite small. Nevertheless, when promulgating the original safe harbors in 1991, the OIG specifically declined to provide particular safe harbor protection for "nephrologists performing services at renal dialysis facilities" comparable to protections afforded with respect to ambulatory surgery centers.[30] Further, in announcing the 2004 Gambro settlement, the DOJ also

---

26 The statute authorizing civil monetary penalties, *see supra* note 18 and accompanying text, defines remuneration as "transfers of items or services for free or for other than fair market value." 42 U.S.C. § 1320a-7a(i)(6). Case law indicates that courts will infer that payments above fair market value are evidence of payment for referrals. *See, e.g.*, *United States v. Lipkis*, 770 F.2d 1447, 1449 (9th Cir. 1985); *United States ex rel Perales v. St. Margaret's Hospital*, 243 F. Supp.2d, 843, 851 (C. D. Ill. 2003).

27 *See, e.g.*, News Release, United States Attorney's Office Eastern District of Missouri (Dec. 2, 2004), *available at* http://www.usdoj.gov/usao/moe/press_release.html (announcing settlement agreement between Gambro Healthcare and the U.S. Attorney's Office involving allegations that, *inter alia*, Gambro Healthcare hired and compensated physicians as medical directors with remuneration that exceeded fair market value) [hereinafter News Release].

28 As discussed below regarding the Stark Law, CMS has given guidance on determination of fair market value for services provided by dialysis facility medical directors. *See* note 48 and accompanying text.

29 The OIG has taken the position that even the *opportunity* to generate a fee can be remuneration. *E.g.*, 58 Fed. Reg. 49008, 49012 (Sept. 21, 1993) (commentary in proposal for additional safe harbors, citing *United States v. Bay State Ambulance and Hospital Rental Service, Inc.*, 874 F.2d 20, 29 (1st Cir. 1989)); OIG Special Advisory Bulletin on Contractual Joint Ventures (April 23, 2003), *available at* http://oig.hhs.gov/fraud/fraudalerts.html#2.

30 Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35971 (July 29, 1991) ("We are . . concerned about the extent to which we should modify this second investment interest safe harbor to protect a physician-investor's profit in other joint venture entities where he or she both makes a referral and performs some level of service for the referred patient at the entity.")

by the signatory or in at least 14-point type, it must be clearly separate from other language on the same page and be executed by a signature whose only purpose is to execute the authorization, it must state the specific uses and limitations of the disclosed medical information, it must state a specific date after which disclosure is no longer authorized, and it must advise the person of the right to receive a copy of the authorization. The Associates authorization that Colleen signed did not meet any of these requirements, and therefore was invalid.

This did not end the Court's inquiry, however. CMIA permits broad exceptions to the ban on disclosing information without the patient's authorization. One such exception permits the disclosure of medical information to the person or entity responsible for payment of the patient's health care services. (Civil Code Section 56.10.) The Court determined that Ronald was qualified as someone who was responsible for payment of Colleen's health care services, and therefore was entitled to the limited information necessary to allow him to determine his responsibility for payment and to make payment. This was analogous to an insurance company whose policy covers certain medical procedures, and inquiring about the medical procedure given to the insured. Therefore, Associates' disclosure of Colleen's in vitro fertilization to Ronald was authorized under CMIA. Another exception under CMIA requires the disclosure of information pursuant to a subpoena, subpoena duces tecum, or any provision authorizing discovery in a proceeding before a court or administrative agency. Therefore, Associates had a complete defense to Colleen's cause of action based on the disclosure of Colleen's medical records to Ronald's attorney. The Court of Appeal affirmed the trial court's judgment.

DENTI-CAL

Reports prepared by a fiscal intermediary on behalf of the California Department of Health Services are admissible as direct evidence, and a dentist can collect payment for services rendered to Denti-Cal beneficiaries by other dentists only if the providers are enrolled in the California Denti-Cal/Medi-Cal Program.

Bhatt v. Department of Health Services, 133 Cal. App. 4th 923 (2nd Dist. 2005).

Shaileshkumar Bhatt, D.D.S., a dentist enrolled as a provider in the California Denti-Cal/Medi-Cal program ("Denti-Cal"), employed nine dentists. Delta Dental, a fiscal intermediary for the California Department of Health Services ("DHS"), audited Dr. Bhatt's records for a three year period. Delta Dental determined that Dr. Bhatt must reimburse DHS for overpayments due to (1) inadequate or no ocumentation to support certain billed services, and (2) services provided to Denti-Cal beneficiaries by three dentists Dr. Bhatt employed who were not enrolled in Denti-Cal. Dr. Bhatt disputed the official review of findings and requested a formal hearing. DHS proffered claim detail reports ("CDRs") that Delta Dental created during the audit as the only evidence of their claims against Dr. Bhatt. Dr. Bhatt argued that the CDRs were hearsay that did not satisfy California Evidence Code Section 1271, the business records exception to the hearsay rule ("Section 1271"), because DHS was unable to authenticate the documents. The administrative law judge ("ALJ") agreed that the CDRs were hearsay, and as such, could not alone establish a finding of fact. The ALJ then concluded that DHS had failed to establish the reliability of the audit findings.

The chief administrative law judge ("Chief ALJ") rejected the lower ALJ's ruling, holding instead that while the CDRs did not satisfy Section 1271, they did satisfy Evidence Code Section 1280 ("Section 1280"), the "official records" exception to the hearsay rule. Therefore, the CDRs were admissible as direct evidence. The Chief ALJ also found that the dentists who actually performed the dental services billed to Denti-Cal must be enrolled in Denti-Cal at the time services were rendered in order to receive reimbursement. Dr. Bhatt filed a petition for writ of administrative mandamus in the superior court. The trial court rejected Dr. Bhatt's petition, and Dr. Bhatt appealed.

The California Court of Appeal affirmed the trial court's holdings, and held that the reports prepared by a fiscal intermediary on behalf of DHS qualified under Section 1280's hearsay exception, provided such records satisfy Section 1280's foundational requirements. The Court also held that dentists employed by a dentist enrolled in Denti-Cal must themselves be enrolled as Denti-Cal providers in order to receive payments for services rendered to Denti-Cal beneficiaries. Section 1280 provides an exception to the hearsay rule if (1) the writing was made by and within the scope of duty of a public employee, (2) the writing was made at or near the time of the act, and (3) the source of information and the time and method of preparation indicate the writing's trustworthiness. The Court found that the CDRs

misleading, deceptive" language and that health care service plans between an employer and an insurer containing a mandatory binding arbitration clause effect an unconstitutional waiver of the employees' right to jury trial. The Court rejected these arguments, and noted that, subject to certain disclosure requirements, the Legislature expressly approved arbitration as a forum for resolution in Section 1363.1 of the Knox-Keene Act ("Section 1363.1"). The Court emphasized that nothing in the Knox-Keene Act authorizes DMHC to mandate that health care service plans include a choice between arbitration and jury trial, as the Plaintiffs requested.

Further, the Court applied the principles of statutory construction, reasoning that the Legislature was aware of the *Madden* holding prior to passing Section 1363.1. In *Madden*, the California Supreme Court held that an employer, acting as an agent of its employees, has implied authority to agree to binding arbitration for malpractice claims arising under the health care service plans it negotiates for its employees. Because the Legislature's approval of binding arbitration in Section 1363.1 does not include limitations on an employer's ability to negotiate such clauses for employee benefit packages, the Court held that the Legislature implicitly approved such negotiations.

Finally, the Court rejected Plaintiffs' argument that inclusion of the binding arbitration clauses created contracts of adhesion. The Court reasoned that the Legislature authorized the waiver of civil jury trail under the Knox-Keene Act. Further, the Plaintiffs could have selected contracts that did not include binding arbitration clauses by contracting individually for medical care. The Court followed the Supreme Court's holding in Madden when it rejected Plaintiffs' argument that adhesion principles prevented enforcement of the binding arbitration clause against them because (1) the contracts were negotiated, (2) the stronger party's liability was not limited, and (3) the weaker party was not oppressed. The Court affirmed the judgment of the trial court.

CONFIDENTIALITY

Disclosure of details of patient's treatment was authorized under the Confidentiality of Medical Information Act exception permitting disclosure to person responsible for patient's health care costs, and in response to subpoena duces tecum.

Colleen M. v. Fertility and Surgical Associates of Thousand Oaks, 132 Cal. App. 4th 1466 (2nd Dist. 2005).

Colleen M. ("Colleen") and Ronald O. ("Ronald"), Colleen's ex-fiancé, entered into an agreement in which Colleen made charges on Ronald's credit card to offset a debt he owed her. Shortly thereafter, she started receiving in vitro fertilization treatments at Fertility and Surgical Associates of Thousand Oaks ("Associates"), and used Ronald's credit card for payment. When Ronald received his credit card statement, he called Associates to inquire about Colleen's treatment. A representative told him she was undergoing in vitro fertilization treatments. Nearly a year later, Ronald filed a lawsuit against Colleen alleging breach of contract, fraud, and charging that she misrepresented the reason she was receiving medical treatment. His attorney served a subpoena duces tecum on Associates for its custodian of records to produce at the arbitrator's office on the arbitration date any and all records pertaining to her medical care. The custodian was not able to appear on the scheduled date, so Associates mailed Colleen's medical records to Ronald's attorney. Colleen filed suit against Associates alleging, among other counts, violation of her right of privacy by informing Ronald of her treatment and for releasing her medical records to his attorney. The trial court granted Associates' motion for summary judgment, finding that Colleen had signed a consent form authorizing the disclosure of the information under the Confidentiality of Medical Information Act ("CMIA") (Civil Code Sections 56 to 56.37), which prohibits health care providers from disclosing a patient's medical information without first obtaining an authorization.

The California Court of Appeal held (1) CMIA authorized the disclosure of Colleen's medical records to Ronald under the exception permitting disclosure to the person responsible for health care costs, and (2) CMIA compelled the disclosure of medical records in response to a subpoena duces tecum. The Court agreed with the trial court that Colleen should have reasonably expected that Ronald would learn that she received treatment at Associates; the Court also recognized that Colleen's cause of action was based on revealing the nature of the treatment – in vitro fertilization. Associates contended Colleen lacked a reasonable expectation of privacy because she signed a consent form that authorized the unrestricted release of her medical information. To be valid under CMIA, an authorization to disclose medical information must meet specific requirements, including the following: it must be handwritten

indicated that the relevant civil FCA complaint alleged that Gambro had "paid its joint venture physician partners illegal remuneration to either refer or retain their patients at Gambro clinics."[31]

Although the OIG has established a "small entities" joint venture safe harbor which might appear applicable to such a dialysis clinic joint venture with a referring nephrologists, it is unlikely that such a venture could be structured to satisfy each element of the safe harbor.[32] The safe harbor requires that no more than 40 percent of the value of the investment interests of each class of investment interests may be held in the previous fiscal year or previous 12-month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity. In a typical arrangement, the joint venture dialysis facility will receive management and other services from an entity affiliated with the non-physician venturer. Because the investor nephrologists(s) who are in a position to make referrals and the non-physician venturer, combined, will hold more than 40 percent of the value of the investment interest in the entity, the 40 percent ownership element of the safe harbor would not be satisfied.

Similarly, the safe harbor requires that no more than 40 percent of the entity's gross revenue related to the furnishing of healthcare items and services in the previous fiscal year or previous 12-month period may come from referrals or business otherwise generated from investors. If, as is typical, the physician investors in the facility are one or more nephrologists with a substantial number of patients at the facility, it is also unlikely that this element of the safe harbor would be satisfied. Again, even if the joint venture cannot satisfy each element of the safe harbor, participants are well-advised to structure the transaction to satisfy as many elements of the safe harbor as possible or conform to the principles embodied in those safe harbors and related OIG pronouncements. In particular, investment returns to the physician venturers should be directly proportional to the amount of the physician's capital investment.[33] There should be no requirement for physician investors to refer patients to the dialysis clinic,[34] and no efforts to track referrals by

---

31 News Release, United States Attorney's Office Eastern District of Missouri, December 2, 2004.

32 The AKS small entities joint venture safe harbor is as follows: Investment interests. As used in section 1128B of the Act, "remuneration" does not include any payment that is a return on an investment interest, such as a dividend or interest income, made to an investor as long as all of the applicable standards are met . . . If the entity possesses investment interests that are held by either active or passive investors, all of the following eight applicable standards must be met -- (i) No more than 40 percent of the value of the investment interests of each class of investment interests may be held in the previous fiscal year or previous 12 month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity. (For purposes of paragraph (a)(2)(i) of this section, equivalent classes of equity investments may be combined, and equivalent classes of debt instruments may be combined.) (ii) The terms on which an investment interest is offered to a passive investor, if any, who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be no different from the terms offered to other passive investors. (iii) The terms on which an investment interest is offered to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must not be related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from that investor to the entity. (iv) There is no requirement that a passive investor, if any, make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor. (v) The entity or any investor must not market or furnish the entity's items or services (or those of another entity as part of a cross referral agreement) to passive investors differently than to non-investors. (vi) No more than 40 percent of the entity's gross revenue related to the furnishing of health care items and services in the previous fiscal year or previous 12-month period may come from referrals or business otherwise generated from investors. (vii) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor in the entity) must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest. (viii) The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor. 42 C.F.R. § 1001.952(a)(2).

33 42 C.F.R. § 1001.952(a)(2)(vii). ("The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.")

34 42 C.F.R. § 1001.952(a)(2)(iv). ("There is no requirement that a passive investor, if any, make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor.")

investor physicians.[35] Physician partner financing should not be provided by the other partner or the joint venture itself.[36] The joint venture facility or facilities affiliated with investors in the facility should not market to physician investors differently than to other physicians.[37] The investment terms under which the physician venturers make their investments should be "no different" from the terms applicable to the other investor(s).[38]

AKS: Purchase of Dialysis Facility from Nephrologists

Purchase of a dialysis facility from one or more practicing nephrologists may also pose AKS risk. Many dialysis clinics initially were developed by nephrologists to deliver care to their own patients. At some point in the economic cycle, the owner nephrologists may elect to liquidate their investment in the clinic by selling it. Buyers of businesses often assign value to a prospective purchase based in part on revenue. For dialysis facilities, patient census is a proxy for revenue (and potential revenue). Thus dialysis facility valuation is often related to patient census. Where the selling nephrologist is also the treating physician for the patients comprising the census and it is expected that the selling nephrologists will continue in medical practice after the sale, the sale transaction can pose AKS risk for the parties. If the transaction is structured as an installment sale, the selling nephrologists(s) may be tempted to continue to refer patients to the facility to ensure that the purchaser has the resources necessary to make the installment payments. If the installment payments are explicitly structured as an "earn out" tied to financial performance of the facility, the connection to referrals is even more explicit. Further, as part of the transaction the selling nephrologist and the purchaser may enter into a medical director agreement. As discussed above, if the compensation under the medical director agreement significantly exceeds fair market value, there would be risk that the enforcement authorities would characterize that excess as remuneration for continued referral of patients to the clinic for their dialysis treatments.

Stark Law

The Medicare Physician Self Referral Act (known as the "Stark Law")[39] generally prohibits Medicare referrals by physicians for designated health services ("DHS") and prohibits the recipient of prohibited referrals from billing for such services. Violators of the Stark Law are not entitled to Medicare reimbursement and may be subject to exclusion from Medicare and to civil money penalties. In addition, because reimbursement is expressly conditioned on compliance with the Stark Law, violations of the Stark Law can be used as predicates to False Claims Act violations.

35 The OIG has indicated that it regards a commitment not to track referrals by investor physicians (or by physicians otherwise affiliated with an investor) as a relevant mitigation factor in analyzing the fraud and abuse risk of a proposed joint venture. *E.g.*, OIG Adv. Op. No. 03-12 (May 29, 2003); OIG Adv. Op. No. 03-2 (Jan. 21, 2003); OIG Adv. Op. 01-17 (Oct. 17, 2001).

36 2 C.F.R. § 1001.952(a)(2)(vii). ("The entity or any investor (or other individual or entity acting on behalf of the entity or any investor in the entity) must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest.")

37 42 C.F.R. § 1001.952(a)(2)(v). ("The entity or any investor must not market or furnish the entity's items or services (or those of another entity as part of a cross referral agreement) to passive investors differently than to non-investors.")

38 42 C.F.R. § 1001.952(a)(2)(ii). ("The terms on which an investment interest is offered to a passive investor, if any, who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be no different from the terms offered to other passive investors."). A conceptually related requirement, that the terms on which an investment interest is offered to an investor who is in a position to make referrals to the entity not be related to the previous or expected volume or referral, 42 CFR § 1001.952(a)(2)(iii), is more problematic. A physician investor typically is one with a patient base. The opportunity to invest is generally offered to the physician, at least in part, because of that patient base. In such circumstances, even if the investment terms are identical for all investors, physician and non-physician, it could be difficult to convince a factfinder that the terms of the investment are not somehow "related" to previous or expected volume of referrals

39 42 U.S.C. § 1395nn

ARBITRATION HEALTH PLAN

Health care plan arbitration clauses must be prominently displayed immediately before the subscriber's signature line.

Robertson v. Health Net of California, 132 Cal. App. 4th 1419 (1st Dist. 2005).

Eva Robertson enrolled in a Health Net of California ("Health Net") health plan. Shortly after enrolling, she received a notice that her health plan was being cancelled. In response, she filed a suit against Health Net for breach of contract, among other allegations. Health Net filed a motion compelling arbitration pursuant to the arbitration clause in the plan enrollment form. The trial court ruled Health Net's arbitration clause was unenforceable because it did not comply with Health & Safety Code Section 1363.1 ("Section 1363.1"). Health Net appealed.

The California Court of Appeal found that Health Net's arbitration clause did not comply with two subdivisions of Section 1363.1, and therefore was unenforceable. Subdivision (d) of Section 1363.1 requires a health plan to place the arbitration agreement "immediately before the signature line provided for the individual enrolling in the health care service plan." Although Health Net argued that "immediately" was equivalent to "close by," the Court found that the statute's plain and ordinary language required that there must be no intervening language between the arbitration agreement and the signature line. In Health Net's enrollment form, five sentences separated the arbitration agreement and the signature line. Subdivision (b) requires a health plan's arbitration clause to be "prominently displayed." The Court observed that Health Net's arbitration clause was not highlighted, bolded, or in a different typeface from that used in the rest of the enrollment form. Rather, only the title of the clause was in bold print. The Court concluded that this did not achieve the prominence required by the statute. The Court dismissed Health Net's claim that it substantially complied with the statute because Health Net did not comply with the essential purpose of the statute. Therefore, because Health Net failed to comply with the mandatory provisions in Section 1363.1, the arbitration provision was unenforceable. The Court of Appeal affirmed the trial court's order denying the petition to compel arbitration.

ARBITRATION HEALTH PLAN

Health care service plans that require insureds to waive their rights to jury trial and agree to binding arbitration as sole form of dispute resolution are not unconstitutional nor contracts of adhesion.

Viola et. al. v. California Department of Managed Health Care et. al., 133 Cal. App. 4th 299 (2nd Dist. 2005).

Eunice Viola, Michael Viola, Michael Giammateo, Moira Giammateo, Muzeyyen Balaban-Zilke, Vicki Magee, and Viola Incorporated (collectively "Plaintiffs") sought injunctive and declaratory relief against the California Department of Managed Health Care ("DMHC"), its former director and acting director. Plaintiffs claimed that their civil jury trial and due process rights guaranteed by the state and federal constitutions were violated when DMHC approved provisions in health plan contracts that included mandatory arbitration clauses, without requiring provisions allowing individual insureds to reject those clauses. Plaintiffs alleged that Health and Safety Code Sections 1340 *et seq.* (the "Knox-Keene Act") compels DMHC to refuse to approve an insurer's health care plan that includes mandatory arbitration language.

The trial court sustained DMHC's demurrer without leave to amend, citing the California Supreme Court's holding in *Madden v. Kaiser Foundation Hospitals* 17 Cal.3d 699 (1976) that binding arbitration agreements are constitutional when an agent (employer) for the employee has waived the right to jury trial. Moreover, the court found that there is no constitutional right to medical insurance, and that the Plaintiffs were not compelled to join the plan. Subsequently, the trial court granted Plaintiffs' motion to reconsider the ruling in light of three newly decided cases. After additional briefing, the trial court again sustained DMHC's demurrer without leave to amend. Plaintiffs appealed.

The California Court of Appeal upheld the trial court decision, holding that because the Legislature expressly approved arbitration as a forum for resolution of disputes arising under health care service plans governed by the Knox-Keene Act, such provisions are not unconstitutional nor contracts of adhesion. Therefore, DMHC did not exceed its authority in approving plans with mandatory arbitration provisions. Plaintiffs argued that DMHC's approval of health care service plan contracts with arbitration provisions violated the Knox-Keene Act's prohibition against "untrue,

the statute designed to prevent strategic lawsuits against public participation (also known as the "anti-SLAPP statute"). If Northern Inyo could establish that the activity forming the basis of Dr. Kibler's lawsuit fell within one of the four categories of speech and petitioning activity described in the anti-SLAPP statute, then Dr. Kibler would have the burden of making a prima facie showing of the probability of prevailing on his claims. If he failed to do so, the case would be dismissed. The trial court granted the anti-SLAPP motion, and Dr. Kibler appealed.

The California Court of Appeal held that the anti-SLAPP statute applies to a hospital peer review proceeding because it is an official proceeding under the law, and it involves the public issue of protecting the health and welfare of the people of California. The Court determined that the peer review proceeding was an official proceeding required by the California Business & Professions Code and by Northern Inyo's medical staff bylaws. Because the proceeding was authorized by law, it was subject to an anti-SLAPP motion. The Court also held that the peer review proceeding involved a public issue because its purpose was to protect the health and welfare of the people of the state of California. In so holding, the Court noted that the confidentiality of the official proceeding did not mean it did not involve a public issue. The Court acknowledged that its decision was contrary to the *O'Meara* court's decision on similar facts and issues, and specifically stated that it disagreed with the *O'Meara* court's conclusions. Finally, the Court held that Dr. Kibler could not show the probability of success on his claims because he had signed the release resolving many of the issues, and because he did not exhaust all his administrative remedies before filing his action. The Court of Appeal affirmed the trial court's decision granting Northern Inyo's anti-SLAPP motion. The California Supreme Court granted a petition for review on April 27, 2005.

ARBITRATION

Arbitration agreement signed during first visit to physician did not compel a patient to arbitrate dispute for unrelated treatment provided during second visit two years later.

Note: Review has been granted by the California Supreme Court, and the following case may not be cited.

Reigelsperger v. Siller, 23 Cal.Rptr.3d 249 (3rd Dist. 2005).

Terry Reigelsperger first visited James Siller, D.C., for lower back pain in 2000. After receiving treatment, Mr. Reigelsperger paid Dr. Siller in cash and signed a form arbitration agreement. The arbitration agreement required the parties to submit to arbitration any medical malpractice dispute. Mr. Reigelsperger did not return to Dr. Siller for further treatment of his lower back. However, two years later, Mr. Reigelsperger returned to Dr. Siller for treatment of his cervical spine and shoulder. Mr. Reigelsperger incurred injuries during that treatment, and filed a complaint for medical malpractice. Dr. Siller then filed a petition for an order compelling arbitration, which Mr. Reigelsperger opposed. The trial court denied the petition, holding that the arbitration agreement was not enforceable because there was no open-book account between the parties. Dr. Siller appealed.

The California Court of Appeal agreed with the trial court that because there was no ongoing doctor-patient relationship, an arbitration agreement signed on Mr. Reigelsperger's first visit was not enforceable with regard to care provided during his second visit. Normally, once an arbitration agreement is signed, the contract governs all subsequent open-book account contracts for medical services for which the contract was signed. However, while the Court acknowledged that there is a strong public policy in favor of arbitration, the Court emphasized that a party cannot be required to arbitrate a dispute that it has not agreed to submit to arbitration. In this case, the parties were not bound to arbitrate. There was no ongoing doctor-patient relationship between the parties established on the occasion of the first treatment. Dr. Siller did not send Mr. Reigelsperger a bill and the parties did not set up any future appointments. Thus, no open-book account existed and the parties did not contemplate possible future transactions with each other. Moreover, the condition for which Mr. Reigelsperger sought treatment on the second visit was wholly unrelated to the treatment he sought on the first visit. As a result, the Court held that the two visits were separate and, because the arbitration agreement signed on the first visit did not apply to treatment provided on the second visit, Mr. Reigelsperger was not required to arbitrate his present claims. The Court of Appeal affirmed the lower court's denial of the petition compelling arbitration.

Stark: Drugs Exception

Dialysis treatments are not included among DHS, but outpatient prescription drugs are.[40] As noted above, drugs, including EPO, routinely are provided in dialysis facilities. Thus, CMS promulgated an exception for EPO and other dialysis-related drugs furnished in or by an ESRD facility.[41]

Stark: Laboratory Services

As noted,[42] laboratory services are a DHS. Laboratory tests routinely are performed on samples drawn from dialysis patients. However, such services, when included in the dialysis facility composite reimbursement rate,[43] are excluded by regulation from the definition of DHS.[44]

In some cases, dialysis clinic operators also operate laboratories and bill Medicare for services provided to dialysis patients. In promulgating the Stark II regulations, CMS noted that, although the Stark Law is limited to referrals by physicians and does not cover referrals among commonly held entities absent involvement of a referring physician, a medical director contract between a physician and a dialysis operator that also operates a laboratory may create an indirect compensation arrangement between the medical director and the laboratory.[45] In such a case, the arrangement "would need to fit in the indirect compensation exception. In other words, the medical director contract creates a link between the physician and the dialysis facility, which is linked through ownership to the parent corporation, which is linked by ownership to the corporation's laboratory (the DHS entity). If the physician's compensation takes laboratory referrals into account, the arrangement would not fit in the exception."[46] Accordingly, in addition to the AKS considerations noted above,[47] and the Stark fair market value considerations discussed below, in cases where the dialysis facility has an affiliated laboratory, care should be taken to assure that the medical director's compensation is in no way related to laboratory referrals.

---

40 DHS includes: clinical laboratory services, physical therapy, occupational therapy, and speech-language pathology services, radiology and certain other imaging services, radiation therapy services 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. 42 C.F.R. § 411.351.

41 The exception is as follows: The prohibition on referrals set forth in § 411.353 does not apply to the following types of services:
. . . *EPO and other dialysis-related drugs furnished in or by an ESRD facility*. EPO and other dialysis-related drugs that meet the following conditions: (1) The EPO and other dialysis-related drugs are furnished in or by an ESRD facility. For purposes of this paragraph (g): "EPO and other dialysis-related drugs" means certain outpatient prescription drugs that are required for the efficacy of dialysis and identified as eligible for this exception on the List of CPT/HCPCS Codes; and "furnished" means that the EPO or dialysis-related drugs are administered to a patient in the ESRD facility, or, in the case of EPO or Aranesp (or equivalent drug identified on the List of CPT/HCPCS Codes) only, are dispensed by the ESRD facility for use at home. (2) The arrangement for the furnishing of the EPO and other dialysis-related drugs does not violate the anti-kickback statute (section 1128B(b) of the Act). (3) All billing and claims submission for the EPO and other dialysis-related drugs does not violate any Federal or State law or regulation governing billing or claims submission. (4) The exception set forth in this paragraph (g) does not apply to any financial relationship between the referring physician and any entity other than the ESRD facility that furnishes the EPO and other dialysis-related drugs to the patient. 42 CFR § 411.355(g).

42 *See supra* note 40.

43 *See supra* note 9.

44 "DHS do not include services that are reimbursed by Medicare as part of a composite rate . . ." 42 C.F.R. § 411.351 (definition of DHS).

45 Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II), 69 Fed. Reg. 16054, 16092 (March 26, 2004).

46 *Id*. at 16092.

47 *See supra* note 17 *et seq*. and accompanying text.

Stark: Fair Market Value for Medical Director Services

In the Stark II rulemaking process, CMS provided guidance with respect to fair market value for dialysis facility medical director services. Responding to a comment requesting that it establish a benchmark for evaluating whether such compensation is fair market value, CMS declined to do so. However, CMS noted that it had created a "safe harbor" provision under the definition of "fair market value" for hourly payments to physicians for their personal services.[48] This "safe harbor" references several specific physician compensation surveys.[49] Although noting that use of this "safe harbor" is "entirely voluntary," CMS nevertheless said, "For example, we believe that nephrology salary data from four surveys could be used to calculate an hourly payment for medical directors of ESRD facilities (that is, the average fiftieth percentile nephrologist salary from four surveys divided by 2000 hours). DHS entities using other methodologies to determine fair market value will continue to bear the risk that their rates may not be considered fair market value."[50]

Stark: Sale of Facility

As noted above, the arrangements under which a dialysis facility is purchased from referring nephrologists may create AKS risk. CMS commented on such arrangements in the Stark II rulemaking, stating, "For purposes of section 1877 of the Act, we would treat a sale of a dialysis facility and an accompanying employment contract as separate arrangements to be evaluated under the isolated transactions exception and the employment exception, respectively. Both exceptions require fair market value compensation."[51]

---

48 Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II), 69 Fed. Reg. at 16092 (March 26, 2004).

49 *See* 42 C.F.R. § 411.351 The rule identifies the following surveys that can be used for this purpose: Sullivan, Cotter & Associates, Inc. -- Physician Compensation and Productivity Survey; Hay Group -- Physicians Compensation Survey; Hospital and Healthcare Compensation Services -- Physician Salary Survey Report; Medical Group Management Association -- Physician Compensation and Productivity Survey; ECS Watson Wyatt -- Hospital and Health Care Management Compensation Report; William M. Mercer -- Integrated Health Networks Compensation Survey.

50 Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II), 69 Fed. Reg. at 16092 (March 26, 2004).

51 *Id.*

Prepared by:
Jeffrey R. Bates,
Sarah G. Benator, and
Patricia Kosich of Foley & Lardner LLP and Lauren R. Polak of Cedars-Sinai Medical Center

ANTI-SLAPP

Physician's lawsuit challenging hospital's peer review proceeding was not subject to an anti-SLAPP motion.

Note: Review has been granted by the California Supreme Court, and the following case may not be cited.

O'Meara v. Palomar-Pomerado Health System, 125 Cal. App. 4th 1324 (4th Dist. 2005).

Dr. Patrick O'Meara sued Palomar -Pomerado Health System ("Palomar") alleging improper retaliation after he complained to the hospital's peer review body about Palomar's interference with his medical decisions. Palomar then brought a motion to strike under California Code of Civil Procedure Section 425.16, the statute designed to strike strategic lawsuits against public participation (also known as the "anti-SLAPP statute"). If Palomar could establish that the activity forming the basis of Dr. O'Meara's lawsuit fell within one of the four categories of speech and petitioning activity described in the anti-SLAPP statute, then Dr. O'Meara would have the burden of making a prima facie showing of the probability of prevailing on his claims. If he failed to do so, the case would be dismissed. The trial court denied Palomar's motion, holding that the anti-SLAPP statute applied, but that Dr. O'Meara met his burden of showing a probability of prevailing on his claims. Palomar appealed.

The California Court of Appeal held that the anti-SLAPP statute did not apply to Dr. O'Meara's action because a peer review proceeding is not an "official proceeding" or a matter regarding a public issue. The Court therefore affirmed the trial court's decision, but on different grounds. The Court first noted that a cause of action is subject to an anti-SLAPP motion to strike if the claim arises from any official proceeding authorized by law in furtherance of the defendant's right of petition or free speech in connection with a public issue. Palomar claimed that the anti-SLAPP law applied because its alleged wrongful conduct was in connection with a peer review process, which was an official proceeding authorized by law. The Court disagreed with Palomar, and held that a peer review committee is not an official proceeding under the anti-SLAPP statute. The Court stated that even though peer review committees are authorized by law, they are not public agencies created and funded by the state. Instead, they are composed of private physicians who ultimately serve to reduce the hospital's exposure to tort liability. According to the Court, the "public" protected by a peer review action are only those patients of the particular hospital. The Court also held that Palomar's actions in imposing discipline did not involve free speech or petition rights about an issue of public concern. Even if free speech rights were implicated, the Court rejected Palomar's claim that the challenged discipline was a public issue because the dispute involved managed health care and because it concerned statements that Dr. O'Meara made to a patient's family. Therefore, the alleged cause of action was not subject to the anti-SLAPP statute, and the Court of Appeal affirmed the trial court's order denying the anti-SLAPP motion. Petition for review to the California Supreme Court was granted, but stayed pending the outcome of the Supreme Court's review of *Kibler v. Northern Inyo County Local Health District*, discussed below.

Hospital's peer review proceeding is an "official proceeding" that is subject to anti-SLAPP motion to strike.

Note: Review has been granted by the California Supreme Court, and the following case may not be cited.

Kibler v. Northern Inyo County Local Hospital District, 24 Cal. Rptr. 3d 220 (4th Dist. 2005).

Northern Inyo County Hospital ("Northern Inyo") suspended Dr. George Kibler's medical staff privileges and sought workplace violence injunctions against him on the basis of his violent and aggressive behavior toward hospital employees. Dr. Kibler and Northern Inyo then executed a release agreement and stipulated to the entry of a permanent injunction, which resolved the summary suspensions and injunctions. Nevertheless, eleven months later, Dr. Kibler filed suit alleging that Northern Inyo tortiously interfered with his right to practice medicine. Northern Inyo filed a special motion to strike under California Code of Civil Procedure Section 425.16,

the federal FCA, the CFCA permits whistleblower suits by private parties,[73] who may receive a portion of any recovery.[74] Thus, to the extent that a dialysis facility provides services to Medi-Cal beneficiaries or other persons for whom payment is made by the state or a political subdivision thereof, then there is potential exposure under the CFCA for false claims.

Francis J. LaPallo
Manatt, Phelps & Phillips LLP

Francis J. LaPallo is a partner in the law firm Manatt, Phelps and Phillips' Palo Alto office in the Healthcare Industry Business and Transactions Division.

Mr. LaPallo's practice focuses on the representation of healthcare enterprises including transactions, fraud and abuse, licensing and certification, operational, regulatory and litigation matters. He represents both publicly traded and privately held operators of hospitals, nursing homes, dialysis clinics, mental health units, home health agencies, physician organizations and other participants in the healthcare business. Mr. LaPallo also represents clients on significant litigation matters and sensitive internal investigations.

Mr. LaPallo has also served in-house for public companies, in both executive and general counsel roles.

Mr. LaPallo received his J.D, with high honors, from George Washington University, in 1977

Mr. La Pallo is admitted to practice in California, the District of Columbia, Maryland and Arizona and is a member of the American Bar Association, the Health Lawyers Association, and the California Society for Healthcare Attorneys.

73 Government Code § 12652(c).

74 Government Code § 12652(g).

FALSE CLAIMS

When assessing risks associated with perceived or actual violations of fraud and abuse laws, healthcare providers must also consider potential false claims liability. Two false claims statutes are relevant, the criminal healthcare false claims statute[52] and the FCA.[53] A detailed analysis of these false claims statutes is beyond the scope of this article.

However, dialysis industry participants must be aware of potential FCA liability derived from violations of the laws discussed earlier in this article – and in particular the increasing use by *qui tam* relators of the FCA's "whistleblower" provisions.

The FCA generally provides a civil remedy for the federal government to recover damages and penalties from those who submit false or fraudulent claims to the United States.[54] Significantly, the FCA permits a private party "whistleblower" to bring an FCA action on behalf of the United States[55] and realize a portion of the recovery – whether or not the government decides to participate in the

52 42 U.S.C. § 1320a-7b(a). The statute provides in pertinent part: Whoever -- (1) knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under a Federal health care program (as defined in subsection (f)) of this section, (2) at any time knowingly and willfully makes or causes to be made any false statement or representation of a material fact for use in determining rights to such benefit or payment, (3) having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized, (4) having made application to receive any such benefit or payment for the use and benefit of another and having received it, knowingly and willfully converts such benefit or payment or any part thereof to a use other than for the use and benefit of such other person, (5) presents or causes to be presented a claim for a physician's service for which payment may be made under a Federal health care program and knows that the individual who furnished the service was not licensed as a physician, or (6) for a fee knowingly and willfully counsels or assists an individual to dispose of assets (including by any transfer in trust) in order for the individual to become eligible for medical assistance under a State plan under subchapter XIX of this chapter, if disposing of the assets results in the imposition of a period of ineligibility for such assistance under section 1396p(c) of this title, shall (i) in the case of such a statement, representation, concealment, failure, or conversion by any person in connection with the furnishing (by that person) of items or services for which payment is or may be made under the program, be guilty of a felony and upon conviction thereof fined not more than $25,000 or imprisoned for not more than five years or both, or (ii) in the case of such a statement, representation, concealment, failure, conversion, or provision of counsel or assistance by any other person be guilty of a misdemeanor and upon conviction thereof fined not more than $10,000 or imprisoned for not more than one year, or both. In addition, in any case where an individual who is otherwise eligible for assistance under a Federal health care program is convicted of an offense under the preceding provisions of this subsection, the administrator of such program may at its option (notwithstanding any other provision of such program) limit, restrict, or suspend the eligibility of that individual for such period (not exceeding one year) as it deems appropriate; but the imposition of a limitation, restriction, or suspension with respect to the eligibility of any individual under this sentence shall not affect the eligibility of any other person for assistance under the plan, regardless of the relationship between that individual and such other person.

53 31 U.S.C. § 3729 *et seq.*

54 In pertinent part, the FCA provides: Any person who -- (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid; (4) has possession, custody, or control of property or money used, or to be used, by the Government and, intending to defraud the Government or willfully to conceal the property, delivers, or causes to be delivered, less property than the amount for which the person receives a certificate or receipt; (5) authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true; (6) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge the property; or (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government, is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person, . . .31 U.S.C. § 3729(a)

55 31 U.S.C. §3730(b).

litigation.[56] Thus, dialysis facility operators must recognize that any employee who becomes aware of "false claims" within the meaning of the FCA is a potential whistleblower and *qui tam* plaintiff.[57]

A claim for a service not actually provided, such as a claim by a facility to have provided a hemodialysis treatment to a nonexistent patient, or a claim by a physician to have provided medical services to an ESRD patient under the MCP when such services were not provided, would clearly constitute presentation of a "false or fraudulent claim for payment or approval."[58] Beyond that, however, the government and FCA plaintiffs have contended that AKS violations provide predicates for FCA liability because of an alleged "implied certification" by the provider of compliance with all applicable law. For example, in its compliance guidance for hospitals, OIG stated, "Hospitals should also be mindful that compliance with the anti-kickback statute is a condition of payment under Medicare and other federal health care programs . . . As such, liability may arise under the False Claims Act where the anti-kickback statute violation results in the submission of a claim for payment under a federal health care program."[59] However, this false implied certification theory of FCA liability has not been universally accepted by the courts.[60] Nevertheless, providers should ensure that they are in compliance with the AKS, both because it provides for its own independent penalties and because of the government's position (as expressed above and in various settlements) than it can form the basis for FCA liability.

As noted above, most services provided in connection with outpatient dialysis either are not DHS or are covered by exceptions. However, CMS has noted that a medical director contract between a physician and a dialysis operator that also operates a laboratory may create an indirect compensation arrangement between the medical director and the laboratory. Under the Stark Law, where a prohibited financial relationship exists, the entity to which the prohibited referral is made "may not present or cause to be presented a claim" for Medicare services,[61] and "no payment may be made [by Medicare] for a designated health service which is provided in violation" of the Stark Law.[62] Thus, it clearly can be argued that a claim made for services ordered in violation of the Stark Law constitutes a false claim.[63]

Finally, FCA liability may be predicated on an expressly false certification. "An expressly false claim is, as the term suggests, a claim that falsely certifies compliance with a particular statute, regulation or contractual term, whose compliance is a prerequisite to payment."[64] FCA plaintiffs have asserted that false certifications of compliance with law on Medicare cost reports provide a basis for FCA liability.[65] Therefore, dialysis facility operators may face claims of FCA liability based upon false certifications on Medicare cost reports.

CMS recently revised the "Independent Renal Dialysis Facility Cost Report Certification" (Form CMS 265-94 (8/95)), adding new language that might provide a basis for FCA liability under the "express certification" theory.

56 31 U.S.C.§ 3730(d).

57 In the Gambro Healthcare settlement discussed at the beginning of this article, the civil suit was filed originally by Gambro's former Chief Medical Officer, who "oversaw medical and nursing services at Gambro's outpatient dialysis centers across the United States." News Release, *supra* note 27.

58 *See* 31 U.S.C. § 3729(a)(1).

59 OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858, 4864 (Jan. 31, 2005) (citation omitted).

60 *See* John T. Boese, *Civil False Claims and Qui Tam Actions* §2.03[G][2][a] (2d ed. Supp. 2005-20 [hereinafter *Boese*].

61 42 U.S.C. § 1395nn(a)(1)(B).

62 42 U.S.C. § 1395nn(g).

63 *See, e.g., United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.* 20 F. Supp.2d 1017, 1047 (S.D. Tex. 1998).

64 *Boese, supra* note 60, § 2.03[G][2][b] (*quoting United States ex rel. Mikes v. Straus*, 274 F.3d 687, 698 (2d Cir. 2001)).

65 *See Boese, supra* note 60, § 2.03[G][2][b] (*citing United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 938 F.Supp. 399 (S.D. Tex. 1996)).

Revision 6 of the form, in effect before 2005, included the following certification, to be given by the "officer or director of the Facility(s): "I hereby certify that I have read the above statement and that I have examined the accompanying cost report prepared by [Facility's name(s) and number(s)] for the cost report period beginning ________ and ending ___________, and to the best of my knowledge and belief, it is [a] true, correct and complete statement prepared from the books and records of the facility in accordance with applicable instructions, except as noted." Revision 7 of the form, issued in 2005, includes the foregoing language (with the omitted "a" now included) and adds the following: "I further certify that I am familiar with the laws and regulations regarding the provision of health care services and that the services identified in this cost report were provided in compliance with such laws and regulation."[66] One would expect that FCA claims will be made based on alleged violations of the AKS or Stark Law – as well as other laws or regulations – by dialysis facilities that have given the new certification. It remains to be seen whether such claims will be successful.

COMMENTS ABOUT CALIFORNIA LAW

As mentioned previously,[67] this article does not address in detail potential fraud and abuse risks arising from California law. Nevertheless, it should be noted that these statutes do present additional sources of potential liability based on principles comparable to those discussed above. For example, although there is sparse case law under the Medi-Cal anti-kickback statute,[68] and there are no regulatory safe harbors, where a dialysis facility provides services to Medi-Cal beneficiaries, payments to referring nephrologists of medical director fees, returns on investments in dialysis facilities or payments for purchase of dialysis facilities could be found to violate the state statute where they bear the risk indicia discussed above.[69] The Speier Law,[70] California's Stark-type law, does not include dialysis treatments among its covered services, but it does include laboratory services.[71] Thus, if a dialysis operator also operates a laboratory, it would be appropriate to analyze whether financial arrangements with any referring nephrologists come within the ambit of the Speier Law and, if so, to satisfy an applicable exception. Finally, the California False Claims Act ("CFCA"),[72] analogous to the federal FCA, provides for actions to recover for false claims made to the state or political subdivisions of the state, and provides for civil penalties for each false claim. Like

66 Independent Renal Dialysis Facility Cost Report Certification, Form CMS 265-94, Ctrs. For Medicare & Medicaid Servs., Dep't. of Health & Human Servs. (Mar. 2005), *available at* http://www.cms.hhs.gov/manuals/pub152/PUB_15_2.asp. The form references instructions in the Provider Reimbursement Manual, which include the following: "Section 1128B(a) of the Act states that, 'Whoever knowingly and willfully makes or causes to be made any false statement or representation of material fact in any application for any benefit or payment under this title – shall (i) in the case of such a statement, representation, concealment, failure or conversion by any person in connection with the furnishing (by that person) of items or service for which payment is or may be made under this title, be guilty of a felony and upon conviction thereof fined not more than $25,000 or imprisoned for not more than 5 years or both, or (ii) in the case of such statement, representation, concealment, failure or conversion by any other person be guilty of a misdemeanor and upon conviction thereof fined not more than $10,000 or imprisoned for not more than 1 year or both.'" Ctrs. For Medicare & Medicaid Servs., Dep't. of Health & Human Servs., Provider Reimbursement Manual, Pub. 15-II, Part II, ch. 34, § 3404.2 (Aug. 1993), *available at* http://www.cms.hhs.gov/manuals/pub152/PUB_15_2.asp.

67 *Supra* note 1.

68 Welfare & Inst. Code § 14107.2.

69 *See* notes 17-38 and accompanying text.

70 Bus. & Prof. Code §§ 650.01 and 650.02.

71 Bus. & Prof. Code §§ 650.01(a).

72 Government Code § 12650 *et seq.*