CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
FRESENIUS MEDICAL CARE HOLDINGS, INC.

I. PREAMBLE

Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America hereby enters into this Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to ensure compliance by Fresenius Medical Care Holdings, Inc. and each of its subsidiaries that provides items or services for which payment may be made by any Federal health care program (hereinafter collectively referred to as "Fresenius"), and by all of Fresenius's employees, contractors, and agents, with the requirements of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (hereinafter collectively referred to as the "Federal health care programs"). This CIA shall be applicable only to those operations of Fresenius that are subject to United States law and regulations. Fresenius's compliance with the terms and conditions in this CIA shall constitute an element of Fresenius's present responsibility with regard

to participation in the Federal health care programs. Contemporaneously with this CIA, Fresenius is entering into Settlement Agreements with the United States, and this CIA is incorporated by reference into the Settlement Agreements.

A. Definitions

1. "Affiliate": subject to the provisions of Section I.A.6 below relating to dialysis facilities which are subsidiaries of Fresenius as of the effective date of this CIA, any corporation, joint venture or other organization or entity that provides or is involved in the provision of dialysis services to beneficiaries of Federal health care programs in which Fresenius holds a direct or indirect equity interest of 5% or more but does not exercise majority voting control; or with respect to which Fresenius has a management contract to provide management and administrative services that gives it control over the day-to-day operations of the dialysis facility.

2. "Business Segment": each of the core business activities of Fresenius, including at a minimum, (i) dialysis services; (ii) medical products; (iii) clinical laboratory services; (iv) diagnostic testing services; and (v) parenteral and enteral nutrition.

3. "Contractor": any individual or entity whose work is performed at a location neither owned nor operated by Fresenius, with whom Fresenius has

entered into a contract or other arrangement to furnish health care items or services for which Fresenius claims reimbursement from any Federal health care program.

4. "Covered Person": any (i) officer, director, or employee of Fresenius; or (ii) agent or other individual (including medical director) who furnishes health care items or services at a Fresenius owned or operated location for which Fresenius claims reimbursement from any Federal health care program or who participates in the preparation or submission of claims for payment on behalf of Fresenius with respect to items or services for which Fresenius claims reimbursement from any Federal health care program (regardless of where such activity takes place). Notwithstanding the above, this term does not include part-time or per diem employees who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during any 12 month period.

5. "Federal Rules": any statutes, regulations, manual provisions, or formal bulletins or notices issued by the Health Care Financing Administration, its contractors (i.e., intermediaries or carriers) or other regulatory agencies (e.g., State Medicaid agencies) or their contractors responsible for

administering Federal health care programs. Any references or citations within the CIA to any particular Federal Rule shall be deemed to apply to such Federal Rule as it may be amended from time to time. In the event of any change to a Federal Rule that has a material effect on the obligations of Fresenius under this CIA, the parties shall negotiate in good faith to amend this CIA to accommodate such change.

6. "Subsidiary": any corporation or other organization that provides items or services for which payment may be made by any Federal health care program and in which Fresenius holds a direct or indirect equity interest and exercises majority voting control; provided, however, that if a dialysis facility meets the definition of subsidiary as of the effective date of this CIA, then that facility shall remain a subsidiary for as long as Fresenius holds a direct or indirect equity interest of 5% or more in the facility and for all purposes during the duration of this CIA, nothwithstanding any subsequent changes in ownership or control that otherwise would change the status of the facility from a subsidiary to an affiliate.

II. TERM OF THE CIA

The period of the compliance obligations assumed by Fresenius under this CIA shall be eight years from the effective date of this CIA (unless otherwise specified). The

effective date of this CIA will be the date on which the final signatory of this CIA executes this CIA. The OIG may, at its sole discretion and in writing, terminate or reduce the compliance obligations assumed by Fresenius under this Agreement after five years.

III. CORPORATE INTEGRITY OBLIGATIONS

Fresenius warrants and represents that it currently operates and maintains a compliance program ("Program"). Pursuant to and for the duration of this CIA, Fresenius shall maintain its current Program, and, as required below, amend the Program to adhere to or include the following obligations or elements.

A. Compliance Officers and Committee

1. *Corporate Compliance Officer.* For the duration of this CIA, Fresenius shall continue to maintain an individual to serve as Corporate Compliance Officer, consistent with the following requirements. The Corporate Compliance Officer shall be responsible for ensuring the development and implementation of policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with the requirements of the Federal health care programs. The Corporate Compliance Officer shall be a member of senior management of Fresenius, shall make regular (at least quarterly) reports regarding compliance matters directly to the CEO and/or to the Board of Directors of Fresenius and shall be authorized to report to the Board of Directors at any time. The Corporate Compliance Officer shall be responsible for monitoring the day-to-

day activities engaged in by Fresenius to further its compliance objectives, as well as any reporting obligations created under this CIA.

2. *Business Unit Compliance Infrastructure.*

(a) Within 90 days of the execution of this CIA, Fresenius shall also appoint compliance officers for each of its corporate Business Units identified in Schedule A. These Business Unit Compliance Officers will cooperate with the Corporate Compliance Officer to ensure the development and implementation of policies, procedures, and practices designed to ensure compliance with applicable Federal Rules and with the requirements of this CIA. The Business Unit Compliance Officers also will be responsible for assisting the Corporate Compliance Officer in meeting the reporting obligations created by this Agreement.

(b) Within 90 days of the execution of this CIA, each of the Business Units shall establish a Compliance Committee. These Compliance Committees shall consist of representatives from departments or functional areas within such Business Unit, including: (i) sales and marketing; (ii) billing and reimbursement; (iii) human resources; and (iv) operations.

4. *Changes in Compliance Officers.* In the event a new Corporate or Business Unit Compliance Officer is appointed during the term of this CIA, Fresenius shall notify the OIG, in writing, within 15 days of such a change.

5. *Corporate Compliance Committee.* For the duration of this CIA, Fresenius shall continue to maintain its "Corporate Compliance Task Force" or similar group however denominated (hereinafter referred to as "the Corporate Compliance Committee") and, to the extent necessary, shall amend the Program within 90 days after the effective date of this CIA to ensure that the Corporate Compliance Committee meets the following requirements. The Corporate Compliance Committee shall, at a minimum, include the Compliance Officer and any other member of senior management within the provider's corporate structure as necessary to meet the requirements of this CIA (e.g., senior executives responsible for major functions, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Corporate Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities.

B. Written Standards.

1. *Code of Conduct.* For the duration of this CIA, Fresenius shall continue to maintain its "Code of Ethics and Business Conduct" or similar code however denominated (hereinafter referred to as "Code of Conduct") and, to the extent necessary, shall amend the Program and/or Code of Conduct within 90 days of the effective date of this CIA to ensure that the Code of Conduct meets the following requirements. The Code of Conduct shall be distributed within 90 days of the effective date of this CIA to all

Covered Persons who have not already received the Code of Conduct. Fresenius shall make adherence to Company policies and procedures designed to ensure compliance with Federal health care program requirements an element in evaluating the performance of managers, supervisors, and all other employees. The Code of Conduct shall, at a minimum, set forth:

a. Fresenius's commitment to full compliance with Federal Rules, including its commitment to prepare and submit accurate billings consistent with Federal Rules;

b. a requirement that all of its Covered Persons shall be expected to comply with all applicable Federal Rules and with Fresenius's own policies and procedures;

c. a requirement that all Covered Persons shall be expected to report to Fresenius suspected violations of any Federal Rules or of Fresenius's own policies and procedures;

d. the possible consequences to both Fresenius and Covered Persons of their failure to comply with the Federal Rules or with Fresenius's own policies and procedures, or of their failure to report such non-compliance; and

e. the right of all Covered Persons to use the Confidential Disclosure Program, as well as Fresenius's commitment to confidentiality and non-retaliation with respect to disclosures.

New Covered Persons shall receive the Code of Conduct within 30 days after becoming a Covered Person and shall certify, in writing, that he or she has received and will abide by Fresenius's Code of Conduct.

Fresenius shall annually review the Code of Conduct and will make any necessary material revisions. These revisions shall be promptly distributed to Covered Persons. Covered persons shall certify on an annual basis that they have received, read, understand and will abide by the Code of Conduct.

2. *Compliance Guidelines*. Within 120 days of the effective date of this CIA, Fresenius shall review and revise or develop written compliance guidelines for each business segment. Such guidelines shall include (i) general Compliance Guidelines; (ii) Sales and Marketing Guidelines; and (iii) Billing and Reimbursement Guidelines (collectively referred to as "Business Segment Compliance Guidelines"). Collectively, the various Business Segment Compliance Guidelines shall, at a minimum, include:

a. Provisions implementing the substantive requirements of this CIA, including those set forth in section III.

b. Disciplinary guidelines and methods for Covered Persons to make disclosures or otherwise report on compliance issues to Fresenius management through the Confidential Disclosure Program required by section III.G.

c. Provisions consistent with those set forth in section III.B.3 below that are appropriate for inclusion in such Guidelines.

Within 150 days of the effective date of the CIA, copies of the applicable set of Business Segment Compliance Guidelines shall be provided to the appropriate Covered Persons. Managers or supervisors shall be prepared to explain the policies and procedures incorporated in the Guidelines to affected Covered Persons. Copies of the Business Segment Compliance Guidelines will be provided to OIG as part of the Implementation Report.

Fresenius shall assess and update the Business Segment Compliance Guidelines at least annually or as necessary when changes in Federal Rules require such updates.

3. *Substantive Area Policies and Procedures.* Within 120 days of the effective date of this CIA, Fresenius shall review and, where appropriate, revise or develop written policies and procedures to address the specific obligations identified below regarding Fresenius's provisions of items and services and submission of claims to

the Federal health care programs. Where appropriate, such policies and procedures shall be incorporated into the Business Segment Compliance Guidelines.

a. Credit balances. Fresenius shall have policies and procedures regarding unreconciled payments and credit balances designed to ensure that overpayments from Federal health care programs are identified promptly and refunded to the appropriate payor in accordance with Federal Rules. At a minimum, such policies and procedures shall address the following issues in the manner prescribed below:

(1) Fresenius shall make adequate provisions for timely and accurate reporting of Federal health care program unreconciled payments and credit balances;

(2) Fresenius shall address the HCFA requirements for reporting credit balances through the filing of credit balance reports (FORM HCFA-838);

(3) Fresenius shall retain an audit trail of patient account transactions involving Federal health care program payors for a period of seven years from the date that at a claim for payment was submitted;

(4) Fresenius shall track accounts with unreconciled payments and/or credit balances involving Federal health care programs payors so that it can determine the status of refund requests and the payment of refunds;

(5) Fresenius's actions with regard to unreconciled payments and credit balances shall be in accordance with Federal Rules; and

(6) Fresenius shall designate at least one individual for each of its business segments as having responsibility for the tracking, recording, reporting and refunding of unreconciled payments and credit balances.

b. Parenteral and Enteral Nutrition (PEN). Fresenius shall have policies and procedures designed to ensure adherence to relevant Federal Rules governing the provision and reimbursement of intradialytic parenteral nutrition or other forms of enteral or parenteral nutrition (e.g., intraperitoneal nutrition) (collectively all of which shall be referred to as "PEN"). At a minimum, such policies and procedures shall address the following issues in the manner prescribed below:

(1) Fresenius shall design and implement internal controls designed to prevent it from receiving Federal health care program reimbursement for PEN that: (a) is not prescribed by the patient's physician; or (b) does not satisfy coverage criteria for such items or services published by HCFA, other appropriate regulatory agencies, or the appropriate contractors. If Fresenius submits a claim for PEN that it reasonably believes does not satisfy the coverage criteria for a Federal health care program, Fresenius shall submit the claim to the appropriate Federal health care program contractor with an appropriate modifier, or other form of notice to permit such contractor to issue a formal denial.

(2) Fresenius shall submit claims for payment for PEN in accordance with HCFA's current coverage criteria for PEN set forth in C.I.M § 65.10 as well as relevant DMERC Supplier Manuals, as in effect at the time the claim is submitted.

(3) Fresenius shall submit claims for PEN only if such claims are properly documented to establish coverage under applicable Federal Rules governing the provision and reimbursement for PEN. If Fresenius is unable to establish coverage and, therefore, is unable to claim reimbursement for the service from a Federal health care program, Fresenius may choose to provide the service without charge if the treating physician determines that PEN is required to treat a life threatening nutritional disorder and Fresenius determines that the patient has no other means for paying for the service; provided that Fresenius make a determination of inability to pay on an individualized, case-by-case basis in accordance with a reasonable set of

income guidelines uniformly applied in all cases. The guidelines should be based on objective criteria and appropriate for the applicable locality.

(4) To the extent that Fresenius utilizes an IDPN Information Sheet ("IIS") or Clinical Nutrition Summary ("CNS") (or any other similar document, however denominated) to accompany the certificate of medical necessity ("CMN") in support of a PEN claim, the IIS or CNS shall fully and accurately describe the patient's medical condition that is the basis for the therapy, as that condition is documented in the medical record and as may be required by the applicable Medicare carrier, and shall not contain false statements by affirmative misrepresentation and/or material omission.

(5) To the extent that Fresenius utilizes an IIS, CNS or similar form to support payment of a PEN claim, the form provides for (i) a certification by the attending physician that to the best of the physician's knowledge, the information contained on the form is a true, accurate and complete representation of the patient's medical condition that is the basis for the therapy; and (ii) a certification by any other person that has entered medical information on the form that to the best of that person's knowledge, the information so entered is a true, accurate and complete representation of the patient's medical condition and/or clinical status that is the basis for the therapy.

(6) Fresenius shall provide memoranda setting forth the policies and procedures regarding PEN documentation, medical necessity and coverage criteria to non-Fresenius facilities and attending physicians for whom Fresenius provides PEN items or services.

(7) Fresenius shall not illegally influence the physician's medical judgment or the physician's documentation of the medical necessity of PEN for a particular patient.

(8) Fresenius shall not pay "hang fees" to individuals or entities for whom Fresenius provides PEN items or services and shall not offer any form of remuneration to its PEN coordinators or to any other individual or entity in a manner that provides illegal incentives to qualify patients for PEN coverage.

(9) Fresenius shall provide and claim reimbursement for PEN administration kits in conformance with applicable Federal Rules. If Fresenius sells an administration kit that does not include the standard components prescribed by the DMERC, Fresenius shall contact the relevant DMERC to arrange for the use of a modifier or other code based upon procedures followed by that DMERC.

c. Laboratory Services. Fresenius shall have policies and procedures designed to ensure adherence to relevant Federal Rules relating to the provision of and reimbursement for clinical laboratory services. At a minimum, such policies and procedures shall address the following issues in the manner prescribed below:

(1) Medical Necessity.

(a) *Generally.* (i) Fresenius shall ensure that it does not engage in any conduct or activities that causes the submission of claims to Federal health care programs for laboratory tests and/or services that lack medical necessity; (ii) Fresenius shall design and implement internal controls (1) designed to prevent Fresenius from receiving reimbursement for medically unnecessary tests and (2) designed to enable Fresenius to identify utilization patterns that may indicate Fresenius is receiving reimbursement for medically unnecessary tests; and (iii) Fresenius shall communicate to physicians that claims submitted for service will only be paid if the services are covered, reasonable and medically necessary for the beneficiary, given his or her clinical condition;

(b) *Denials.* Fresenius shall ensure that its claims for Federal health care program reimbursement for clinical laboratory tests are either consistent with coverage rules or are accompanied by the appropriate modifier or other indication to the relevant contractor that the claims are being submitted to obtain denials of payment from the contractor;

(c) If Fresenius is unable to obtain required documentation of medical necessity from the ordering physician after a good faith effort to obtain it, and therefore, is unable to claim reimbursement for a service from a Federal health care program, and the ordering physician has not provided an appropriately completed advance beneficiary notice ("ABN"), Fresenius may choose to provide the service at no charge to the patient, the dialysis facility where the patient obtains the service, or the ordering physician, provided that Fresenius (1) undertakes to educate the ordering physician on the need to document medical necessity for tests that under Federal Rules or local medical review policy require a diagnosis code in order to obtain reimbursement or obtain an ABN and the potential for violations of sections 1128A(a)(5) and 1128B(b) of the Social Security Act for failure to provide required documentation, including an ABN, to the laboratory; and (2) monitors orders from such ordering physician to assess compliance with proper documentation requirements. In the event that a pattern of physician non-compliance continues notwithstanding these efforts, Fresenius shall either bill and obtain payment from the ordering physician, obtain payment from the dialysis facility with which the ordering physician is affiliated, or cease processing such physician's orders.

(2) Test Ordering Procedure and Forms.

(a) *Generally.* Fresenius shall ensure that all requisition forms (including computer-based ordering forms) are constructed to eliminate any improper influence on the independence of the medical necessity decision by the physician or other authorized individual with regard to each test that Fresenius bills for; and that the forms contain the following bold-faced and easily readable statements: (i) Medicare generally does not cover routine screening tests; (ii) Medicare will only pay for those tests that are reasonable and necessary; (iii) Tests ordered pursuant to panels and/or profiles should be reviewed to ensure that the tests are medically necessary; and (iv) Diagnosis codes should be reviewed to ensure that they accurately reflect the patients condition which supports the medical necessity of the tests ordered.

(b) *Individual Requisition Form Design* . Fresenius shall require that its Individual Patient Custom Profile ("IPCP") or any other form which identifies a routine battery of tests to appear on the requisition form for a

patient on a regular basis is signed and dated by the ordering physician, or person authorized by the physician and are reviewed annually to ensure that the IPCP continues accurately to reflect the individual medical needs of the patient. At least annually, Fresenius will contact each physician that has established an IPCP for his or her patient to request confirmation in writing that the selected tests should continue to appear on the IPCP and that any diagnoses codes indicated on the IPCP are appropriate given the patient's clinical condition.

Such review shall be appropriately documented in Fresenius's files. For the purposes of this section, "physician" includes any person authorized by state law to order clinical laboratory tests.

(c) Fresenius shall ensure that it does not use as part of its computerized test scheduling and reporting system any type of function that, except for tests where Medicare has established frequency rules and the tests are performed within those rules, allows non-composite rate tests to be automatically assigned to multiple patients (e.g., patients receiving dialysis through the same modality).

(3) Panels. Fresenius shall ensure that to the extent its laboratories permit physicians to order tests by panels, the laboratories fully disclose the contents of their panels on their test ordering forms or other test ordering system and give physicians the option of ordering each test in a panel individually. If Fresenius permits tests to be ordered as panels, procedures shall be in place to assure that the tests that compose the panels are properly billed to Federal health care programs.

(4) Billing. Fresenius shall ensure that each claim submitted for payment to Federal health care programs reflect services that have been ordered pursuant to a valid order from the ordering physician or other authorized person and have been performed.

(a) *CPT/HCPCS Codes*. Fresenius shall ensure that the CPT/HCPCS codes used to bill services accurately describe the service that was ordered and performed.

(b) *ICD-9 Codes*. Fresenius shall request physicians or other authorized individuals to submit diagnostic information for all non-composite tests

ordered as documentation of the medical necessity of the service. Fresenius shall encourage ordering physicians and other persons authorized to order tests to submit diagnoses in ICD-9 code format. Fresenius shall ensure that when diagnoses received in non-ICD-9 format are translated into ICD-9 code format, such translations will be performed by persons with appropriate technical expertise.

(c) *Dialysis Billing Rules*. Fresenius shall ensure that claims submitted for clinical laboratory tests provided to ESRD patients are submitted consistent with the special rules applicable to dialysis testing, including the "50-50 rule," as such rules may be in effect during the term of this CIA.

(d) *Calculations*. Fresenius shall not bill for calculations (i.e., clinical data mathematically derived from the results of individual laboratory tests ordered by a physician or other authorized person as part of a calculation panel), but only for such tests that are ordered and performed in order to derive such calculations.

(5) OIG Fraud Alert Compliance. Fresenius shall comply with the OIG Fraud Alert for clinical laboratories published by the HHS/OIG in October 1994, which provides standards for the pricing of ESRD composite rate tests and the provision of phlebotomists and computers to customers. See 59 F.R. 65372 (December 19, 1994). During the term of this CIA, Fresenius shall review annually the fair market value of the laboratory composite rate offered to dialysis facilities. Each annual review shall be set forth in a report in which Fresenius shall explain the methodology used in the review and provide its calculations for determining the fair market value of its composite rate. Fresenius shall provide the OIG with a copy of this report in its Annual Reports.

d. Diagnostic Testing Services. Fresenius shall have policies and procedures designed to ensure adherence to relevant Federal Rules relating to diagnostic testing services. At a minimum, such policies and procedures shall address the following issues in the manner prescribed below:

(1) Test Ordering Procedures. Fresenius shall ensure that all diagnostic procedures performed by Fresenius's independent diagnostic testing facilities ("IDTFs") are specifically ordered in writing by a physician or other authorized person, and are provided in accordance with state and federal regulatory requirements governing IDTFs, including but not limited to federal requirements set forth in 62 Fed. Reg. 59,099 (Oct. 21, 1997).

(2) Medical Necessity. (i) Fresenius shall ensure that all diagnostic procedures performed by Fresenius's IDTFs and billed to Federal health care programs are specifically ordered in writing by a physician or other authorized person; (ii) Fresenius shall ensure that it does not engage in any conduct or activities that causes the submission of claims to the Federal health care programs for diagnostic testing that lacks medical necessity; (iii) Fresenius shall design and implement internal controls (1) designed to prevent Fresenius from receiving reimbursement for medically unnecessary tests and (2) designed to enable Fresenius to identify utilization patterns that may indicate Fresenius is receiving reimbursement for medically unnecessary tests; and (iv) Fresenius shall communicate to physicians that claims submitted for a service will only be paid if the service is covered, reasonable and medically necessary for the beneficiary, given his or her clinical condition.

(3) ICD-9 Codes. Fresenius shall request and encourage ordering physicians and other persons authorized to order tests to submit diagnoses in ICD-9 code format. Fresenius shall ensure that when diagnoses received in non-ICD-9 format are translated into code format, such translations will be performed by persons with appropriate technical expertise.

(4) Supervising Physician. Fresenius shall ensure that each IDTF has one or more supervising physicians who: (a) are responsible for the direct and ongoing oversight of the quality of the testing performed; (b) are responsible for the proper operation and calibration of the equipment used to perform tests; (c) have proficiency in the performance and interpretation of each type of diagnostic procedure performed; and (d) are responsible for the qualification of non-physician personnel who use the equipment in accordance with applicable State law, licensing and certification requirements.

(5) CPT Codes. Fresenius shall ensure that the CPT codes used to bill for diagnostic testing and/or services accurately describe the service that was ordered and performed.

e. Kickbacks and Self-Referrals

(1) Generally. Fresenius shall refrain from offering or paying anything of value (i.e., remuneration) to dialysis facilities, their medical directors, physicians, hospitals or other referral sources in violation of the anti-kickback statute (codified at 42 U.S.C. § 1320a-7b(b)), the federal physician self referral prohibition (also known as the "Stark Statute" and codified at 42 U.S.C. § 1395nn), or other applicable statutes, regulations, and program requirements relating to payments to and from referral sources.

(2) Sales and Marketing. Fresenius shall have policies and procedures designed to ensure that its sales and marketing practices and information are clear, accurate, informative and non-deceptive, and are designed to ensure that physicians and other individuals authorized to order tests, items, or services provided by Fresenius understand the services offered by Fresenius and the services that will be provided when tests, items or services are ordered. Fresenius shall ensure that its marketing materials and sales tactics are not designed for the purpose of generating orders for unnecessary tests or services. Fresenius shall not calculate the commissions it pays to sales staff in a manner that causes the sales staff illegally to influence a physician's judgment regarding the medical necessity of tests or services offered by Fresenius.

(3) Discounts. Fresenius shall not offer discounts on one item or service in exchange for an agreement to purchase a different item or service from Fresenius, unless the discount meets all of the applicable requirements to fall within the Safe Harbor described at 42 C.F.R. 1001.952(h), as in effect at the time of the offer.

C. Training and Education. Fresenius shall maintain and further develop its compliance training program to provide necessary training and information to Covered Persons about applicable Federal Rules and related Fresenius policies and procedures. The objective of the program shall be to enable Fresenius to operate in conformity with

Federal Rules and to satisfy the requirements of this CIA. At a minimum, the compliance training program shall include the following elements:

1. Corporate Integrity Agreement. Fresenius shall take steps to inform Covered Persons of the existence of, and obligations imposed by, this CIA. Copies of this CIA shall be made available to all Covered Persons.

2. General Compliance Training. Fresenius shall maintain a compliance training and orientation program for all Covered Persons. Such training shall cover:

a. the requirements of this Corporate Integrity Agreement;

b. Fresenius's Compliance Program (including the policies and procedures pertaining to general compliance issues); and

c. Fresenius's Code of Conduct.

3. Functional Compliance Training. In addition to the general compliance training described in paragraph (2), all Covered Persons, excluding medical directors, shall receive at least two (2) hours of additional compliance training relating to legal and regulatory issues specifically affecting their business segment. This training shall cover relevant Federal Rules, general and substantive area policies and procedures, including those addressed in the Business Segment Compliance Guidelines, as well as other relevant regulatory matters.

4. Specialized Training for PEN Program Personnel. In addition to the compliance training described in paragraphs (2) and (3), all Covered Persons assigned to the PEN program who are nurses, dietitians, pharmacists, or other clinical personnel who (i) provide educational and nutrition consulting services to dialysis facilities relating to PEN therapy; (ii) assess the eligibility of patients for PEN therapy, or (iii) monitor the provision of PEN therapy to beneficiaries of Federal health care programs shall receive at least two (2) additional hours of training relating to legal and regulatory issues affecting their responsibilities. This training shall cover relevant Federal Rules, the general and substantive area policies and procedures, including those addressed in the Business Segment Compliance Guidelines, as well as other relevant regulatory matters relating to coverage and medical necessity requirements for PEN therapy.

5. Specialized Training for Sales and Marketing Personnel. In addition to the compliance training described in paragraphs (2) and (3), all Covered Persons involved directly in sales or marketing activities relating to items or services furnished to beneficiaries of Federal health care programs shall receive at least two (2) additional hours of training relating to legal and regulatory issues affecting their responsibilities. This training shall cover relevant Federal Rules, the general and substantive area policies and procedures, including those addressed in the Business Segment Compliance

Guidelines, as well as other relevant regulatory matters relating to illegal kickbacks and prohibitions on physician self-referral arrangements.

6. Specialized Training for Billing Personnel. In addition to the compliance training described in paragraphs (2) and (3), all Covered Persons who participate in the preparation or submission of bills, claims, or cost reports (either in paper or electronic format) to any Federal health care program shall receive at least six (6) hours additional training relating to legal and regulatory issues specifically affecting their billing-related responsibilities. This training shall cover relevant Federal Rules, the general and substantive area policies and procedures, including those addressed in the Business Segment Compliance Guidelines, as well as other relevant regulatory matters. Specifically, the training shall address:

a. the submission of correct and accurate bills for services rendered to all Federal health care program beneficiaries;

b. the personal obligation of each individual to make reasonable efforts to ensure that information provided in support of a submission for reimbursement for items or services furnished to beneficiaries of the Federal health care programs is accurate;

c. applicable Federal Rules;

d. examples of improper billing and documentation practices; and

e. the legal, regulatory, and internal Fresenius sanctions for improper billings.

7. Timeframes. The training required by paragraph III.C.2 shall be provided to all Covered Persons who have not already received such training within 60 days of the effective date of the CIA. The training required by paragraphs III.C.3, C.4 and C.5 shall be provided to all applicable Covered Persons within 9 months of the effective date of this CIA. The training required by paragraph III.C.6 shall be provided within 90 days of the effective date of this CIA with respect to personnel responsible for PEN, diagnostic testing and clinical laboratory claims, and within 6 months of the effective date of this CIA with respect to personnel responsible for dialysis services billing. Training of any type provided to applicable Covered Persons within 6 months prior to the effective date of this CIA which meets the requirements of paragraph C shall be deemed to meet the timeframe obligation imposed by this paragraph.

8. New Covered Persons. Affected new Covered Persons shall receive the applicable training required by this CIA within the following time frames: General Compliance Training pursuant to paragraph III.C.2 within 30 days of commencing work or within 150 days of the effective date of this CIA, whichever is later; Functional Compliance Training pursuant to paragraph III.C.3 within 60 days of commencing work or within 9 months of the effective date of this CIA, whichever is later; Specialized

Training pursuant to paragraphs III.C.4 or C.5 within 60 days of commencing work or within 9 months of the effective date of this CIA, whichever is later; and Specialized Training pursuant to paragraph III.C.6 within 30 days of commencing work or within 90 days of the effective date of the CIA, whichever is later. If a new Covered Person is in a position for which training is required under this CIA and begins to perform his/her position responsibilities prior to receiving all the training required for that position, a Fresenius employee who has completed all the necessary training shall take appropriate steps to supervise that untrained person's work related to that substantive area in such a manner as to ensure that the person's work is performed in accordance with the applicable Federal Rules, this CIA, and Fresenius' own policies and procedures.

9. Medical Director Training. Within 6 months of the effective date of this CIA, Fresenius shall develop and implement a special training and education program for physicians with whom it contracts to furnish administrative services as Medical Directors of its dialysis facilities. Medical Directors shall only be required to receive the training delineated in this subsection III.C.9. Such program shall consist of at least two elements:

a. baseline training of at least 2 hours duration covering (i) the purpose and elements of the Fresenius corporate compliance program and this CIA; (ii) requirements for determining and documenting that services furnished to beneficiaries of Federal

health care programs meet applicable medical necessity and coverage requirements, and (iii) the application of other Federal Rules and Fresenius policies and procedures directly related to the duties and responsibilities of medical directors; and

b. annual supplemental compliance training covering material changes in Federal Rules, changes in Fresenius policies and procedures, or changes in the Fresenius corporate compliance program.

All new contracts or contract amendments between Fresenius and its Medical Directors executed following the effective date of this CIA shall include a specific obligation on the part of the Medical Director to receive at least 2 hours of baseline compliance training within 6 months of the effective date of this CIA or within 30 days of first providing medical director services for Fresenius, whichever is later; and thereafter the annual supplemental compliance training. For all other contracts between Fresenius and its Medical Directors which are in force on the effective date of this CIA, Fresenius shall make a reasonable good faith effort to provide the baseline compliance training and annual supplemental compliance training to the Medical Directors as set forth in this paragraph, encourage attendance by the Medical Directors, and report to the OIG on the percentage of participation.

10. Annual Supplemental Training. Beginning 12 months following the effective date of this CIA, Covered Persons shall receive at least one hour of supplemental compliance training on an annual basis. Such training shall address material changes in Federal Rules, changes in Fresenius policies and procedures relating to such rules, or other changes in Fresenius's corporate compliance program. It shall also review and reemphasize the obligations of Fresenius and Covered Persons to comply with Federal Rules.

11. Annual Compliance Training Plan. Fresenius shall prepare an annual compliance training plan which shall outline specific actions and schedules to be undertaken to meet the requirements of this section. An initial compliance training plan shall be provided to OIG within 60 days of the effective date of this CIA. Subsequent annual compliance training plans shall be provided to the OIG not later than October 30 for the following calendar year.

12. Certification and Retention. Fresenius shall ensure that each Covered Person who is required to receive training certifies that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer shall retain the certification, along with specific course materials. These shall be made available to OIG upon request.

D. Application of CIA Obligations to Affiliates

If Fresenius enters a new contract or arrangement to form an Affiliate after the effective date of this CIA, Fresenius shall ensure, by including as terms of the contract or arrangement, that the Affiliate: (1) has a Compliance Officer; (2) adopts a Code of Conduct that meets the requirements of section III.B.1 of this CIA, subject to appropriate modifications to address the particular circumstances of the Affiliate; (3) has written policies and procedures that incorporate, to the extent relevant to the Affiliate, the policies and procedures identified in section III.B.3 of this CIA; (4) provides training to Affiliate employees consistent with the requirements of section III.C of this CIA, other than section III.C.11 (which requires the submission of an annual training plan to the OIG); (5) permits the Independent Review Organization named under section III.F of this CIA (the "IRO") access to records necessary to include the Affiliate in the IRO review required under section III.F of this CIA; and (6) screens for ineligible persons under section III.H of this CIA. Notwithstanding the requirements of this section, no Affiliate may be subject to the Breach and Default provisions contained in section X of this CIA; however, the OIG can apply those provisions to Fresenius for any failure by Fresenius to comply with its obligations under the provisions of this section.

With respect to any Affiliate that was established prior to the effective date of this CIA, Fresenius shall, within 90 days of the execution of this CIA, communicate the requirements of this section to the Affiliate, and attempt in good faith to obtain agreement

by the Affiliate to submit to all the terms of this section; or if agreement cannot be reached to include all the terms, then as many as possible.

E. Application of CIA Obligations to Contractors.

Fresenius shall take the following steps with respect to a Contractor: (1) require in its contract with the Contractor that the Contractor acknowledge Fresenius's compliance program and Code of Conduct; and (2) ensure that the Code of Conduct, the Business Segment Compliance Guidelines and relevant portions of the Substantive Area policies and procedures described in section III.B above, and a description of the Confidential Disclosure Program are provided to the Contractor. Fresenius shall require future contracts with such Contractors to include the above-described provisions.

F. Review Procedures.

1. *Retention of Independent Review Organization.* Fresenius shall retain an entity, such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO") to perform review procedures to assist Fresenius in assessing the adequacy of its policies and procedures and compliance practices pursuant to this CIA. The reviews will be performed annually and cover each of the one-year periods beginning on the effective date of this CIA or the anniversary of that date. The Independent Review Organization must have expertise in the billing, coding, reporting and other requirements of the Federal health care programs from which Fresenius seeks

reimbursement. The Independent Review Organization must be retained to conduct the audit of the first year within 90 days of the effective date of this CIA.

2. *Types of Reviews.* The Independent Review Organization will conduct the reviews consistent with the IRO workplan attached as Schedule B, and made part of this Agreement.

3. *Statistical Sampling and Appraisal.* All matters related to this CIA that involve statistical sampling or appraisal shall be conducted using the OIG's Office of Audit Services Statistical Sampling Software, also known as "RAT-STATS," available on the Internet at www.hhs.gov/oas/ratstat.html. Wherever the CIA requires the use of a random sample, the sample shall be selected and appraised using RAT-STATS and Fresenius or its IRO shall retain all of the supporting documentation related to the selection and appraisal of the samples. Whenever the IRO workplan requires a "Statistically Valid Sample Audit," the following requirements will apply. The sample size for each review shall be determined through the use of a probe sample. The probe sample must contain at least 30 sample units and cannot be used as part of the full sample. The full sample must contain a sufficient number of units so that when the sample results are projected to the population of claims for that review, the projection provides a minimum 90% confidence level and a maximum precision of plus or minus 25% of the point estimate (i.e., the upper and lower bounds of the 90% confidence interval shall not

exceed 125% and shall not fall below 75% of the midpoint of the confidence interval, respectively). Both the probe sample and the full sample must be selected through random number sampling.

4. *Billing Reviews Methodology*. Each of the annual billing reviews shall include the following components in its methodology:

a. Billing Review Objective: a clear statement of the objective intended to be achieved by the billing review and the procedure or combination of procedures that will be applied to achieve the objective.

b. Billing Review Population: the identity of the population, which is the group about which information is needed and an explanation of the methodology used to develop the population and provide the basis for this determination.

c. Sources of Data: a full description of the source of the information upon which the billing review conclusions will be based, including the legal or other standards applied, documents relied upon, payment data, and/or any contractual obligations.

d. Sampling Unit: a definition of the sampling unit, which is any of the designated elements that comprise the population of interest.

e. Sampling Frame: the identity of the sampling frame, which is the totality of the sampling units from which the sample will be selected.

5. *Billing Reviews Findings*. Each of the annual billing reviews shall provide findings regarding the following as they relate to the billings covered by that review:

a. Fresenius's billing and coding operation (including, but not limited to, the operation of the billing system, strengths and weaknesses of this system, internal controls, effectiveness of the system);

b. whether Fresenius is submitting accurate claims and/or cost reports for services billed to the Federal health care programs.

c. Fresenius's procedures to correct inaccurate billing, coding or reporting to Federal health care programs;

d. whether Fresenius has complied with its obligation under the Settlement Agreements: (a) not to resubmit any previously denied claims related to the conduct addressed in the Settlement Agreements, and its obligation not to appeal any such denials of claims, and (b) not to charge to or otherwise seek payment for unallowable costs (as defined in the Settlement Agreements) and its

obligation to identify and adjust any past charges of unallowable costs; and

e. the steps Fresenius is taking to bring its operations into compliance or to correct problems identified by the audit.

6. *Contract Review*. The IRO shall review a sample of at least 30 of Fresenius's contracts and other financial relationships that Fresenius has with physicians, dialysis providers, and other persons who may be in a position to refer or otherwise generate business for which Fresenius may submit claims to or be reimbursed by any Federal health care program to determine whether these contracts comply with applicable Federal Rules and the obligations of this CIA.

7. *Credit Balance Review*. The IRO shall review whether Fresenius is complying with its obligations under Federal Rules and the obligations of this CIA to identify and report credit balances to Federal health care programs.

8. *Compliance Review*. The compliance review shall provide findings regarding whether Fresenius's program, policies, procedures, and operations comply with the terms of this CIA. This review shall include section by section findings regarding the requirements of this CIA.

9. *Review Reports*. The IRO shall annually produce reports corresponding to all of the required reviews and including all of the information required by this section

of the CIA. A complete copy of all of the IRO's review reports with respect to each year shall be included in each of Fresenius's Annual Reports to OIG.

10. *Verification/Validation.* In the event that the OIG has reason to believe that any of Fresenius's Billing Reviews conducted by the IRO fail to conform to its obligations under the CIA or indicate improper billings not otherwise adequately addressed in the annual review report(s), and thus determines that it is necessary to conduct an independent review to determine whether or the extent to which Fresenius is complying with its obligations under this CIA, Fresenius agrees to pay for the reasonable cost of any such review by the OIG or any of its designated agents. Prior to proceeding with such an independent review, the OIG shall notify Fresenius of its intent to do so and its reasons for believing such a review is necessary, and shall in good faith attempt to resolve any Billing Review issues without proceeding with an independent review. However, it shall remain in the sole discretion of the OIG to proceed with an independent review as described above.

11. Fresenius shall require that the IRO provide annual certifications that no IRO members or other employees who are involved in the IRO engagements with Fresenius hold direct or material indirect financial interests or other arrangements that would be considered to impair their independence under the standards of the AICPA Code of Professional Conduct and Security and Exchange Commission regulations and

policies. The annual certifications shall be included in the IRO's report to Fresenius and in the Annual Reports submitted by Fresenius to the OIG.

G. Confidential Disclosure Program. For the duration of this CIA, Fresenius shall maintain its "Compliance Action Line" or similar hotline however denominated (hereinafter referred to as the "Confidential Disclosure Program"). The Confidential Disclosure Program must include measures (e.g., a toll-free compliance telephone line) to enable Covered Persons and other individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Fresenius's policies, practices or procedures with respect to a Federal health care program, believed by the individual to be inappropriate (hereinafter "compliance disclosure"). Fresenius shall publicize the existence of the Confidential Disclosure Program to Covered Persons.

The Confidential Disclosure Program shall include a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communication. Upon receipt of a compliance disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary good faith inquiry into the allegations set forth in every compliance disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be

conducted. For any compliance disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice, and (2) provides an opportunity for taking corrective action, Fresenius shall conduct an internal review of the allegations set forth in such a compliance disclosure and ensure that proper follow-up is conducted.

The Compliance Officer shall maintain a confidential compliance disclosure log, which shall include a record and summary of each allegation received, the status of the respective investigations, and any corrective action taken in response to the investigation.

H. Ineligible Persons.

1. *Definition.* For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, suspended, debarred or otherwise ineligible to participate in the Federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the Federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.

2. *Screening Requirements.* Fresenius shall not hire as employees or engage as contractors any Ineligible Persons. To prevent hiring or contracting with any Ineligible Persons, Fresenius shall screen all prospective employees and prospective contractors prior to engaging their services by (i) requiring applicants to disclose whether

they are Ineligible Persons, and (ii) reviewing General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.arnet.gov/epls) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.dhhs.gov/progorg/oig) (these lists shall hereinafter be referred to as the "Exclusion Lists"). The employment or retention of all employees or contractors shall be contingent upon confirmation that the individual or entity is not an Ineligible Person.

3. *Review and Removal Requirement.* Within 90 days of the effective date of this CIA, Fresenius will review its list of current Covered Persons and Contractors against the Exclusion Lists. Thereafter, Fresenius will review the lists once semi-annually. If Fresenius has notice that a Covered Person or Contractor has become an Ineligible Person, Fresenius will remove such person from responsibility for, or involvement with, Fresenius's business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions*. If Fresenius has notice that a Covered Person is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract, Fresenius shall take all appropriate actions to ensure that the responsibilities of that Covered Person do not adversely affect the quality of care rendered to any patient or resident, or the accuracy of any claims submitted to any Federal health care program.

I. Notification of Proceedings. Within 30 days of discovery, Fresenius shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that Fresenius has committed a crime or has engaged in fraudulent activities. This notification shall be made within 30 days of the date that Fresenius receives notice of the investigation or proceeding and shall (to the extent known to Fresenius) include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Fresenius shall also provide written notice to OIG within 30 days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

J. Reporting.

1. *Reporting of Overpayments*. If, at any time, Fresenius determines that it has received an overpayment from a Federal health care program, Fresenius shall notify

the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of discovering the overpayment and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct any operational or policy deficiencies on Fresenius's part which may have caused the overpayments to occur, including preventing the underlying problem and the overpayments from recurring.

2. *Reporting to OIG.* If Fresenius determines that there is a Reportable Event, Fresenius shall notify the OIG within 30 days of such determination. Fresenius's notification to the OIG shall include the following information; provided however, that if the Reportable Event does not involve an overpayment, the requirements of a and b below do not apply:

a. all of the information provided to the payor in returning the overpayment;

b. the name and the address of the payor to whom the overpayment was returned;

c. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and program authorities;

d. Fresenius's actions to correct any operational or policy deficiency; and

e. any further steps Fresenius plans to take to address such operational or policy deficiency and prevent it from recurring.

3. *Definition of "Overpayment."* For purposes of this CIA, an "overpayment" means the amount of money the provider has received in excess of the amount due and payable under the Federal Rules.

4. *Definition of "Reportable Event."* For purposes of this CIA, a "Reportable Event" means anything that involves: (i) a substantial overpayment; (ii) a matter that a reasonable person would consider a potential violation of criminal, civil or administrative laws applicable to any Federal health care program for which penalties or exclusion are authorized; or (iii) a violation of the obligation to provide items or services of a quality that meet professionally recognized standards of health care where such violation has occurred in one or more instances that presents an imminent danger to the health, safety, or well-being of a Federal health care program beneficiary or places the beneficiary unnecessarily in a high-risk situation. A Reportable Event may be the result of an isolated event or a series of occurrences.

IV. NEW LOCATIONS

In the event, after the effective date of this CIA, that Fresenius purchases or establishes new locations or business units, which furnish health care items or services to beneficiaries of the Federal health care programs and are required by Federal Rules to obtain or maintain a separate provider or supplier number, Fresenius shall notify OIG of this fact through a report on a quarterly basis. This notification shall include the location

of the new operation(s), phone number, fax number, Federal health care program provider number(s) (if any), and the corresponding payor(s) (contractor specific) that has issued each provider number. All Covered Persons at such locations shall be subject to the requirements in this CIA that apply to new Covered Persons (e.g., training requirements). In the case of acquired facilities, the obligations of this CIA shall apply only to services or activities occurring after the effective date of the acquisition.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 180 days after the effective date of this CIA, Fresenius shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:

1. the name, address, phone number and position description of the Corporate Compliance Officer and the Business Unit Compliance Officers required by section III.A;
2. the names and positions of the members of the Compliance Committees required by section III.A;
3. a copy of Fresenius's Code of Conduct required by section III.B.1;
4. A copy of the Business Segment Compliance Guidelines required by section III.B.2 ;

5. a description of the training programs required by section III.C, including a description of the targeted audiences and a schedule of when the training sessions have been or will be held;

6. a certification by the Compliance Officer that, except as otherwise described in the Report:

a. the Business Segment Compliance Guidelines required by section III.B.2 have been completed and distributed to all pertinent Covered Persons;

b. new Covered Persons have completed the Code of Conduct certification required by section III.B.1; and

c. for training required under III.C.2 and C.6, all Covered Persons have completed the training and executed the certification required by section III.C; and for any other training under III.C, implementation steps are being taken consistent with the CIA.

7. a description of the Confidential Disclosure Program required by section III.G;

8. the identity of the Independent Review Organization(s) and the proposed start and completion date of the first audit; and

9. a summary of actions taken pursuant to section III.H.

B. Annual Reports. Fresenius shall submit to OIG Annual Reports with respect to the status and findings of Fresenius's compliance activities.

Each Annual Report shall include:

1. any change in the identity or position description of the Corporate Compliance Officer, the Business Unit Compliance Officer, members of the Compliance Committees described in section III.A or any other material change in the organization or management of the Company's corporate compliance program;

2. a certification by the Compliance Officer that, except as otherwise described in the Report:

   a. all Covered Persons have completed the annual Code of Conduct certification required by section III.B.1;

   b. all Covered Persons have completed the applicable training and executed the certification as required by section III.C; and

   c. Fresenius has complied with its obligations under the Settlement Agreements: (i) not to resubmit any previously denied claims related to the conduct addressed in the Settlement Agreements, and its obligation not to appeal any such denials of claims, and (ii) not to charge to or otherwise seek payment for unallowable costs (as

defined in the Settlement Agreements) and its obligation to identify and adjust any past charges of unallowable costs; and

d. Fresenius has complied with its obligations regarding Affiliates as required by section III.D.

3. notification of any material changes or amendments to the Business Segment Compliance Guidelines required by section III.B and the reasons for such changes (e.g., change in contractor policy);

4. a complete copy of the report prepared pursuant to the Independent Review Organization's billing and compliance reviews, including a copy of the methodologies used and a copy of the certification of IRO financial independence required under section III.F;

5. Fresenius's response/corrective action plan to any issues raised by the Independent Review Organization;

6. a summary of Reportable Events identified and reported throughout the course of the previous 12 months pursuant to III.J;

7. a report of the aggregate overpayments that have been returned to the Federal health care programs that were discovered as a direct or indirect result of implementing this CIA. Overpayment amounts should be broken

down into the following categories: Medicare, Medicaid (report each applicable state separately), and other Federal health care programs;

8. a copy of the confidential compliance disclosure log required by section III.G;

9. a description of any personnel action (other than hiring) taken by Fresenius as a result of the obligations in section III.H, and the name, title, and responsibilities of any person that falls within the ambit of section III.H.4, and the actions taken in response to the obligations set forth in that section;

10. a summary describing any ongoing investigation or legal proceeding that was required to have been reported pursuant to section III.I. The statement shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation, legal proceeding or requests for information;

11. a corrective action plan to address all Reportable Events (as defined in section III.J) identified over the previous 12 months;

12. a listing of all of Fresenius's locations or business units, which furnish health care items or services to beneficiaries of Federal health care programs and are required by Federal Rules to obtain or maintain a separate

provider or supplier number (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program provider identification number(s) and the payor (specific contractor) that issued each provider identification number; and

13. A copy of the annual review and analysis of the fair market value of the laboratory testing composite rate as required by section III.B.3.c.(5).

The first Annual Report shall be received by the OIG not later than April 1, 2001. The Reporting Periods for this CIA shall be as follows:

January 1, 2000 - December 31, 2000
January 1, 2001 - December 31, 2001
January 1, 2002 - December 31, 2002
January 1, 2003 - December 31, 2003
January 1, 2004 - December 31, 2004
January 1, 2005 - December 31, 2005
January 1, 2006 - December 31, 2006
January 1, 2007 - December 31, 2007

Subsequent Annual Reports shall be received by the OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer under penalty of law, that: (1) except as otherwise described in the Report, Fresenius is in compliance with all the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance Officer has

reviewed the Report and has made reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing subsequent to the effective date of this CIA, all notifications and reports required under this CIA shall be submitted to the entities listed below:

OIG:

Civil Recoveries Branch - Compliance Unit
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201
Phone 202.619.2078
Fax 202.205.0604

Fresenius:

John Markus
Senior Vice President - Corporate Compliance
Fresenius Medical Care North America
Two Ledgemont Center
95 Hayden Drive
Lexington, MA 02420
Phone: (781) 402-9359
Fax: (781) 402-9777

VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s), may examine Fresenius's books, records, and other documents and supporting materials and/or conduct an onsite review of any of Fresenius's facilities, units, or locations for the purpose of verifying and evaluating: (a) Fresenius's compliance with the terms of this CIA; and (b) Fresenius's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Fresenius to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Fresenius's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Fresenius agrees to assist OIG in contacting and arranging interviews with such individuals upon OIG's request. Fresenius's employees may elect to be interviewed with or without a representative of Fresenius present.

VIII. DOCUMENT AND RECORD RETENTION

Fresenius shall maintain for inspection all documents and records: (1) relating to reimbursement from the Federal health care programs for at least 7 years after the

submission of the request for reimbursement; and (2) necessary to establishing Fresenius's compliance with this CIA for at least three years following the submission of the Annual Report covering the relevant year.

IX. Disclosures and Privileges

Subject to HHS's Freedom of Information Act ("FOIA") procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify Fresenius prior to any release by OIG of information submitted by Fresenius pursuant to its obligations under this CIA and identified upon submission by Fresenius as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. With respect to the disclosure of such information, Fresenius shall have the rights set forth in 45 C.F.R. § 5.65(d). Fresenius shall refrain from identifying any information as trade secrets, commercial or financial information and privileged and confidential that does not meet the criteria for exemption from disclosure under FOIA.

Nothing in this CIA, or any communication or report made pursuant to this CIA, shall constitute a waiver of, or be construed to require Fresenius to waive its attorney-client, work product or other applicable privileges. Notwithstanding that fact, the existence of any such privilege does not affect Fresenius's obligation to comply with the provisions of this CIA.

X. BREACH AND DEFAULT PROVISIONS

Fresenius is expected to fully and timely comply with all of the obligations herein throughout the term of this CIA or other time frames herein agreed to.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Fresenius and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day, beginning 120 days after the effective date of this CIA and concluding at the end of the term of this CIA, Fresenius fails to have in place any of the following:

a. a Compliance Officer;

b. a Business Unit Compliance Officer for each Business Unit identified in Schedule A;

c. a Corporate Compliance Committee and Business Unit Compliance Committee for each Business Unit identified in Schedule A;

d. a written Code of Conduct;

e. written Business Segment Compliance Guidelines;

f. a training program; or

g. a Confidential Disclosure Program;

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Fresenius fails meet any of the deadlines to submit the Implementation Report or the Annual Reports to the OIG.

3. A Stipulated Penalty of $2,000 (which shall begin to accrue on the date the failure to comply began) for each day Fresenius:

a. hires or enters into a contract with an Ineligible Person at the time when that person is listed by a federal agency as excluded, debarred, suspended or otherwise ineligible for participation in the Federal health care programs (this Stipulated Penalty shall not be demanded for any time period during which Fresenius can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.H) as to the status of the person);

b. employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Fresenius's business operations related to the Federal health care programs or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (this Stipulated Penalty shall not be demanded for any time period during which

Fresenius can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.H) as to the status of the person).

4. A Stipulated Penalty of $1,500 (which shall begin to accrue on the date the Fresenius fails to grant access) for each day Fresenius fails to grant access to the information or documentation as required in section VII of this CIA.

5. A Stipulated Penalty of $1,000 (which shall begin to accrue 10 days after the date that OIG provides notice to Fresenius of the failure to comply) for each day Fresenius fails to comply fully and adequately with any obligation of this CIA, where the failure to comply does not form the basis for Stipulated Penalties under the provisions of section X.A.1 through X.A.4. In its notice to Fresenius, OIG shall state the specific grounds for its determination that the Fresenius has failed to comply fully and adequately with the CIA obligation(s) at issue. With respect to the Stipulated Penalty provision described in this section X.A.5 only, the OIG shall not seek a Stipulated Penalty if Fresenius demonstrates to the OIG's satisfaction that the alleged failure to comply could not be cured within the 10-day period, but that: (i) Fresenius has begun to take action to cure the failure to comply, (ii) Fresenius is pursuing such action with due diligence, and (iii) Fresenius has provided to OIG a reasonable timetable for curing the failure to comply.

B. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Fresenius has failed to comply with any of the obligations described in section X.A and determining that Stipulated Penalties are appropriate, OIG shall notify Fresenius by personal service or certified mail of (a) Fresenius's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

Within ten (10) days of receiving the Demand Letter, Fresenius shall either (a) cure the breach to the OIG's satisfaction and pay the applicable stipulated penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.D. In the event Fresenius elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Fresenius cures, to the OIG's satisfaction, the alleged breach in dispute; however, the payment of such accrued Stipulated Penalties shall remain pending until the ALJ determination. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under section X.C.

2. *Timely Written Requests for Extensions.* Fresenius may submit a timely written request for an extension of time to perform any act or file any notification or

report required by this CIA. Notwithstanding any other provision in this section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Fresenius fails to meet the revised deadline set by the OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until two business days after Fresenius receives OIG's written denial of such request. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in section VI.

4. *Independence from Material Breach Determination.* Except as otherwise noted, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for the OIG's determination that Fresenius has materially breached this CIA, which decision shall be made at the OIG's discretion and governed by the provisions in section X.C, below.

C. Exclusion for Material Breach of this CIA

1. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Fresenius constitutes an independent basis for Fresenius's exclusion from participation in the Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). Upon a determination by OIG that Fresenius has materially breached this CIA and that exclusion should be imposed, the OIG shall notify Fresenius by certified mail of (a) Fresenius's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

2. *Opportunity to cure.* Fresenius shall have 30 days from the date it receives the Notice of Material Breach and Intent to Exclude to demonstrate to the OIG's satisfaction that:

a. Fresenius is in full compliance with this CIA;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Fresenius has begun to take action to cure the material breach, (ii) Fresenius is pursuing such action with due diligence, and (iii) Fresenius has provided to OIG a reasonable timetable for curing the material breach.

3. *Exclusion Letter.* If at the conclusion of the 30-day period, Fresenius fails to satisfy the requirements of section X.C.2, OIG may exclude Fresenius from participation in the Federal health care programs. OIG will notify Fresenius in writing of its determination to exclude Fresenius (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.D below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and will also apply to all other federal procurement and non-procurement programs. If Fresenius is excluded under the provisions of this CIA, Fresenius may seek reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.

4. *Material Breach.* A material breach of this CIA means:

a. a failure by Fresenius to report a Reportable Event, take corrective action and pay the appropriate refunds, as provided in section III.J;

b. repeated or flagrant violations of the obligations under this CIA, including, but not limited to, the obligations addressed in section X.A of this CIA;

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section X.B above; or

d. a failure to retain and use an Independent Review Organization for review purposes in accordance with section III.F.

D. Dispute Resolution

1. *Review Rights.* Upon the OIG's delivery to Fresenius of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this CIA, Fresenius shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, the OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days of the receiving the Demand Letter and the request for a hearing involving exclusion shall be made within 30 days of the date of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be (a) whether Fresenius was in full and timely compliance with the obligations of this CIA for which

OIG demands payment; (b) the period of noncompliance and (c) with respect to a Stipulated Penalty authorized under section X.A.5 only, whether the failure to comply could not be cured within the 10-day period, but that by the end of that period (i) Fresenius had begun to take action to cure the failure to comply, (ii) Fresenius was and is pursuing such action with due diligence, and (iii) Fresenius had provided to OIG a reasonable timetable for curing the material breach which is being followed. Fresenius shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ finds for OIG with regard to a finding of a breach of this CIA and orders Fresenius to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision notwithstanding that Fresenius may request review of the ALJ decision by the DAB.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be (a) whether Fresenius was in material breach of this CIA; (b) whether such breach was continuing on the date of the Exclusion Letter; and (c) whether the alleged material breach could not have been cured within the 30 day period, but that (i) Fresenius had begun to take action to cure the material breach within that period, (ii) Fresenius has pursued and is pursuing such action with due diligence, and (iii) Fresenius provided to OIG within that period a

reasonable timetable for curing the material breach. For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision that is favorable to the OIG. Fresenius's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Fresenius upon the issuance of the ALJ's decision. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Fresenius may request review of the ALJ decision by the DAB.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, Fresenius and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of Fresenius;

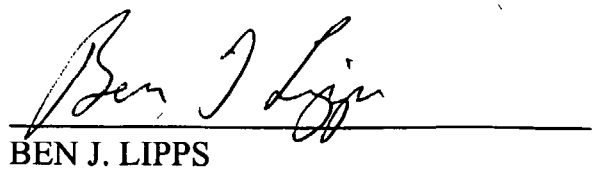
B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

C. No modifications to this CIA shall be made without the prior written consent of the parties to this CIA;

D. This CIA supersedes the CIA entered into between the OIG and Spectra Laboratories, Inc. executed on December 10, 1996 rendering the Spectra CIA no longer in effect.

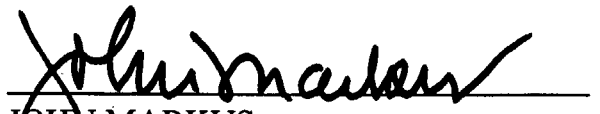
E. The undersigned Fresenius signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF FRESENIUS



BEN J. LIPPS
President
Fresenius Medical Care Holdings, Inc.

1/18/00
DATE



JOHN MARKUS
Senior Vice President - Corporate Compliance
Authorized Signatory for
Fresenius Medical Care Holding, Inc.

1/18/00
DATE

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

LEWIS MORRIS
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

1/18/00
DATE