

## Ethics and Compliance Program Overview 2010

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### Introduction

Fresenius Medical Care North America (“FMCNA” or “Fresenius” or the “Company”) is the largest private provider of dialysis and related renal services and products in the United States. Through its national network of approximately 1,600 clinics and its staff of approximately 40,000 employees, the Company provides dialysis services to approximately 121,000 end stage renal failure (“ESRD”) patients within the United States.

The Company also provides support services and products to ESRD patients of other providers through its clinical laboratories and renal products business.

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### Organization

The Company has established a Corporate Ethics and Compliance Program to ensure that the Company and its employees comply with applicable laws, regulations, and established Company standards in operating the business.

The Ethics and Compliance Program oversees the Company's principal lines of business:

- Fresenius Medical Services, including dialysis services, pharmacy, U.S. Vascular Access and other renal related services to patients;
- The Renal Therapies Group, including the manufacturing and distribution of renal products and renal drugs, case management, and the Fresenius Medical Care Health Plan; and
- Other entities within the Company.

The Compliance Program also addresses regulatory standards applicable to operating the business. The structure of the Compliance Program provides a systematic approach that incorporates the elements of an effective Compliance Program as outlined in the revised 2004 U.S. Sentencing Guidelines.

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### Chief Compliance Officer

A Chief Compliance Officer directs the Ethics and Compliance Program with the support of the staff of the Office of Ethics and Compliance, and Divisional Ethics and Compliance Officers.

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**Chief  
Compliance  
Officer**  
(continued)

The Chief Compliance Officer reports directly to the Executive Vice President and Chief Administrative Officer of FMCNA, who reports to the Member of the Managing Board of Fresenius Medical Care AG responsible for Law and Compliance.

The Chief Compliance Officer provides monthly reports to the Fresenius Medical Care Holdings (“FMCH”) Board of Directors. A Compliance Plan is updated annually and is approved by the Corporate Compliance Committee and the FMCH Board of Directors.

The staff of the Office of Ethics and Compliance Department have training in, and knowledge of:

- Compliance regulations and policies
- Audits
- Investigations
- Health care clinical services
- HIPAA privacy and security
- Records management
- Self-monitoring
- Enterprise risk management; and
- Operations.

*The Chief Compliance Officer, with the staff members of the Office of Ethics and Compliance and all Divisional Ethics and Compliance Officers and Directors, is responsible for the compliance performance of the Company.*

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**Officers and  
Directors**

Divisional Ethics and Compliance Officers and Directors work directly with the Office of Ethics and Compliance staff on:

- Policy development
  - Risk assessment
  - Compliance issues resolution
  - Training
  - Compliance program implementation; and
  - Other compliance-related activities.
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### **Officers and Directors** (continued)

Divisional Ethics and Compliance Officers and Directors tailor compliance programs to the specific needs and risks of the business groups they support.

A Privacy and Security Officer oversees compliance with HIPAA privacy and security regulations and directs a Privacy and Security Task Force that implements the program in the field.

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### **Corporate Compliance Committee**

A Corporate Compliance Committee (“CCC”) oversees the operations of the FMCNA Compliance Program. The senior executives of the Company and Divisional Ethics and Compliance Officers and Directors are members of the CCC.

The CCC meets on a monthly basis and is chaired by the Chief Compliance Officer. Each operating business has a compliance committee that has oversight responsibility for the Compliance Program within the business.

Additionally, Ethics and Compliance Officers chair compliance committees and/or communicate and address compliance concerns appropriately within the business.

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### **Program Objectives**

The objectives of the Corporate Compliance Program are:

- To establish and enforce systems and controls to promote compliance with applicable regulatory and legal requirements, as well as Company policies and standards;
  - To identify and address compliance risks and violations in an effective and timely manner;
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**Program Objectives**  
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- To promote shareholder, payor, employee and patient confidence in the Company's clinical quality and business practices; and
  - To work with the Business in promoting an ethical workplace where employees embrace the Fresenius Code of Business Conduct and the Company values of:
    - Quality
    - Honesty and Integrity
    - Innovation and Improvement
    - Respect and Dignity
    - Teamwork; and
    - People Make the Difference.
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**Code of Business Conduct**

The Company's *Code of Business Conduct* ("Code") describes the Company's business standards and was initially implemented in January 1997.

This publication emphasizes FMCNA's commitment to operate in accordance with:

- Standards of business conduct
- Company policies; and
- Applicable laws and regulations.

Upon hire, FMCNA employees sign a written acknowledgment that they have reviewed the *Code* and will perform their work in compliance with laws and FMCNA policies.

The *Code* is reviewed annually and updated as necessary.

***The Code is posted on the FMCNA Intranet.***

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### **Compliance Guidelines and Standards**

The Company has developed and distributed compliance guidelines to further assist employees in complying with Company policies and procedures related to informing employees.

Compliance Guidelines for Fresenius Medical Services and related services, Spectra Renal Management, Dialysis Products, and US Vascular Services, along with more specialized guidelines for medical directors, billing functions, and sales and marketing personnel, are available to guide employees.

The Company also has established standards in written policies and procedures to help employee perform their day-to-day work.

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### **Compliance Training**

The compliance training program includes:

- Mandatory new hire compliance training and HIPAA privacy and security training
- Function-specific compliance training programs tailored to the divisional business
- Specialized training programs such as those developed for billing personnel and sales and marketing personnel; and
- Annual training on compliance updates.

Training programs are mandatory for employees and contracted staff who work 160 hours or more in a calendar year.

New hire compliance training must be completed within designated timeframes.

The Company also provides mandatory compliance training for its medical directors.

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### Reporting Compliance Concerns

*FMCNA supports the reporting of compliance concerns by operating a toll-free telephone service called the Compliance Action Line (1-800-362-6990).*

Company employees are encouraged to seek guidance regarding potential regulatory issues or concerns, and to report suspected violations of applicable law or Company policies via the Compliance Action Line. Callers may choose to remain anonymous.

In addition to the phone reporting system, in 2009 FMCNA added an on-line reporting tool. This tool has all the same features and protections as the phone reporting system and can be used to both initiate and follow-up on reports.

Company policies prohibit retaliation against anyone who in good faith reports a legal or compliance concern.

The Compliance Action Line is staffed twenty-four (24) hours a day, seven (7) days a week, with translation services available through a contract with Global Compliance Services.

Compliance Action Line calls are reviewed objectively and promptly by the staff of the Office of Ethics and Compliance in collaboration with the divisional management or other appropriate departments as necessary, such as:

- Law
- Human Resources
- Health
- Safety
- Environmental Affairs; and
- Risk Management or Clinical Services.

The availability of the Compliance Action Line, as well as other compliance resources available, is advertised to the FMCNA community using methods such as the *Code of Business Conduct*, Divisional Compliance Guidelines, office posters, training programs and the Company intranet.

Compliance Action Line activity is reviewed regularly with members of the Corporate Compliance Committee and at the divisional compliance committee meetings.

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### **Investigations**

Allegations of potential violations of law or Company policy are assessed by the Office of Ethics and Compliance. Depending on the nature of the issue, an investigation may be conducted with the assistance of the Law Department or outside counsel or investigator.

If an allegation involves a Human Resources or Clinical Quality concern, the case may be referred to members of the Human Resources or Clinical Services Departments.

The Office of Ethics and Compliance works closely with business management to investigate and resolve the issue and take necessary corrective actions, including any required disciplinary actions.

A determination is also made as to whether a violation requires a disclosure to government authorities or repayment of previously received funds.

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### **Risk Assessments and Internal Controls**

The Company has established an enterprise risk management program within the organization in areas where statutes and regulations expressly require risk analyses and documentation of internal controls, such as financial reporting and HIPAA.

Compliance, Operations and Business Development risk assessments, and assessment of control systems, are also performed to identify and analyze where noncompliance could potentially result in a significant risk or penalty to the Company.

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### **Audits**

Compliance-related audits are conducted as a result of an investigation or as a proactive means of monitoring compliance in areas of actual or potential risk.

The Office of Ethics and Compliance is authorized to conduct independent audits, review the audit results of other departments within the Company, and contract for the use of external audit resources, as warranted.

An annual Compliance Audit Plan is developed and approved by the Corporate Compliance Committee and FMCH Board. Audit projects are selected and prioritized based on:

- Risk assessment
- Prior audits
- Compliance concerns; and
- Regulatory requirements.

The scope of audits ranges from process reviews and probe samples to full statistical analyses. Audit findings and recommendations are reported to operational managers and to the Corporate Compliance Committee.

Response plans are received from operational management and incorporated into the audit report. As necessary, follow-up audits are conducted on the response plans agreed to by management.

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### **Screening for Excluded Parties**

The Company screens current and new employees, independent contractors, and vendors against the Office of Inspector General's List of Excluded Individuals/Entities and the General Services Administration's List of Parties Excluded from Federal Programs.

FMCNA will not engage a person or company that is excluded from participating in federally funded health care programs such as Medicare.

The Company performs additional background checks on selected employees (*e.g.*, Administrator level and above, as well as Billing Center staff) who have discretionary authority.

The Company validates the professional licenses and/or certifications of certain employee categories as required by federal, state or local laws and regulations.

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Office of Ethics and Compliance  
*Doing it right the first time, every time*

**Discipline**

***FMCNA employees are expected to conduct Company activities in conformance with applicable corporate policies and regulatory obligations.***

Employees who fail to meet this standard (including managers and supervisors who condone or fail to prevent improper conduct) are subject to appropriate disciplinary action, up to and including termination of employment.

The Human Resources Department is responsible for ensuring that disciplinary processes and sanctions are enforced on a fair and consistent basis. Employees are evaluated on business integrity in annual performance reviews.

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**Contact  
Information**

***To obtain additional information regarding Fresenius Medical Care North America's Corporate Compliance Program, contact:***

Office of Ethics and Compliance  
Fresenius Medical Care North America  
920 Winter Street  
Waltham, MA 02451  
Tel 800-662-1237 x9099

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**Fresenius Medical Care North America  
Corporate Headquarters  
920 Winter Street  
Waltham, MA 02451**