

Conditions For Coverage For ESRD Facilities: New Legal Challenges for Medical Directors

The Renal Network, Inc.
October 21, 2008

Presented by:
James B. Riley, Jr.
McGuireWoods LLP
77 W. Wacker Drive, Suite 4100
Chicago, IL 60601-1818
(312) 750-8665
jriley@mcguirewoods.com

Copyright ©2008 by James B. Riley, Jr.
All rights reserved.

I. Medicare Conditions For Coverage for ESRD Facilities

A. Background

- Adopted: April 15, 2008
- Effective: October 14, 2008
- Expanded requirements for facilities and duties and responsibilities for employees and medical directors

B. Medicare Conditions for Coverage for ESRD Facilities: Medical Director Responsibilities

Effective October 14, 2008, there must be a single medical director. Medical Director responsibilities include, but are not limited to (42 CFR 494.150):

- The delivery of patient care and outcomes in the facility
- Accountable to the governing body for the quality of medical care provided to patients
- Quality assessment and performance improvement program
- Staff education, training, and performance

The Medical Director also must:

- Address reports of infection control issues (42 CFR 494.30)
- Approve training program for patient care dialysis technicians (42 CFR 494.140)
- Participate in the development, periodic review and approval of a patient care policies and procedures manual for the facility
- Ensure that all policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by individuals who treat patients in the facility
- Ensure the interdisciplinary team adheres to discharge and transfer policies and procedures – however, the Medical Director is not necessarily a member of the interdisciplinary team (42 CFR 494.80)
- Sign off on patient discharge or transfer (42 CFR 494.180)

C. Medicare Conditions For Coverage for ESRD Facilities: Governing Body Responsibilities

The governing body's (which in many cases includes the Administrator, Charge Nurse and Medical Director) responsibilities include, but are not limited to (42 CFR 494.180):

- Ensuring adequate number of qualified and trained staff
- Ensuring the medical staff, appointed in accordance with the law, are properly informed on the policies and procedures and communicate expectations to staff for their participation in improving the quality of medical care provided to facility patients
- Implementing internal grievance process
- Ensuring discharge and transfer policies and procedures are followed
- Ensuring that patients are provided instructions for emergency medical care

II. Expanded Responsibilities Enhance Risk of Liability

A. Enhanced responsibilities present enhanced opportunities for breach of Medical Director Agreement and damages

1. Possible breaches of MDA
 - By the Medical Director
 - By the Facility
2. Breach of MDA may result in damages
 - Compensatory Damages
 - Consequential Damages

➤ **Compensatory Damages**

Compensatory damages, also called actual damages, are paid to compensate the claimant for loss, injury, or harm suffered by another's breach of duty.

On breach of contract by a defendant, a court generally awards the sum which would restore the injured party to the economic position that he or she expected from performance of the promise or promises (known as an "expectation measure" or "benefit-of-the-bargain" measure of damages).

When it is either not possible or desirable to award damages measured in that way, a court may award money damages designed to restore the injured party to the economic position that he or she had occupied at the time the contract was entered (known as the "reliance measure"), or designed to prevent the breaching party from being unjustly enriched.

➤ **Consequential Damages**

Consequential damages are awarded to a claimant where the terms of an agreement were not honored.

When a contract is breached, the recognized remedy for an owner is recovery of damages that result directly from the breach, such as the cost to repair or complete the work in accordance with the contract documents, the loss of value of lost or damaged work. Consequential damages (also sometimes referred to as indirect or "special" damages), include loss of product and loss of profit or revenue and may be recovered if it is determined such damages were reasonably foreseeable or "within the contemplation of the parties" at the time of the contract. This is a factual determination that could lead to the contractor's liability for an enormous loss. For example, the cost to complete unfinished work on time may pale in comparison to the loss of operating revenue an owner might claim as a result of late completion.

Expanded Responsibilities Enhance Risk of Liability (cont'd.)

B. The failure to perform enhanced responsibilities resulting in patient injury may give rise to expanded risk of liability

1. Negligence per se
2. Vicarious Liability

Expanded Responsibilities Enhance Risk of Liability (cont'd.)

> Negligence per se

- is the legal doctrine whereby an act is considered negligent because it violates a statute (or regulation). In order to prove negligence per se, the plaintiff must show that (1) the defendant violated the statute, (2) the statute is a safety statute, (3) the act caused the kind of harm the statute was designed to prevent, and (4) the plaintiff was within the zone of risk. In some jurisdictions, negligence per se creates merely a presumption of negligence.

As a typical example, suppose a contractor violated a building code when constructing a house. The house then collapses and somebody is injured. The violation of the building code establishes *negligence per se* and the contractor will be found negligent, so long as the contractor's breach of the code was the cause and actual cause) of the injury.

Norman v. Life Care Centers of America, Inc. (Cal., 2003).

Dorothy Quartermaine, 87 fell several times over a three-week period while a resident of a LifeCare nursing facility. The final fall resulted in broken bones and other injuries, and Mrs. Quartermaine died shortly thereafter at another facility. The California Department of Health Services (DHS) subsequently found that the facility had violated regulations relating to care planning and communication with a resident's physician.

Ms. Quartermaine's daughter, filed an action against LifeCare alleging causes of action for wrongful death and violation of the Elder Abuse and Dependent Adult Civil Protection Act. In support of her neglect theory, Mrs. Norman presented evidence that LifeCare violated certain DHS regulations that apply to nursing facilities.

The California Court of Appeal held that violation of the nursing facility licensure regulations is to be considered neglect under the California elder abuse statute and that therefore instruction on negligence per se is a correct statement of the law. "The doctrine of negligence per se," the court writes, "... generally can apply to any causes of action based on or involving negligence, including an elder abuse cause of action on a neglect theory." (emphasis in original).

Expanded Responsibilities Enhance Risk of Liability (cont'd.)

> Vicarious Liability

- is the form of strict, secondary liability that arises under the common law doctrine of agency – *respondet superior* – the responsibility of the superior for the acts of their subordinate, or, in a broader sense, the responsibility of any third party that had the "right, ability or duty to control" the activities of a violator.

Gilbert v. Sycamore Municipal Hospital (Illinois, 1993).

In this case, the decedent presented to the hospital's emergency room with chest pain, which was staffed by Dr. Frank, an independent physician on the medical staff of the hospital. After a series of tests performed showed no indication of heart disease, the decedent was discharged to his home with pain medication. He then died that evening of a heart attack. The estate of the deceased brought action against Dr. Frank as well as hospital in the theory of apparent authority and vicarious liability. Plaintiff alleged that the hospital can be held as vicariously liable for the negligent action of a physician providing care at a hospital, regardless of whether the physician is an independent contractor. The court concluded, because the hospital held itself out as a provider of emergency room care, and did not inform the patient that the care was performed by an independent contractor, that the hospital can be held to be supervising the independent contractor, and therefore, have apparent authority over his actions.

S&C SCHMIDT & CLARK
A NATIONAL LAW FIRM

Injured by Dialysis Side Effects?

[Send to Friend](#) | [Bookmark](#) | [Link Site](#)

Dialysis Resources



S&C Related Contents

[>> Dialysis Side Effects](#)

"NEW" Attention Heart Surgery Patients – Trasyol (Generic: aprotinin) a drug administered to heart surgery and heart operation patients has been linked to increased risk of death, kidney failure or renal failure, heart attacks, strokes and encephalopathy. Many heart surgery patients are unaware that their resulting need for dialysis treatment is a direct result of a defective drug administered to them during their surgery>>> [Learn More: Trasyol Lawsuits](#)

Do I have a Dialysis Side Effects Lawsuit?

The Medical Device and Product Liability Litigation Group at our law firm is an experienced team of trial lawyers that focus exclusively on the representation of plaintiffs in Trasyol lawsuits. We are handling individual litigation nationwide and currently accepting new Trasyol cases.

Attention Attorneys: We do not publish prior verdict/settlements. If you are an attorney and would like to refer us a case or for us to send you a profile of prior award judgments or average referral fees, please visit the [attorney referral](#) section of our website.

Free Confidential Case Evaluation
Toll Free 24 hrs/day (866) 588-0600

<http://www.schmidtandclark.com/Dialysis> 10/19/2008

III. New Responsibilities May Require That Certain Provisions Of MDAs Be Revisited

- Authority
- Insurance
- Indemnity
- Compensation

A. Authority

- How to "ensure"

B. Insurance

- Parties are not of comparable resources: Parallel insurance requirements are no longer fair and reasonable. Greater risk to Medical Director must be addressed.
- Example of typical provision

Practice Insurance Coverage. The Practice shall purchase and maintain at its expense for itself and each of the Practice Physicians professional and general liability insurance, with an insurance company reasonably acceptable to the Company, with policy limits of at least \$1,000,000 per occurrence and \$3,000,000 in the aggregate, including coverage for acts and omissions in rendering medical services to patients of the Facilities.

Company Insurance Coverage. The Company shall procure and maintain throughout the term of this Agreement professional and general customary liability insurance (through self-insurance or an insurance carrier) with policy limits of \$1,000,000 per occurrence and \$3,000,000 in the aggregate. The insurance maintained by the Company shall include coverage for acts and omissions of the Practice and Practice Physicians in rendering medical director services under this Agreement (as opposed to professional services as an attending physician).

C. Indemnification

- Parties are not of comparable resources: parallel indemnity obligations are no longer fair and reasonable. Greater risk to Medical Director must be addressed.
- Example of typical provision

[Practice] hereby covenants and agrees to indemnify, defend and hold harmless Company and its Affiliates from any and all liability, claims, damages, losses, costs, obligations and expenses (including but not limited to reasonable attorneys' fees) which it may incur as a result of either the gross negligence or willful misconduct of [Practice] and/or any Medical Director or their agents or employees, or the breach by [Practice] or Medical Director(s) of the provisions of this Agreement.

Company hereby covenants and agrees to indemnify, defend and hold harmless [Practice] and each Medical Director from any and all liability, claims, damages, losses, costs, obligations and expenses (including but not limited to reasonable attorneys' fees) which it may incur as a result of either the gross negligence or willful misconduct of Company or its agents or employees, or the breach by Company of the provisions of this Agreement.

D. Compensation

- Greater duties, greater responsibilities and greater risk must be addressed.

E. Bases For Renegotiation

- Regulatory Change
- Not Contemplated by MDA
- Reopener Clause
- No Meeting of the Minds

IV. Conclusion

THE END

NW #66003 1/2011

Commercial Litigation | Complex Products Liability & Mass Tort Litigation
Corporate Services | Financial Services | Health Care | Labor &
Employment

Real Estate & Environmental | Taxation & Employee Benefits | Technology
& Business

ATLANTA • BALTIMORE • CHARLOTTE • CHARLOTTESVILLE • CHICAGO • JACKSONVILLE • LOS
ANGELES
NEW YORK • NORFOLK • PITTSBURGH • RICHMOND • TYSONS CORNER • WASHINGTON, D.C.
