

# MANAGING HOME HEALTH AND HOSPICE REGULATORY RISK IN THE NEW HEALTH CARE ECONOMY

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# I. WHAT IS THE LAW?

- A. U.S. Constitution.
- B. The Common Law.
- C. Federal Statutes and Regulations.
  - 1. Federal Regulations.
  - 2. Administrative Procedure Act.

# I. WHAT IS THE LAW?

- D. Federal Courts.
- E. Federal Manuals.
- F. State Statutes and Regulations.
- G. State Courts.
- H. The Modern Practice of Law.

## **II. WHAT MAKES THE HEALTH CARE INDUSTRY UNIQUE?**

- A. Prominence of the Health Care Economy.
- B. The Role of Federal Law in Health Care.

# HOW CAN WE UNDERSTAND AND COMPLY WITH THE LAWS GOVERNING THE GOVERNMENTAL REIMBURSEMENT PROGRAMS?

There can be no doubt but that the statutes and provisions in question, involving the financing of Medicare and Medicaid, are among the most completely impenetrable texts within human experience. Indeed, one approaches them at the level of specificity herein demanded with dread, for not only are they dense reading of the most tortuous kind, but Congress also revisits the area frequently, generously cutting and pruning in the process and making any solid grasp of the matters addressed merely a passing phase.

**REHABILITATION ASSOCIATION OF VIRGINIA v. KOZLOWSKI**, 42 F.3d 1444 (4th Cir. 1994)

# IS THE ACA THE FINAL WORD? NOT LIKELY....

- Tax Equity and Fiscal Responsibility Act of 1983
- Omnibus Budget Reconciliation Act of 1987
- The Medicare and Medicaid Patient and Program Protection Act of 1987
- Medicare Catastrophic Coverage Act of 1988
- Omnibus Budget Reconciliation Act of 1989
- Omnibus Budget Reconciliation Act of 1993
- Health Insurance Portability and Accountability Act of 1996
- Balanced Budget Act of 1997
- Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000
- Medicare Prescription Drug, Improvement, and Modernization *Act of 2003*
- Deficit Reduction Act of 2005
- The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)
- Patient Protection and Affordable Care Act of 2010
- Whatever comes next.....

### **III. EVOLUTION OF THE LAW GOVERNING INDIVIDUAL LIABILITY FOR CORPORATE ACTS**

- A. Evolution of the Law.
- B. Responsible Officer Doctrine.
  - 1. Managers are Responsible for Corporate Acts.
  - 2. Knowledge Not Required.
  - 3. Willfulness Arising from Responsibility.

### III. EVOLUTION OF THE LAW GOVERNING INDIVIDUAL LIABILITY FOR CORPORATE ACTS

C. Individual Director Liability for  
Corporate Acts Under *In re: Caremark  
International, Inc.* Derivative Litigation.

1. Standard of Conduct Applicable to  
Corporate Directors.
2. The Role of the Federal Sentencing in  
Determining the Standard of Care.

### III. EVOLUTION OF THE LAW GOVERNING INDIVIDUAL LIABILITY FOR CORPORATE ACTS

3. The Duty Under Delaware Law.
4. The Danger of Misplaced Reliance on Prior Standards.
5. Expansion of *Caremark* Duties to Officers.

### **III. EVOLUTION OF THE LAW GOVERNING INDIVIDUAL LIABILITY FOR CORPORATE ACTS**

- D. Sarbanes-Oxley Act of 2002.**
  - 1. Rationale of Act.**
  - 2. CEO and CFO Certification of Financial Statements and Periodical Reports.**
  - 3. Certification Requirements.**
  - 4. The Role of Independent Directors.**
  - 5. Penalties.**

### **III. EVOLUTION OF THE LAW GOVERNING INDIVIDUAL LIABILITY FOR CORPORATE ACTS**

#### **E. Intermediate Sanctions Against Tax Exempt Organizations.**

- 1. Purpose.**
- 2. Individual Liability.**
- 3. Disqualified Person.**
- 4. Penalties.**

### **III. EVOLUTION OF THE LAW GOVERNING INDIVIDUAL LIABILITY FOR CORPORATE ACTS**

- F. Forfeiture Provisions of Health Insurance Portability and Accountability Act of 1996.**
  - 1. Forfeiture Provisions.**
  - 2. Trust Fund.**

### **III. EVOLUTION OF THE LAW GOVERNING INDIVIDUAL LIABILITY FOR CORPORATE ACTS**

- G. False Claims Act.**
  - 1. Qui Tam Actions.**
  - 2. Damages.**
  - 3. Whistle Blowers.**
  - 4. Individual Liability.**

### **III. EVOLUTION OF THE LAW GOVERNING INDIVIDUAL LIABILITY FOR CORPORATE ACTS**

#### **H. Piercing the Corporate Veil.**

- 1. General Rule.**
- 2. When the Corporate Veil May Be Pierced.**
- 3. Corporate Trust Doctrine.**
- 4. Key Element to Liability.**

### **III. EVOLUTION OF THE LAW GOVERNING INDIVIDUAL LIABILITY FOR CORPORATE ACTS**

- I. Corporate Integrity Agreements.**
  - 1. Governmentally Imposed Compliance Plans.**
  - 2. Individual Responsibility.**

## **IV. WHAT ARE THE TWO PRIMARY AREAS OF REGULATORY COMPLIANCE AND WHAT CAN YOU DO TO MANAGE REGULATORY RISK?**

- A. Claims for Payment.
- B. Relationships With Referral Sources.
- C. Managing Regulatory Risk.

## V. WHAT IS STARK?

- A. Stark.
- B. Stark Regulations and Modifications.
- C. What is the General Rule Under Stark?
- D. How Do You Determine Whether a Referral Implicates Stark?
  - 1. Is There a Physician Involved?
  - 2. Is There a "Designated Health Service" ("DHS") Involved?

## V. WHAT IS STARK?

3. Is There a "Referral"?
4. Is There a "Financial Relationship"?
5. Does the Financial Relationship Qualify as One of the Specified Exceptions Under Stark?

## V. WHAT IS STARK?

E. What Exceptions Are Available for Ownership Interests?

1. Publicly Traded Securities.
2. Rural Exceptions.

## V. WHAT IS STARK?

### F. What Exceptions are Available for Compensation Arrangements?

1. Bona Fide Employment Relationships.
2. Personal Services Arrangements.
3. Non-Monetary Compensation.
4. Fair Market Value Compensation (“Catch All Exception”).
5. Space and Equipment Leases.

## V. WHAT IS STARK?

G. What are the Stark Compliance Requirements for Medical Director Agreements?

1. Bona Fide Employment.
2. Personal Services Agreement.
3. Fair Market Value Exception.

## V. WHAT IS STARK?

H. How is "Fair Market Value" Determined?

I. What Sanctions Arise from Violation of Stark?

1. Claim Denial.
2. Refund.
3. Civil Monetary Penalties.
4. Exclusion.
5. False Claims Act.
6. Self Disclosure Protocol.

## **VI. WHAT IS THE FEDERAL ANTI-KICKBACK STATUTE AND HOW IS IT DISTINGUISHED FROM STARK?**

### **A. How is Medicare Anti-Kickback Statute Applied?**

- 1. The role of the OIG.**
- 2. Criminal Sanctions.**
- 3. Intent.**
- 4. The Anti-Kickback Statute is Not Limited to Physicians.**
- 5. Civil Monetary Penalties.**
- 6. Direct Link to False Claims Act.**

## **VI. WHAT IS THE FEDERAL ANTI-KICKBACK STATUTE AND HOW IS IT DISTINGUISHED FROM STARK?**

### **B. Safe Harbors.**

- 1. Small Investment Interests.**
- 2. Investments in Medically Underserved Areas (MUAs).**
- 3. Space Rental.**
- 4. Equipment Rental.**
- 5. Personal Services and Management Contracts.**
- 6. Bona Fide Employment Relationships.**

## **VII. WHAT CHANGES FOR HOME HEALTH AND HOSPICE WERE IMPOSED BY THE AFFORDABLE CARE ACT?**

A. Overview of ACA Provisions.

B. What did the ACA Impose?

1. Home Health Payment Reductions.
2. Home Health Physician Encounters.
3. Home Health Studies and Demonstration Projects.
4. Hospice Physician Encounters.
5. Future Hospice Payment Changes.

## **VIII. FEDERAL SENTENCING GUIDELINES: THE BIRTHPLACE OF CORPORATE COMPLIANCE**

- A. Creation of the Sentencing Guidelines.
- B. Application of the Guidelines to Organizational Defendants.
  - 1. Curing the Harm.
  - 2. Divestiture of Assets.
  - 3. Effect of Corporate Acts on Fines.
  - 4. Possibility of Probation.

## **VIII. FEDERAL SENTENCING GUIDELINES: THE BIRTHPLACE OF CORPORATE COMPLIANCE**

- C. Mitigation of Sentencing Through  
Implementation of a Corporate  
Compliance Plan.**
- D. Changes to the Guidelines.**

## **IX. CHARACTERISTICS OF CORPORATE COMPLIANCE PLANS**

- A. Corporate Compliance Plans Are Mandatory.**
- B. Self-Assessment and Detection of Fraud.**
- C. Culture of Compliance.**
- D. Protection and Avoidance of Sanctions.**

# **X. STARTING THE COMPLIANCE PROCESS: THE REGULATORY ASSESSMENT**

- A. Assessment.
- B. Review of Claims for Payment.
- C. Employee Interviews.
- D. Documents and Records Review.
- E. Attorney-Client Privilege.
  - 1. Protection of Attorney-Client Communications.

# **X. STARTING THE COMPLIANCE PROCESS: THE REGULATORY ASSESSMENT**

3. Limitations on Attorney-Client Privileges, Including the “Crime-Fraud” Exception.
4. Duties and Obligations to Disclose Certain Information and Penalties for Failure to Do So.

## **XI. REQUIRED ELEMENTS OF A CORPORATE COMPLIANCE PLAN**

### **A. Seven Requirements.**

- 1. Standard of Conduct.**
- 2. Responsibilities.**
- 3. Delegation of Authority.**
- 4. Communication.**
- 5. Monitoring and Auditing.**
- 6. Discipline.**
- 7. Prevention.**

### **B. Formality of Compliance Plan Will Vary.**

## **XII. IMPLEMENTATION OF A CORPORATE COMPLIANCE PROGRAM.**

- A. Implementation Challenges.
- B. All Compliance Programs Shall Include Written "Codes of Conduct."
  - 1. Ethical Standards.
  - 2. Employee Notification.
  - 3. Description of Laws and False Claims Act Educational Requirements.
  - 4. Distribution.

## **XII. IMPLEMENTATION OF A CORPORATE COMPLIANCE PROGRAM.**

### **C. Compliance Officers or Committee and Access to Upper Management.**

- 1. Description of Duties.**
- 2. Continuing Assessment.**
- 3. Access to Management.**
- 4. Appointment of Compliance Committee.**

## **XII. IMPLEMENTATION OF A CORPORATE COMPLIANCE PROGRAM.**

- D. Government Audits and Investigations.**
  - 1. Communications with Government Agents.**
  - 2. Reporting Outside Inquiries.**

## **XII. IMPLEMENTATION OF A CORPORATE COMPLIANCE PROGRAM.**

### **E. Internal Mechanisms for Reporting Suspected Misconduct.**

- 1. Anonymity.**
- 2. Discipline.**

## **XII. IMPLEMENTATION OF A CORPORATE COMPLIANCE PROGRAM.**

### **F. Corporate Document Retention System.**

- 1. Retention System: Remember Arthur Anderson.**
- 2. Cornerstone of Compliance.**

## **XIII. WHAT HAPPENS IF A COMPLIANCE ISSUE IS DISCOVERED?**

- A. The Rule of Two D's**
- B. ACA Disclosure Requirement**
- C. Overpayment and Disclosure  
Protocols**

## **XIV. THE ROLE OF BUSINESS ETHICS IN REGULATORY COMPLIANCE**

### **A. The Relationship Between Fraud, Compliance, and Ethics.**

- 1. Relationship Between Compliance and Fraud.**
- 2. Relationship Between Ethical Conduct and Compliance.**
- 3. Avoidance of Allegations.**

### **B. Code of Ethics.**