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PROFESSIONAL LIABILITY

MICRA’s statute of limitations governs claims for negligent failure by healthcare providers 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 338(a), part of the Medical Injury Compensation Reform Act (“MICRA”), controlled the action.

MICRA requires that suits for professional negligence be filed within the meaning of MICRA were limited to professional negligence claims, MICRA’s statute of limitations applies and 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(c), 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 practiced 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 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 statute of limitations 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 racial conduct because medical staff bylaws did not provide applicable administrative procedures.


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 pursuing 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.

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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 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
- Nassaman, Gutner, Knox & Elliott LLP
- Paul Hastings Janofsky & Walker LLP

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@khv.edu

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


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 holding 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 Sections 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. The Court similarly rejected Dr. Mileikowsky’s argument that the hearing officer’s conduct was ineffective. The Court found that Dr. Mileikowsky’s conduct was such that no plan of action arising from or related to the summary suspension and recommendation was possible. The Court similarly rejected Dr. Mileikowsky’s argument that the hearing officer’s conduct was such that no plan of action arising from or related to the summary suspension and recommendation was possible.

The Court also rejected the assertion 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 in its burden of showing that CalOptima’s policy was arbitrary or capricious. Life Care’s attempts to compare CalOptima’s policies with other COEIs’ policies were not helpful because Life Care did not produce any evidence that those 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 online of its proceedings pertaining to his completion of probation. Dr. Szold filed a petition for writ of mandamus and appealed.

The California Court of Appeal rejected Dr. Szold’s appeal, and concluded 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 (“TPMC”) 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(b) 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 statutes to support the assertion that a physician is excused from exhausting an administrative remedy 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

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**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, Renal America. Shortly before that transaction closed, Gambro announced a multi-state settlement of charges that it improperly billed Medicaid programs, agreeing to pay $50 million. In March 2005, DaVita announced that it had received a subpoena from the U.S. Attorney for 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 concerned 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 for end stage renal disease (“ESRD”) treatments and explores the main areas of federal 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, an procedure in which the patient’s blood is circulated through a machine and filtered, three or four times per week on

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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 (Med-Cal anti-kickback statute); physician financial relationship statutes (e.g., Bus. & Prof. Code §§ 409.01 and 602.02); physician financial interest disclosure obligations (e.g., Bus. & Prof. Code § 654.1), and false claims (e.g., Government Code § 12680).  
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 for all elements of dialysis care except for separate reimbursements for bad debts and certain specified items and services, including certain drugs – notably 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 receiving the same reimbursement regardless of treatment modality.\(^2\) 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"), 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") for reimbursement, with a special adjustment for patients under age 18.\(^4\) Certain drugs and biologicals, including EPO, are reimbursed separately based upon rates determined by CMS.\(^5\) 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.\(^6\) The compensating factor 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 capitatively reimbursable for such treatments on a "prospectively determined composite rate” per treatment basis.

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 pays providers 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 service 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 retrospectively to the date of admission. If CalOptima receives the TAR after the 21-day deadline, repayment 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 tolerance requirement for treatment authorization requests. The Court rejected Life Care’s argument that Medi-Cal reimbursement systems must be 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 recognized that a COHS operates under a statutory scheme different from that of Medi-Cal. Furthermore, the COHS may 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 14133.05, which specifies the application of certain remedies to Medi-Cal reimbursement systems. The Court noted that the California 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 was unreasonable.

\(^3\) 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, § 1.30.


\(^7\) 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.


\(^10\) See 42 C.F.R. § 413.431.
Plaintiffs appealed. The California Court of Appeal upheld the trial court’s decision and found that Dr. Sievert’s belief was immune from liability. Section 5154(a) grants immunity to psychiatrists from civil or criminal liability arising out of any 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’s provisions were 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.

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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 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.

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 treatment at the facility. As discussed below, this arrangement can prompt fraud and abuse exposure risks for the facility.

**Medicare-Medicaid Anti-Kickback Statute**

The Medicare-Medicaid Anti-Kickback Statute, 42 U.S.C. § 1320a-7(b)(1), 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, and also may initiate administrative proceedings to exclude the person from federal health care programs. Pursuant to the AKS, the OIG has authority to issue advisory opinions, which serve as precedent to other healthcare enterprises.

**SOURCES OF POTENTIAL FRAUD AND ABUSE LIABILITY**

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

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16 Medicare Benefits Policy Manual, supra note 2, § 802.2, 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. They are distinct from the facility 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-7(b)(1). 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, 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-7(a)(7).

19 42 U.S.C. § 1320a-7(b)(17).

overruling the demurrer and fixing the time in 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 3043.1, 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 in return for services furnished under the HLA. The Court affirmed the appellate court decision based on the 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 recover 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 Coburn 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 recuperate losses from discounted insurance rates, and that its ruling may result in significant financial losses 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 those losses from 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.


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 arising from Mr. Coburn releasing patient 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, 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 are exempted from the hearsay rule. First, Delta Dental employees acted as agents of DHSS when they conducted various audits and payment duties, including the preparation of CDRs, on behalf of DHSS. 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 the burden to establish the CDRs’ lack of trustworthiness. Therefore, the CDRs satisfied Section 12807’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 the 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 payment 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 DHSS to reimburse payments made to any provider who does not meet the condition of participation in the Medicare 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.


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 1317.4 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 room physicians and other 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 opposed Dr. Bell’s action, 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 1314 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 alternative 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 1317.4 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 their contracts and professional 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

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,” where one purpose of the 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. An element of this safe harbor, however, is the requirement that “if the 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.” Because the medical director rarely performs duties in accordance with such a schedule, the medical director arrangement cannot be said to conform to this requirement, and safe harbor protection would not be available.

20 31 U.S.C. § 7707A(a)
21 2 U.S.C. §§ 1320a-7b(b)(3)(E); 3729(i)(2) (9th Cir. 1989); see 42 C.F.R. § 1001.952(c)(2).
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. Katz, 871 F.2d 105 (9th Cir. 1989). United States v. Greber, 760 F.2d 65 (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 conditions are met: (i) the agreement is set out in writing and signed by the parties; (ii) the agreement covers all of the services the agent provides to the principal for the term of the agreement; (iii) no remuneration is paid or provided to an agent other than a bona fide employee of the principal; (iv) the aggregate services contracted for do not exceed those which the agent would perform in the agent’s usual and customary manner that takes into account the volume or value of any referrals or business otherwise generated between the parties; (v) the agreement specifies the services to be provided by the agent; (vi) the agent 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; (vii) the aggregate compensation paid to the agent for 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 any other Federal health care program; (viii) 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 commercial or competitive 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).
safe harbor, as well as related law.26 Parties. Payment of 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 role in informally 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 protects a physician-investor” over the patient care operations.28 A physician measured by volume or number of the medical director’s patients may be characterized as related to the performance of services for determining the medical director’s compensation.29 This has the potential to result in compensation paid to the nephrologist for referral of patients to the joint venture facility, or to any other facility in which the operator partner has an interest.30

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 pro-mulgating 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 protection afforded with respect to ambulatory surgery centers.31 Further, in announcing the 2004 Gambro settlement, the DODJ also by the signatory or in at least 14 calendar days by the third party to a separate from other language on the same page and be executed by a signature when appropriate. It 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 Coellem 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 medical records to Ronald’s attorney. The Court of Appeal affirmed the trial court’s judgment.32

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.


Shahleskumar Bhatt, D.D.S., a dentist enrolled as a provider in the California Denti-Cal/Medi-Cal program ("Denti-Cal") operated 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 documentation 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 appealed 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 Section 1271 of the civil evidence code section 1270, the “official records” exception to the hearsay rule. Therefore, the CDRS were admissible as direct evidence.

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 satisfied 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, and the administrative 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 are not CDRS entitled to the subsection 1271 of the civil evidence code section 1270, the “official records” exception to the hearsay rule. Therefore, the CDRS were admissible as direct evidence, and Dr. Bhatt was entitled to the disclosure of Dr. Bhatt’s medical records to Ronald’s attorney. The Court of Appeal affirmed the trial court’s judgment.33

**Notes:**

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-7(a)(6). Case law indicates that the amount of remuneration will reflect what fair market value is for services rendered. See, e.g., United States v. Kofas, 770 F.2d 1447, 1449 (9th Cir. 1985); United States ex rel Penda v. St. Margaret’s Hospital, 243 F. Supp.2d 843, 851 (C.D. Ill. 2003).


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 proposed additional safe harbors, citing United States v. Bay State Ambulance and Hospital Renders, 20 J.A. 690 (lst Cir. 1989)]; OIG, Special Advisory Bulletin on Contractual Joint Ventures (April 23, 2004), 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. 35992, 35997 (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.")
misleading, deceptive” language and that the 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, under the 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 DMC to mandate that health care service plans include a clause on the 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-related authority to agree to binding arbitration for malpractice claims arising under the health care service plans it negotiates with the 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 a clause, the Court held that the Legislature implicitly approved such negotiations.

Finally, the Court rejected Plaintiffs’ argument that inclusion of the arbitration clause created contracts of adhesion. The Court reasoned that the Legislature authorized the waiver of civil jury trial under the Knox-Keene Act. Further, the Plaintiffs could have negotiated different contracts that did not include binding arbitration clauses by contracting individually with each provider. The Court followed the Supreme Court’s holding in Madden when it rejected Plaintiffs’ argument that arbitration clauses 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. ("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 claim individually for each provider. The Court followed the Supreme Court’s holding in Madden when it rejected Plaintiffs’ argument that arbitration clauses 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.

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 Associates’ motion for summary judgment, finding that Colleen had signed a consent form authorizing disclosure of the medical information. 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.

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32 The AKS small entities joint venture safe harbor is as follows: Investment interests. As used in section 1128B of the Act, “investment interest” means any investment in an investment interest in an investment under common control as a condition for the receipt of a payment that is a return on an investment interest or the return of capital. (vi) that the passive investor is not in a position to make referrals to the entity. (v) the passive investor is not in a position to make referrals to the entity. (iv) that the passive investor is not in a position to make referrals to the entity. (iii) that the passive investor is in a position to make referrals to the entity. (ii) that the passive investor is in a position to make referrals to the entity. (i) that the passive investor is in a position to make referrals to the entity. No more than 40 percent of the value of the investment interests of the passive investor (or any investor acting on behalf of the entity or any investor in the entity) may be invested in a position to make referrals to the entity. (v) that a passive investor is in a position to make referrals to the entity.

33 42 C.F.R. § 1001.92(a)(2).

34 42 C.F.R. § 1001.92(a)(2)(iv). ("There is no requirement that a passive investor, if any, make referrals to, in a position to make referrals to, or otherwise generate business for the entity as a condition for receiving items or services from the entity.

35 42 C.F.R. § 1001.92(a)(2)(iii). ("There is no requirement that a passive investor, if any, make referrals to, in a position to make referrals to, or otherwise generate business for the entity as a condition for receiving items or services from the entity.

36 42 C.F.R. § 1001.92(a)(2)(ii). (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.

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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.

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The Medicare Physician Self Referral Act (known as the “Stark Law”) 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.

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the statute designed to prevent strategic lawsuits against public participation (also known as the “anti-SLAPP statute”). If Northern Inyo cannot establish 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 is 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’Mara court’s decision on similar facts and issues, and specifically stated that it disagreed with the O’Mara 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 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 claim. The Court of Appeal affirmed the lower court’s denial of the petition compelling arbitration.

Stark: Drugs Exception

Dialysis treatments are not included in or by an ESRD facility. For purposes of this paragraph (g), 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 claim. The Court of Appeal affirmed the lower court’s denial of the petition compelling arbitration.

In some cases, dialysis clinic operators also operate laboratories and bill Medicare for services provided to dialysis patients. In promulgating the Stark regulations, CMS noted that, although the Stark Law is limited to referring 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. Thus, such services, when included in the facility’s billing returns, are excluded from regulation by the definition of DHS.

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, home health services, outpatient prescription drugs, and inpatient and outpatient hospital services. 42 C.F.R. § 411.351.

40 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; (2) The arrangement for the furnishing of the EPO and other dialysis-related drugs does not violate the anti-kickback statute; (3) CMS promulgated an exception for EPO and other dialysis-related drugs furnished in or by an ESRD facility.

41 Stark: Laboratory Services

As noted, laboratory services are a DHS. Laboratory tests routinely are performed on samples drawn from dialysis patients. However, such services, when included in the facility’s billing returns, are excluded from regulation by the definition of DHS.

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. 16094, 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. This “safe harbor” references several specific physician compensation surveys. 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 fifteenth percentile nephrologist salary from four surveys divided by 2000 hours).” 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.”

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.”

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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.


Dr. Patrick O’Meara sued Palomar-Pomerado Health System (“Palomar”) alleging improper retaliation after he complained to the hospital’s peer review board 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.

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 false claims liability by providers of potential false claims liability. 73, 74 who may receive a portion of any recovery. 75 Thus, to the extent 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, there is potential exposure under the CFCA for false claims.

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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

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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 76 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 tamrelators 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. 77, 78 Significantly, the FCA permits a private party “whistleblower” to bring an FCA action on behalf of the United States and realize a portion of the recovery – whether or not the government decides to participate in the

52 42 U.S.C. § 1396p(c). 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 healthcare program (as defined in section (f) of this section), 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 to 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 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 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 his 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.


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 paid or approved, (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 to which the person is entitled, (5) knowingly makes or delivers a document certifying receipt of property 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 to which the person is entitled, (6) knowingly makes or delivers the receipt without completely knowing that the information on the receipt is true, (7) 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)


73 Government Code § 12652(c).

74 Government Code § 12652(g).

75 Government Code § 12652(g).

76 Government Code § 12652(g).

77 Government Code § 12652(g).

78 Government Code § 12652(g).
litigation. Thus, dialysis facility operators should not require any employee who becomes aware of “false claims” within the meaning of the FCA to provide a whistleblower and qui tam plaintiff. 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 MCF when such services were not provided, would clearly constitute presentation of a “false or fraudulent claim for payment or approval.” 

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 laws. 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.” However, this false implied certification theory of FCA liability has not been universally accepted by the courts. 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 DSHs 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 indeterminate 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, and “no payment may be made [by Medicare] for a designated health service which is provided in violation of the Stark Law.” Thus, it clearly can be argued that a claim made for services ordered in violation of the Stark Law constitutes a false claim.

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.” FCA plaintiffs have asserted that false certifications of compliance with law on Medicare cost reports provide a basis for FCA liability. 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 (F/95)), adding new language that might provide a basis for FCA liability under the “express certification” theory. 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.” 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, 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, 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. The Spier Law, California’s Stark-type law, does not include dialysis treatments among its covered services, but it does include laboratory services. 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 Spier Law and, if so, to satisfy an applicable exception. Finally, the California False Claims Act (“CFCA”), 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

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.
60 See John T. Boese, Civil False Claims and Qui Tam Actions §1210(c)(2)[a] (2d ed. Supp. 2005-20 [hereinafter Boese]).
61 42 U.S.C. § 1395nn(a)(1).Y
64 Boese, supra note 60, at 2.07[1][b] (quoting United States ex rel. Milks v. St. Mary’s, 767 F.2d 1007, 1011 (2d Cir. 2003)).
65 See Boese, supra note 60, at 2.07[1][c][i] (citing United States ex rel. Thompson v. Columbia/HCA Healthcare Corp., 938 F.Supp. 399 (S.D. Tex. 1996)).
66 Independent Renal Dialysis Facility Cost Report Certification, Form CMS 265-94, Ctrs. For Medicare & Medicaid Servs., Dep’t of Health & Human Servs., 62 Federal Register 46233, 46429 (2007), available at http://www.cms.hhs.gov/manuals/pubs152/PUB_15_2.asp. The form references instructions in the Provider Reimbursement Manual, which include the following: “Section 1210B(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 or representation, concealment, failure or conversion by any person in connection with the furnishing (by that person) of items or services for which payment or reimbursement is made 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 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. 15-11, Part II, ch. 34, § 3404.2 (Aug. 1993), available at http://www.cms.hhs.gov/manuals/pubs152/PUB_15_2.asp.
67 Supra note 1.
69 See notes 17-38 and accompanying text.
70 Bus. & Prof. Code §§ 650.01 and 650.02.
71 Bus. & Prof. Code §§ 650.11(a).
72 Government Code § 12600 et seq.