CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
GAMBRO HEALTHCARE, INC.

I. PREAMBLE

Gambro Healthcare, Inc. together with its indirect, direct, wholly-owned, and partially-owned subsidiaries and joint ventures in which Gambro Healthcare, Inc. owns an interest of 5 per cent or greater that provide outpatient dialysis services, including any holding companies owned by Gambro Healthcare, Inc., which in turn own the clinics providing outpatient dialysis services, and their predecessors and successors, (collectively, Gambro) 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 promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, Gambro is entering into Settlement Agreements with the United States in the Eastern District of Missouri, and the Eastern District of Pennsylvania, and this CIA is incorporated by reference into those Settlement Agreements.

Prior to the execution of this CIA, Gambro established a Corporate Compliance Program (Compliance Program). This Compliance Program includes policies and procedures, an education and training component, mechanisms for ongoing monitoring and auditing of Gambro operations to assess compliance, mechanisms for employees and agents to report incidents of noncompliance in an anonymous way, disciplinary actions for individuals violating compliance policies and procedures, and oversight of the compliance program by the Gambro Compliance Officer, Division Compliance Officers, and Gambro's Compliance Committee. Gambro agrees to continue to operate its Compliance Program for the term of this CIA. The Compliance Program may be modified as appropriate but, at a minimum, shall comply with the integrity obligations enumerated in this CIA.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Gambro under this CIA shall be 5 years from the effective date of this CIA, unless otherwise specified. The effective date of this CIA shall be the effective date of the Settlement Agreement between the United States Attorney's Office for the Eastern District of Missouri and Gambro. (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Gambro's final annual report; or (2) any additional materials submitted by Gambro pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "Gambro Clinic" includes each outpatient dialysis clinic in which Gambro owns an interest of 5 percent or greater.

2. "Covered Persons" includes:

a. all officers, directors, and employees of Gambro;

b. all contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions related to patient care on behalf of Gambro;

c. all Gambro Clinic medical directors (Medical Directors); and

d. all physicians credentialed and privileged as active staff with Gambro who do not serve as Medical Directors (Covered Physicians).

Notwithstanding the above, with the exception of Medical Directors and Covered Physicians, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons 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 the calendar year.

3. "Relevant Covered Persons" shall include:

a. *Negotiators*: all Covered Persons who approve Arrangements, and shall include Regional Directors, Regional Vice Presidents, Materials Management Personnel, Legal Personnel, Compliance Personnel, and Executives of Gambro;

b. *Programmers*: all Covered Persons involved in the design or programming of systems that impact diagnosis or procedure coding, reimbursement, billing, or clinical documentation (collectively, Relevant Software);

c. *Billers*: all Covered Persons who input, code, or bill claims;

d. *Medical Directors:* the medical directors of all Gambro Clinics;

e. *Clinic Compliance Liaisons*: all Covered Persons designated by Gambro to act as liaison between a Gambro Clinic and the Compliance Officer, as defined at Section III.A.3 below; and

f. *Human Resources Staff*: all Covered Persons involved directly in human resource functions that include (1) excluded person background checks and/or (2) intake of Human Resource Employee Hotline telephone calls, and all Covered Persons who manage or supervise such Covered Persons.

4. "Arrangements" includes every arrangement or transaction that (a) involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and (b) is between Gambro and any actual or potential source of health care business or referrals to Gambro or any actual or potential recipient of health care business or referrals from Gambro. The term "source" shall mean any physician, contractor, vendor, or agent, and the term "health care business or referrals" shall be read to include referring, recommending, arranging for, ordering, leasing, or purchasing of any good, facility, item, or service for which payment may be made in whole or in part by Medicare, Medicaid, or any other Federal health care program (as defined in 42 U.S.C. § 1320a-7b(f)). The other party to an Arrangement shall be referred to herein as a "Contractor."

III. CORPORATE INTEGRITY OBLIGATIONS

Gambro shall maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* Gambro certifies that it has appointed an individual to serve as the Compliance Officer for Gambro. Gambro shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of Gambro, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Gambro, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall not be, or be subordinate to, the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Gambro as well as for any reporting obligations created under this CIA.

Gambro shall not assert a privilege to the OIG with respect to legal advice or counsel Gambro obtains regarding Federal health care programs or Gambro's compliance with the terms of this CIA from the Compliance Officer or any employee reporting to the Compliance Officer. The Compliance Officer or any employee reporting to the Compliance Officer may seek legal advice without advance waiver of any applicable privilege from attorneys outside the Compliance Department.

Gambro shall report to OIG, in writing, any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

2. *Compliance Committee.* Gambro certifies that it has a Compliance Committee in place that includes the Gambro Compliance Officer and other members of senior management (senior executives supervising relevant departments, such as billing, clinical, human resources, audit, and operations) necessary to meet the requirements of

this CIA. The Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (*e.g.*, shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).
Gambro shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

3. *Clinic Compliance Liaison.* Gambro shall designate the regional director for each Gambro Clinic to act as Clinic Compliance Liaison (CCL). CCLs shall be responsible for overseeing compliance efforts at the clinic level. CCL duties shall include ensuring that clinic staff members complete applicable CIA and compliance-related activities in a timely and effective manner and working with the Compliance Officer to increase compliance awareness at the clinic level. The Compliance Officer shall maintain a list of all CCLs and the Gambro Clinics for which each CCL is responsible. This list shall be made available to OIG upon request.

B. Written Standards.

1. *Standards of Business Conduct.* Gambro has represented to OIG that it has a Standards of Business Conduct, and provided a copy of said document to OIG. Within 120 days after the Effective Date, Gambro shall revise, as necessary, and make available the written Standards of Business Conduct to all Covered Persons, except Medical Directors and Covered Physicians. Gambro shall make the promotion of, and adherence to, the Standards of Business Conduct a requirement of continued employment and an element in evaluating the performance of all employees where performance evaluations are conducted. The Standards of Business Conduct shall, at a minimum, set forth:

a. Gambro's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;

b. Gambro's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Gambro's own Policies and Procedures as implemented pursuant to this Section III.B (including the requirements of this CIA);

c. the requirement that all of Gambro's Covered Persons shall be expected to report to the Compliance Officer or other appropriate individual designated by Gambro suspected violations of any Federal health care program requirements or of Gambro's own Policies and Procedures;

d. the possible consequences to both Gambro and Covered Persons of failure to comply with Federal health care program requirements and with Gambro's own Policies and Procedures and the failure to report such noncompliance; and

e. the right of all individuals to use the Disclosure Program described in Section III.F, and Gambro's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 120 days after the Effective Date, each Covered Person, except Medical Directors and Covered Physicians, shall certify, in writing or electronically, that he or she has been provided electronic access to, and training on, and shall abide by Gambro's Standards of Business Conduct. New Covered Persons, except Medical Directors and Covered Physicians, shall receive the training and access to the Standards of Business Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

Within 60 days of the Effective Date, Gambro shall provide each Medical Director and Covered Physician a copy of the Compliance Critical Concepts as well as electronic access to Gambro's Standards of Business Conduct. This document will cover the topics discussed in Section III.B.1. New Medical Directors and Covered Physicians shall receive a copy of the Compliance Critical Concepts and electronic access to Gambro's Standards of Business Conduct within 30 days after becoming a Medical Director or Covered Physician or within 60 days after the Effective Date, whichever is later. In addition, Gambro shall obtain certification from Medical Directors and Covered Physicians through training and in accordance with the requirements specified in Sections III.C.3 and III.C.4.

Gambro shall periodically review the Standards of Business Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review.

Any revised Standards of Business Conduct shall be distributed within 30 days after any revisions are finalized.

2. *Policies and Procedures*. Within 120 days after the Effective Date, Gambro shall review, and where appropriate revise, its written Policies and Procedures regarding the operation of Gambro's compliance program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

a. the subjects relating to the Standards of Business Conduct identified in Section III.B.1;

b. the applicability of Federal health care program requirements to Gambro's various business activities, including the negotiation of Arrangements, the designing and programming of Relevant Software, and the billing and coding of claims;

c. 42 U.S.C. § 1320a-7b(b) (the "Anti-Kickback Statute"), and the regulations and other guidance documents related to the Anti-Kickback Statute, and business or financial arrangements or contracts that induce the unlawful referral of Federal health care program beneficiaries in violation of the Anti-Kickback Statute;

d. the requirements set forth in Sections III.D and E; and

e. the billing of Stat Lab tests, as defined in Appendix E, in a manner that will protect the Federal health care program from overpayments.

Within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be made available to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Gambro shall assess and update as necessary the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be made available to all individuals whose job functions relate to those Policies and Procedures.

C. Training and Education.

1. *General Training*. Within 120 days after the Effective Date, Gambro shall provide at least two hours of General Training to each Covered Person, excluding Medical Directors and Covered Physicians. This training, at a minimum, shall explain:

a. Gambro's CIA requirements; and

b. Gambro's Compliance Program (including the Standards of Business Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training annually in subsequent Reporting Periods.

If, pursuant to Gambro's Compliance Program, Gambro has provided General Training to Covered Persons that satisfies the requirements set forth above in Section III.C.1 within one (1) month prior to the Effective Date, the OIG shall credit the training for purposes of satisfying Gambro's General Training obligations for the first Reporting Period of this CIA.

2. *Specific Training*. Within 150 days after the Effective Date, the following Specific Training shall be provided to the applicable Relevant Covered Persons.

a. *Negotiation Training*: Each Negotiator shall receive at least two hours of Negotiation Training in addition to the General Training required above. This Negotiation Training shall include a discussion of:

i. the legal sanctions and consequences for improper contracting or financial arrangements;

ii. examples of violations of the Anti-Kickback Statute;

iii. a review of Gambro's contracting Policies and Procedures related to Arrangements, as defined in Section II.C.3 above and as developed pursuant to Sections III.B.2 and III.D, and the personal obligation of each individual involved in the development or maintenance of Arrangements to know applicable legal requirements and Gambro's Policies and Procedures; and

iv. the specific applicability of the Anti-Kickback Statute, Federal health care program requirements, and Gambro policies and procedures to the negotiation and maintenance of all types of Arrangements entered into by Gambro, including joint ventures with physicians and Federal health care providers, Medical Director contracts, and physician credentialing.

b. *Billing Training*: Each Biller shall receive at least two hours of Billing Training, which shall include a discussion of:

i. the Federal health care program requirements regarding the accurate coding and submission of claims;

ii. policies, procedures, and other requirements applicable to the documentation of medical records;

iii. the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate;

iv. applicable reimbursement statutes, regulations, and program requirements and directives;

v. the legal sanctions for violations of the Federal health care program requirements; and

vi. examples of proper and improper claims submission practices.

c. *Programming Training*: Each Programmer shall receive at least one hour of Programming Training, which shall include a discussion of:

i. the obligation of each Programmer to comply with all Federal health care program rules and regulations;

ii. the Federal health care program requirements regarding the accurate coding and submission of claims;

iii. Federal health care program requirements, internal Policies and Procedures, and other requirements applicable to the documentation of medical records;

iv. the process by which Gambro codes claims for reimbursement by Medicare and Medicaid;

v. the effect of programming and design choices on the submission of claims to Medicare and Medicaid;

vi. the legal, regulatory, and internal Gambro sanctions for improper conduct; and

vii. examples of proper and improper conduct.

The Programming Training shall be designed to assist each Programmer in recognizing the potential effects of Programming decisions on Gambro's compliance with Federal health care program requirements, *e.g.* how a Relevant Software program or program element might cause Gambro to engage in noncompliant acts or result in the submission of a false or inaccurate claim to Medicare or Medicaid.

d. *CCL Training*: Each CCL shall receive one hour of CCL Training, which shall include a discussion of:

i. the purpose of the CIA;

ii. the obligations of Clinic staff members under the CIA;

iii. the role of the Compliance Officer and compliance staff;

iv. the role and availability of Gambro's Disclosure Program; and

v. methods of explaining the importance of, and encouraging the practice of, compliance and CIA requirements to Clinic staff.

e. *Human Resources Personnel Training*. Each Human Resources Staff member shall receive one hour of training, which shall include a discussion of the following:

i. statutes and regulations pertaining to the exclusion of individuals and companies from the Federal health care programs;

ii. the legal consequences to Gambro of employing or contracting with excluded individuals or companies;

iii. Gambro's Disclosure Program, with specific reference to the purpose and operation of the Employee Hotline;

iv. the role and duties of the Compliance Officer; and

iv. the identification and referral of compliance complaints or matters to the Compliance Officer.

Relevant Covered Persons shall receive the applicable Specific Training within 60 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later. A Gambro employee who has completed the applicable Specific Training shall supervise a new Relevant Covered Person's work, to the extent that the work relates to the topics covered by the applicable Specific Training, until such time as the new Relevant Covered Person completes his or her applicable Specific Training.

If, pursuant to Gambro's Compliance Program, Gambro has provided Specific Training to Covered Persons that satisfies the requirements set forth above in Section III.C.2 within four (4) months prior to the Effective Date, the OIG shall credit the training for purposes of satisfying Gambro's Specific Training obligations for the first Reporting Period of this CIA.

After receiving the initial applicable Specific Training described in this Section, each Relevant Covered Person shall receive, as applicable, at least two hours of Negotiation Training, one hour of Billing Training, one hour of Programming Training, one hour of CCL Training, and/or one hour of Human Resources Staff Training annually in subsequent Reporting Periods.

3. *Medical Director Training:* Within seven months after the Effective Date, Gambro shall develop and implement a special Medical Director training and education program (Medical Director Training). Medical Directors shall only be required to receive the Medical Director Training delineated in this Section III.C.3, which shall include two hours of Initial Medical Director Training covering:

a. the purpose of the CIA;

b. Gambro's compliance program (including the Standards of Business Conduct and the Policies and Procedures as they pertain to Medical Directors);

c. medical necessity and coverage requirements of the Federal health care programs;

d. documentation requirements of the Federal health care programs;

e. the requirements of the Anti-Kickback Statute;

f. the legal consequences to Gambro and Medical Directors of Anti-Kickback Statute violations; and

g. other Federal health care program requirements and Gambro policies and procedures directly related to the duties and responsibilities of Medical Directors.

After receiving the Initial Medical Directors Training, each Medical Director shall receive at least two hours of Supplemental Medical Director Training annually in subsequent Reporting Periods, which shall review the topics covered in the Initial Medical Director Training and include material changes in Federal health care program requirements, changes in Gambro policies and procedures, and changes in the Gambro corporate compliance program.

All new contracts or contract amendments between Gambro and its Medical Directors executed after the Effective Date of this CIA shall include a specific obligation on the part of the Medical Director to receive at least two hours of Initial Medical Director Training within seven months after the Effective Date or within 60 days after beginning to provide medical director services under the first new contract or contract amendment executed on or after the Effective Date, whichever is later; and thereafter the annual Supplemental Medical Director Training. For all other contracts between Gambro and its Medical Directors that are in force on the Effective Date, Gambro shall provide the Initial Medical Director Training and annual Supplemental Medical Director Training to the Medical Directors as set forth in this Paragraph and use its best efforts to encourage attendance and participation by the Medical Directors.

Each Medical Director who attends Medical Director Training shall certify, in writing, (or in electronic form, if they have received computer-based training) that he or she has received the training. The certification shall specify the type of training received and the date received. The Compliance Officer shall retain the certifications, along with all course materials. The certifications shall be made available to OIG, upon request.

The Compliance Officer shall also maintain records of the number of Medical Directors and the percentage of Medical Directors who attend Medical Director Training, and shall provide such records to OIG as part of its Implementation and Annual Reports.

4. *Covered Physician Training* Within six months of the Effective Date, Gambro shall develop and implement a special Covered Physician training and education program (Covered Physician Training). Covered Physicians shall only be required to receive the Covered Physician Training delineated in this Section III.C.4, which shall include two hours of Initial Covered Physician Training covering:

a. the purpose of the CIA;

b. Gambro's compliance program (including the Standards of Business Conduct and the Policies and Procedures as they pertain to Covered Physicians);

c. medical necessity and coverage requirements of the Federal health care programs;

d. documentation requirements of the Federal health care programs;

e. the requirements of the Anti-Kickback Statute;

f. the legal consequences to Gambro and Covered Physicians of Anti-Kickback Statute violations; and

g. other Federal health care program requirements and Gambro policies and procedures directly related to the duties and responsibilities of Covered Physicians.

After receiving the Initial Covered Physician Training, each Covered Physician shall receive at least two hours of Supplemental Covered Physician Training in subsequent Reporting Periods, which shall review the topics covered in the Initial Covered Physician Training and include material changes in Federal health care program requirements, changes in Gambro policies and procedures, and changes in the Gambro corporate compliance program.

Gambro shall make Covered Physician Training available to all Covered Physicians, and shall use its best efforts to encourage their attendance and participation at such training. Each Covered Physician who attends Covered Physician Training shall certify, in writing, (or in electronic form, if they have received computer-based training) that he or she has received the training. The certification shall specify the type of training received and the date received. The Compliance Officer shall retain the certifications, along with all course materials. The certifications shall be made available to OIG, upon request.

The Compliance Officer shall also maintain records of the number of Covered Physicians and the percentage of Covered Physicians who attend Covered Physician Training, and shall provide such records to OIG as part of its Implementation and Annual Reports.

5. *Certification.* Each individual who is required to attend training shall certify, in writing, or in electronic form, if applicable, 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 (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG upon request.

6. *Qualifications of Trainer.* Persons providing the training (Trainers) shall be knowledgeable about the subject area.

7. *Update of Training.* Gambro shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or the IRO Claims Review, Unallowable Cost Review, Stat Lab Systems Review, Arrangements Review, or Heightened Arrangements Review, and any other relevant information.

8. *Computer-based Training.* Gambro may provide the training required under this CIA through appropriate computer-based training approaches. If Gambro chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or Trainers to answer questions or provide additional information to the individuals receiving such training.

9. *Self-Guided Study.* All training, except for Computer-based Training, shall be conducted as a class by a Trainer, unless otherwise agreed upon in writing by OIG.

D. Contractual Compliance With the Anti-Kickback Statute.

This Section applies to all Arrangements, as defined at Section II.C.3. As used in this Section, Arrangements shall also refer to all written versions of Arrangements. The party(ies) to an Arrangement other than Gambro shall be referred to herein as a "Contractor."

1. *Arrangements Procedures.* Within 120 days after the Effective Date, Gambro shall create procedures reasonably designed to ensure that each Arrangement does not violate the Anti-Kickback Statute. Within 210 days after the Effective Date, Gambro shall implement the procedures. As part of these procedures Gambro shall ensure that the following requirements are implemented for each Arrangement:

a. the Arrangement shall be set forth in writing and signed by Gambro and the Contractor(s);

b. Gambro shall make available to all individuals who meet the definition of Covered Persons the applicable training, as set forth in Section III.C; and

c. Gambro shall provide each Contractor with a copy of its Critical Compliance Concepts and Anti-Kickback Policies and Procedures.

Gambro shall create an appropriate corrective action plan for any existing Arrangement that does not meet the requirements set forth above or that violate the Anti-Kickback Statute.

2. *Relevant Arrangements Review.* Within 210 days after the Effective Date, Gambro shall create a database following the instructions set forth in Appendix A pertaining to all Relevant Arrangements, as defined in Appendix A. This database shall be available for OIG review upon request. Gambro shall create an appropriate corrective action plan for any Relevant Arrangement that does not meet the requirements set forth at Section III.D.1 or that violates the Anti-Kickback Statute.

3. *New Arrangements and Renewed Existing Arrangements.* Prior to entering into any new Arrangements or renewing any existing Arrangements, Gambro shall ensure that the Arrangements do not violate the Anti-Kickback Statute. In addition to the requirements set forth in Section III.D.1, Gambro shall also ensure that all new Arrangements and renewed existing Arrangements comply with the following requirements:

a. the Arrangement shall include a provision that all individuals who meet the definition of Covered Persons shall comply with Gambro's Compliance Program, including the training related to the Anti-Kickback Statute;

b. Gambro shall certify and shall require Contractor(s) to certify, at the time of signing the Arrangement, and upon contract renewal, that the Arrangement is not intended to generate referrals for services or supplies for which payment may be made in whole or in part under any Federal health care program; and

c. Gambro shall require the Contractor(s) to certify, at the time of signing the Arrangement, that the Contractor(s) shall comply with Gambro's compliance program and with the Anti-Kickback Statute in all matters involving Gambro.

4. *Heightened Review of Arrangements.* During each of the five Reporting Periods, Gambro shall perform Heightened Arrangements Review on its existing Relevant Arrangements. The Heightened Arrangements Review shall consist of three separate samples (Arrangement Samples). The Arrangement Samples shall be selected according to the procedure set forth in Appendix B. The Heightened Arrangements Review shall consist of an investigation on the initiation, negotiation, maintenance, performance, and, if relevant, dissolution of each Relevant Arrangement in the Arrangement Samples. The Heightened Arrangements Review shall be conducted according to the instructions set forth in Appendix B.

5. *Heightened Arrangements Review Report.* Gambro shall prepare a summary of its findings from the Heightened Arrangements Review (Heightened Arrangements Review Report). The Heightened Arrangements Review Report shall be included in Gambro's Annual Report to the OIG.

6. *Documents Related to Arrangements.*

a. Gambro shall retain for a period of six years, and make available to OIG upon request: (1) copies of all Arrangements subject to Section III.D; and (2) all non-privileged documents and communications relating to the Arrangements and the actual performance of duties under the Arrangements.

b. Nothing in this CIA, or any other communication or report made pursuant to the CIA, shall constitute a waiver by Gambro of its attorney-client, attorney-work product, or other applicable privileges. Notwithstanding that fact, the existence of any such privilege shall not be used by Gambro to avoid its obligations to comply with the provisions of this CIA.

c. With respect to the documents reviewed, created, used, or relied upon in connection with the Heightened Arrangements Review, Gambro shall not assert any rights or privileges that may otherwise apply to the production of such documents to the OIG.

E. Review Procedures.

1. *Independent Review Organization*

a. *Engagement of Independent Review Organization.*

i. Within 120 days after the Effective Date, Gambro shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist Gambro in assessing and evaluating its billing and coding practices pursuant to the obligations of this Agreement and the Settlement Agreement. The applicable requirements relating to the IRO are outlined in Appendix C to this Agreement, which is incorporated by reference.

Each IRO engaged by Gambro shall have expertise in the billing, coding, reporting, and other requirements of the Federal health care programs' end-stage renal disease benefit and in the general requirements of the Federal health care program(s) from which Gambro seeks reimbursement. Each IRO shall assess, along with Gambro, whether it can perform the IRO review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist.

ii. In the second or any subsequent Reporting Period Gambro may submit to OIG a request to conduct internal reviews of the billing review required by Sections III.E.2 and III.E.3 (the "Billing Review"). At the sole discretion of OIG, Gambro may perform the Billing Review for the first six months of the Reporting Period, which Billing Review shall comply with all of the requirements outlined in Sections III.E.2 and III.E.3. Gambro shall submit such Billing Review to OIG within eight (8) months after the beginning of the Reporting Period. The Billing Review performed by Gambro shall also include a

report from an IRO that verifies that the Billing Review requirements have been satisfied. As part of any such verification performed by an IRO under this CIA, the IRO shall conduct a review of at least 20% of the claims reviewed by Gambro in performing its internal review. If, in its sole discretion, OIG determines that such internal review satisfactorily establishes the adequacy of Gambro's billing practices pursuant to this CIA, OIG may allow Gambro to perform the Billing Review (with verification from the IRO) covering the second six months of the second Reporting Period in conformance with Section III.E.2 and III.E.3 in lieu of the IRO conducting the Billing Review for the entire second Reporting Period. Similarly, OIG may, in its sole discretion, allow Gambro to continue to perform the Billing Review (with verification by the IRO) in conformance with Sections III.E.2 and III.E.3 for the remaining Reporting Periods of this CIA in lieu of the IRO conducting the Billing Review for those Reporting Periods. To the extent that OIG permits Gambro to perform the Billing Review, then Gambro must submit all the information required in the sections of this CIA governing the Billing Review performed (Sections III.E.2 and/or III.E.3), as well as the results of the IRO's verification.

b. General Review Procedures.

i. *Reviews*. The IRO(s) review shall evaluate and analyze:

A. Gambro's coding, billing, and claims submission to the Federal health care programs and the reimbursement received (Claims Review);

B. whether Gambro sought payment for certain unallowable costs (Unallowable Cost Review); and

C. Gambro's requests for Stat Lab services and whether any double billing has occurred for laboratory

tests performed as Stat Lab tests (Stat Lab Systems Review).

ii. *Frequency of Claims and Stat Lab Systems Review.* The Claims Review and the Stat Lab Systems Review shall be performed annually and shall cover each of the Reporting Periods. The IRO(s) shall perform all components of each annual Claims Review and Stat Lab Systems Review, except by prior agreement with OIG under the provisions set forth elsewhere in this CIA.

iii. *Frequency of Unallowable Cost Review.* If applicable, the IRO shall perform the Unallowable Cost Review for the first Reporting Period.

c. *Retention of Records.* The IRO and Gambro shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Gambro) related to the reviews.

2. Claims Review. The Claims Review shall include a Discovery Sample and, if necessary, a Full Sample. The applicable definitions, procedures, and reporting requirements are outlined in Appendix D to this Agreement, which is incorporated by reference.

a. *Discovery Sample.* The IRO shall randomly select and review a sample of 10 Beneficiary Paid Claims from each of the Clinics in the Sampling Frame.

All the Paid Claims shall be reviewed based on the supporting documentation available at Gambro's office or under Gambro's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed.

i. If the Error Rate (as defined in Appendix D) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The

guidelines listed above do not imply that this is an acceptable error rate. Accordingly, Gambro should, as appropriate, further analyze any errors identified in the Discovery Sample. Gambro recognizes that OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample or any other segment of the universe.)

ii. If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall perform a Full Sample and a Systems Review, as described below.

b. *Full Sample.* If necessary, as determined by procedures set forth in Section III.E.2.a, the IRO shall perform an additional sample of Beneficiary Paid Claims using commonly accepted sampling methods and in accordance with Appendix D. The Full Sample shall be designed to: (i) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate; and (ii) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on supporting documentation available at Gambro's office or under Gambro's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, Gambro may use the Beneficiary Paid Claims sampled as part of the Discovery Sample, and the corresponding findings for those 10 Beneficiary Paid Claims from each of the Clinics in the Sampling Frame, as part of its Full Sample, if: (i) statistically appropriate and (ii) Gambro selects the Full Sample Items using the seed number generated by the Discovery Sample. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from Gambro to the appropriate Federal health care program payor, including the Medicare contractor (*e.g.*, fiscal intermediary), for appropriate follow-up by that payor.

c. *Systems Review.* If Gambro's Discovery Sample identifies an Error Rate of 5% or greater, Gambro's IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO shall perform a "walk through" of the system(s) and process(es), that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

d. *Repayment of Identified Overpayments.* In accordance with Section III.I.1 of this Agreement, Gambro shall repay within 30 days any Overpayment(s) identified in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. Gambro shall make available to OIG any and all documentation and the associated documentation that reflects the refund of the Overpayment(s) to the payor.

3. Claims Review Report. The IRO shall prepare a report based upon the Claims Review performed (Claims Review Report). Information to be included in the Claims Review Report is described in Appendix D.

4. Unallowable Cost Review. If applicable, the IRO shall conduct a review of Gambro's compliance with the unallowable cost provisions of the Settlement Agreement. The IRO shall determine whether Gambro has complied with its obligations not to charge to, or otherwise seek payment from, federal or state payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable federal or state payors any unallowable costs included in payments previously sought from the United States, or any state Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Gambro or any affiliates. To the extent that such cost reports, cost statements, information reports, or payment requests, even if already settled, have been adjusted to account for the effect of the inclusion of the unallowable costs, the IRO shall determine if such adjustments were proper. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous years.

5. Unallowable Cost Review Report. If applicable, the IRO shall prepare a report based upon the Unallowable Cost Review performed. The Unallowable Cost Review Report shall include the IRO's findings and supporting rationale regarding the Unallowable Costs Review and whether Gambro has complied with its obligation not to charge to, or otherwise seek payment from, federal or state payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable federal or state payors any unallowable costs included in payments previously sought from such payor.

6. Stat Lab Systems Review. The Stat Lab Systems Review shall consist of a review of Stat Lab requisitions, invoices and associated Stat Lab agreements, where available. The purpose of this review is to identify Overpayments for Stat Lab tests through an examination of systems and processes connected to the billing of Stat Lab tests to Federal health care programs. The applicable definitions, procedures, and reporting requirements are outlined in Appendix E to this Agreement, which is incorporated by reference.

a. Sample Selection. The IRO shall randomly select and review a sample of 50 Stat Lab Requisitions from the Sampling Frame.

b. Review Process. All Stat Lab Requisitions shall be reviewed based on the supporting documentation available at Gambro's office or under Gambro's control.

i. Each Stat Lab requisition shall be reviewed for instructions for billing, test results, indication of billing by the Stat Lab to Gambro, and Stat Lab agreements, where available (collectively, Stat Lab Files). For each Stat Lab test where there is no indication that the laboratory billed Gambro for the Stat Lab test, the IRO shall determine whether an Overpayment occurred through reimbursement under the composite rate. Upon determination of that an Overpayment exists, Gambro shall repay within 30 days any amounts due to the appropriate payor and in accordance with payor refund policies as required Section III.I.1. Gambro shall make available to OIG any and all documentation and the associated documentation that reflects the repayment of the Overpayment(s) to the payor.

ii. If there are Overpayments, incomplete Stat Lab Files, or no indication of appropriate billing by the Stat Lab, Gambro should further analyze and determine the root cause of any deficiencies identified in the Sample. In conjunction with the IRO, Gambro will develop improvements to the system(s) and process(es) that created the deficiency.

During subsequent Reporting Periods, Gambro shall submit a workplan for OIG approval setting forth a modified systems review for Stat Lab Systems Review. In the third or any subsequent Reporting Period, Gambro may request that the Stat Lab Systems Review be discontinued. The decision to discontinue the Stat Lab Systems Review shall be at the sole discretion of OIG.

7. Stat Lab Systems Review Report. The IRO shall prepare a report based upon the Stat Lab Systems Review performed (Stat Lab Systems Review Report). Information to be included in the Stat Lab Systems Review Report is described in Appendix E.

8. Validation Review. In the event OIG has reason to believe that: (a) Gambro's Heightened Arrangements Review, Claims Review, Unallowable Cost Review, or Stat Lab Systems Review fails to conform to the requirements of this Agreement; or (b) Gambro's or the IRO's findings or Heightened Arrangements Reviewed results, Claims Review results, Unallowable Cost Review results, or Stat Lab Systems Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Heightened Arrangements Review, Claims Review, Unallowable Cost Review, or Stat Lab Systems Review complied with the requirements of the Agreement and/or the findings or Heightened Arrangements Review results, Claims Review results, Unallowable Cost Review results, or Stat Lab Systems Review results are inaccurate (Validation Review). Gambro shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Gambro's final Annual Report shall be initiated no later than one year after Gambro's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Gambro of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Gambro may request a meeting with OIG to: (a)

discuss the results of any Heightened Arrangements Review, Claims Review, Unallowable Cost Review, or Stat Lab Systems Review submissions or findings; (b) present any additional information to clarify the results of the Heightened Arrangements Review, Claims Review, Unallowable Cost Review, or Stat Lab Systems Review or to correct the inaccuracy of the Heightened Arrangements Review, Claims Review, Unallowable Cost Review, or Stat Lab Systems Review; and/or (c) propose alternatives to the proposed Validation Review. Gambro agrees to provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Heightened Arrangements Review, Claims Review, Unallowable Cost Review, or Stat Lab Systems Review issues with Gambro prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

9. Independence/Objectivity Certification. The IRO(s) shall include in its report(s) to Gambro a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity, as appropriate to the nature of the engagement, with regard to the Claims Review, Unallowable Cost Review, or Stat Lab Systems Review and that it has concluded that it is, in fact, independent and/or objective.

F. Disclosure Program.

Gambro shall maintain a Disclosure Program that includes a mechanism (*e.g.*, a toll-free compliance telephone line) to enable 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 Gambro's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Gambro shall appropriately publicize the existence of the disclosure mechanism (*e.g.*, via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a 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 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 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, Gambro shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be made available to OIG, upon request.

G. Ineligible Persons.

1. *Definitions*. For purposes of this CIA:

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov).

c. "Screened Persons" include prospective and current owners (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading), officers, directors, employees, contractors, and agents of Gambro.

2. *Screening Requirements.* Gambro shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements:

a. Gambro shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such persons to disclose whether they are an Ineligible Person.

b. Gambro shall screen all Screened Persons against the Exclusion Lists within 120 days after the Effective Date and on an annual basis thereafter.

c. Gambro shall implement a policy requiring all Screened Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section affects the responsibility of (or liability for) Gambro to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person.

3. *Removal Requirement.* If Gambro has actual notice that a Screened Person has become an Ineligible Person, Gambro shall remove such person from responsibility for, or involvement with, Gambro's business operations related to the Federal health care programs and shall remove such person from any position for which the person's compensation or the items or services furnished, 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 Gambro has actual notice that a Screened Person is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during his or her employment or contract term or, in the case of a Covered Physician, during the term of the Covered Physician's clinic privileges, Gambro shall take all appropriate actions to ensure that the responsibilities of that person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceedings.

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

I. Reporting.

1. *Overpayments.*

a. *Definition of Overpayments*. For purposes of this CIA, an "Overpayment" shall mean the amount of money Gambro has received in excess of the amount due and payable under any Federal health care program requirements.

b. *Reporting of Overpayments*. If, at any time, Gambro identifies or learns of any Overpayment, Gambro shall notify the payor (*e.g.*, Medicare fiscal intermediary) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, Gambro shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, Gambro shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies, and, for Medicare contractors, shall include the information

contained on the Overpayment Refund Form, provided as Appendix F to this CIA. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

2. *Reportable Events.*

a. *Definition of Reportable Event*. For purposes of this CIA, a "Reportable Event" means anything that involves:

i. a substantial Overpayment; or

ii. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.

A Reportable Event may be the result of an isolated event or a series of occurrences.

b. Reporting of Reportable Events. If Gambro determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Gambro shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

i. If the Reportable Event results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section III.I.1, and shall include all of the information on the Overpayment Refund Form, as well as:

(A) the payor's name, address, and contact person to whom the Overpayment was sent; and

(B) the date of the check and identification number (or electronic transaction number) by which the Overpayment was repaid/refunded;

ii. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

iii. a description of Gambro's actions taken to correct the Reportable Event; and

iv. any further steps Gambro plans to take to address the Reportable Event and prevent it from recurring.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, Gambro changes locations or sells, closes, purchases, or establishes a new business unit or location related to the furnishing of outpatient dialysis, Gambro shall enter this information into a log as soon as possible, but no later than within 15 days after the date of change of location, sale, closure, purchase, or establishment. Each log shall include the address of the new business unit or location, phone number, fax number, Medicare number, Gambro identification number and/or supplier number, the corresponding contractor's name and address that has issued each Medicare number, and the name, address, phone number, and provider and/or supplier number (if applicable) for each business partner of the new business unit or location. Each new business unit or location shall be subject to all the requirements of this CIA. This log shall be made available to OIG upon request.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, Gambro shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

2. the names and positions of the members of the Compliance Committee required by Section III.A;

3. a certification that each clinic has a CCL in place, as required by Section III.A;

4. a copy of Gambro's Standards of Business Conduct required by Section III.B.1;

5. a copy of all Policies and Procedures required by Section III.B.2;

6. the number of individuals required to complete the Standards of Business Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

7. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;

b. number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

8. a description of the Disclosure Program required by Section III.F;

9. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) a summary and description of any and all current and prior engagements and agreements between Gambro and the IRO; and (d) the proposed start and completion dates of the Claims Review, Unallowable Cost Review, and Stat Labs Billing Review.

10. a certification from the IRO regarding its professional independence and/or objectivity with respect to Gambro;

11. a description of the process by which Gambro fulfills the requirements of Section III.G regarding Ineligible Persons;

12. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken in response to the screening and removal obligations set forth in Section III.G; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered, or prescribed by an Ineligible Person;

13. a list of all of Gambro's locations (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 Medicare provider number(s), Gambro identification number(s), and/or supplier number(s); and the name and address of each Medicare contractor to which Gambro currently submits claims;

14. a description of Gambro's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

15. the certifications required by Section V.C.

B. Annual Reports. Gambro shall submit to OIG annually a report with respect to the status of, and findings regarding, Gambro's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in Section III.A;

2. a certification that each clinic has its own CCL, as described in Section III.A;

3. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (*e.g.*, change in contractor policy) and copies of any compliance-related Policies and Procedures;

4. the number of individuals required to complete the Standards of Business Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

5. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;

b. number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

6. a complete copy of all reports prepared pursuant to Section III.E, along with a copy of the IRO's engagement letter;

7. Gambro's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.E;

8. summary and description of any and all current and prior engagements and agreements between Gambro and the IRO, if different from what was submitted as part of the Implementation Report;

9. a certification from the IRO regarding its professional independence and/or objectivity with respect to Gambro;

10. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

11. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: Medicare, Medicaid (report each applicable state separately, if applicable), and other Federal health care programs. Overpayment amounts that are

routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report;

12. a summary of the disclosures in the disclosure log required by Section III.F that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;

13. any changes to the process by which Gambro fulfills the requirements of Section III.G regarding Ineligible Persons;

14. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken by Gambro in response to the screening and removal obligations set forth in Section III.G; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services relating to items or services furnished, ordered or prescribed by an Ineligible Person;

15. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

16. a description of all changes to the most recently provided list of Gambro's locations (including addresses) as required by Section V.A.13; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare provider number(s), Gambro identification number(s), and/or supplier number(s); and the name and address of each Medicare contractor to which Gambro currently submits claims; and

17. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by 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 that:

1. to the best of his or her knowledge, except as otherwise described in the applicable report, Gambro is in compliance with all of the requirements of this CIA;

2. he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information in the Report is accurate and truthful; and

3. Gambro has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs;

D. Designation of Information. Gambro shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Gambro shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
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, S.W.
Washington, DC 20201
Telephone: (202) 619-2078
Facsimile: (202) 205-0604

Gambro:

Christopher J. Riopelle
Senior Vice President and Chief Compliance Officer
Gambro Healthcare, Inc.
10810 W. Collins Avenue
Lakewood, CO 80215
Telephone: (303) 542-5196
Facsimile: (303) 209-7615

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

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 or request copies of Gambro's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Gambro's locations for the purpose of verifying and evaluating: (a) Gambro's compliance with the terms of this CIA; and (b) Gambro's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Gambro 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 Gambro'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. Gambro shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Gambro's employees may elect to be interviewed with or without a representative of Gambro present.

VIII. DOCUMENT AND RECORD RETENTION

Gambro shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for six years (or longer if otherwise required by law).

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Gambro prior to any release by OIG of information submitted by Gambro pursuant to its obligations under this CIA and identified upon submission by Gambro as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Gambro shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Gambro is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Gambro and OIG hereby agree that failure to comply with certain obligations as 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 Gambro fails to establish and implement any of the following obligations as described in Section III:

a. a Compliance Officer;

b. a Compliance Committee;

c. a written Standards of Business Conduct;

d. written Policies and Procedures;

e. the training of Covered Persons;

f. a Disclosure Program;

g. Ineligible Persons screening and removal requirements; and

h. Notification of Government investigations or legal proceedings.

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 Gambro fails to engage an IRO, as required in Section III.E and Appendix C.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Gambro fails to submit the Implementation Report or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Gambro fails to submit the annual Claims Review Report, the Unallowable Cost Review Report, the annual Stat Labs Billing Review Report, or the annual Heightened Arrangements Review Report in accordance with the requirements of Sections III.D and .E and Appendixes B, C, D, and E.

5. A Stipulated Penalty of $1,500 for each day Gambro fails to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Gambro fails to grant access.)

6. A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of Gambro as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of $1,000 for each day Gambro fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Gambro, stating the specific grounds for its determination that Gambro has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Gambro shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Gambro receives this notice from OIG of the failure to comply.) A Stipulated

Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.

B. Timely Written Requests for Extensions. Gambro may, in advance of the due date, 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 Gambro fails to meet the revised deadline set by 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 three business days after Gambro receives OIG's written denial of such request or the original due date, whichever is later. 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.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Gambro has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Gambro of: (a) Gambro's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Gambro shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Gambro elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Gambro cures, to OIG's satisfaction, the alleged breach in dispute. 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.D.

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 set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Gambro has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

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

a. a failure by Gambro to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.I;

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

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

d. a failure to engage and use an IRO in accordance with Section III.E.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Gambro constitutes an independent basis for Gambro's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Gambro has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Gambro of: (a) Gambro'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").

3. *Opportunity to Cure*. Gambro shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. Gambro is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;

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) Gambro has begun to take action to cure the material breach; (ii) Gambro is pursuing such action with due diligence; and (iii) Gambro has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter*. If, at the conclusion of the 30-day period, Gambro fails to satisfy the requirements of Section X.D.3, OIG may exclude Gambro from participation in the Federal health care programs. OIG shall notify Gambro in writing of its determination to exclude Gambro (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Gambro's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Gambro may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights*. Upon OIG's delivery to Gambro of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Gambro 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, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS 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 after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Gambro was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Gambro shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Gambro to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Gambro requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 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 Gambro 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) Gambro had begun to take action to cure the material breach within that period; (ii) Gambro has pursued and is pursuing such action with due diligence; and (iii) Gambro provided to OIG within that period a reasonable timetable for curing the material breach and Gambro has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Gambro, only after a DAB decision in

favor of OIG. Gambro's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Gambro upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Gambro may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Gambro shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Gambro, Gambro shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or the 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, Gambro and OIG agree as follows:

A. This CIA shall be applicable only to those operations of Gambro that are subject to United States laws and regulations;

B. This CIA shall be binding on the successors, assigns, and transferees of Gambro;

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

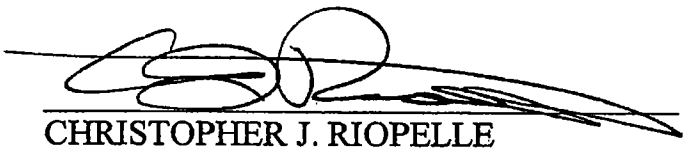
D. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;

E. OIG may agree to a suspension of Gambro's obligations under the CIA in the event of Gambro's cessation of participation in Federal health care programs. If Gambro withdraws from participation in Federal health care programs and is relieved of its CIA obligations by OIG, Gambro shall notify OIG at least 30 days in advance of Gambro's intent to reapply as a participating Gambro or supplier with any Federal health care

program. Upon receipt of such notification, OIG shall evaluate whether the CIA should be reactivated or modified; and

F. The undersigned Gambro 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 GAMBRO HEALTHCARE, INC.



CHRISTOPHER J. RIOPELLE
Senior Vice President & Chief Compliance Officer
Gambro Healthcare, Inc.

11/29/04
DATE

JUDITH A. WALTZ, ESQ.
Foley & Lardner LLP
Counsel for Gambro Healthcare, Inc.

DATE

program. Upon receipt of such notification, OIG shall evaluate whether the CIA should be reactivated or modified; and

F. The undersigned Gambro 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 GAMBRO HEALTHCARE, INC.

CHRISTOPHER J. RIOPELLE
Senior Vice President & Chief Compliance Officer
Gambro Healthcare, Inc.

DATE

JUDITH A. WALTZ, ESQ.
Foley & Lardner LLP
Counsel for Gambro Healthcare, Inc.

Nov. 29, 2004
DATE

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

LEWIS MORRIS
Chief Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services

11/30/04
DATE

GAMBRO HEALTHCARE, INC. CORPORATE INTEGRITY AGREEMENT
APPENDIX A
INSTRUCTIONS FOR ARRANGEMENTS REVIEW

Gambro shall review and evaluate all Relevant Arrangements to ensure that each Relevant Arrangement does not violate Anti-Kickback Statute.

A. Relevant Arrangements consist of the following:

1. All Arrangements with physicians;
2. Lease Agreements with potential sources of patient referrals;
3. Joint Ventures;
4. Pharmaceutical Vendors;
5. Stat Lab Agreements;
6. Management Agreements; and
7. Dialysis Transfer Agreements with nursing homes.

B. Gambro shall create a database, which shall contain the information Gambro considers necessary to evaluate the Relevant Arrangement's compliance with the Anti-Kickback Statute including, at a minimum, the following:

1. each party involved in the Arrangement (*e.g.*, physician, Gambro subsidiary);
2. the relationship(s) between or among the parties (*e.g.* physician employment contract, medical directorship, lease agreement);
3. the term of the Arrangement, including start and expiration dates (including any automatic renewal provisions);
4. the nature and material terms of the Arrangement, including the subject of the contract and type of service or supplies provided;

5. the methodology for determining compensation, including fair market value, and the means by which compensation is paid (*e.g.*, bonus, salary, services); and

6. potentially applicable safe harbor(s).

GAMBRO HEALTHCARE, INC. CORPORATE INTEGRITY AGREEMENT
APPENDIX B
HEIGHTENED ARRANGEMENT REVIEW

I. The Arrangement Samples

A. Definitions

All terms defined in Gambro's Corporate Integrity Agreement (CIA) and Appendix A retain their meaning for this Appendix. In addition, the following terms are defined as follows.

1. *Joint Venture*: For purposes of this CIA, a Joint Venture exists when Gambro owns less than 100% of a Gambro Clinic.

2. *Population*: the universe of Gambro Clinics from which a Sample Frame is formed.

3. *Sample Frame*: the portion of the Population from which a sample is drawn.

4. *Sample Unit*: a Gambro Clinic.

B. Selecting the Samples. Gambro shall randomly select three different Arrangement Samples of Gambro Clinics.

1. The Arrangement Samples shall consist of the following.

a. *Joint Venture Sample*
The Joint Venture Sample shall consist of 10 percent of the Sample Frame for the Joint Venture Sample. The Sample Frame for the Joint Venture Sample shall consist of all Gambro Clinics for which Gambro has a Joint Venture agreement.

b. *Medical Director Sample*
The Medical Director Sample shall consist of 10 percent of all Gambro Clinics. The Sample Frame for the Medical Director Sample shall consist of all Gambro Clinics except those Gambro Clinics that have been selected as Sample Units in the Joint Venture Sample for the current Reporting Period. For the first Reporting Period, the Sample Units shall be ranked according to the dollar value of their Medical Director compensation package and selected at random according to the following strata distribution.

Top 50 Clinics	45%
Next 100 Clinics	45%
Remaining 400	10%

For each Reporting Period after the first Reporting Period, Gambro shall formulate a work plan that describes how the Medical Director Samples shall be stratified. This work plan shall be submitted to OIG for approval within the first ninety days of the Reporting Period.

c. *Other Relevant Arrangement Sample*
The Other Relevant Arrangement Sample shall consist of 1.5 percent of all Gambro Clinics. The Sample Frame shall consist of all Gambro Clinics except for those Gambro Clinics that have been selected as Sample Units in the Joint Venture and Medical Director Samples for the current Reporting Period.

2. *Use of First Samples Drawn.* For the purposes of all Arrangement Samples, the Gambro Clinics selected in each first sample (or first sample for each strata in the case of the Medical Directors Sample) shall be used (*i.e.*, it is not permissible to generate more than one list of random samples and then select one for use with any of the Arrangement Samples).

II. The Heightened Review

For each Gambro Clinic selected as part of the Arrangement Samples, Gambro shall conduct a thorough investigation of all Relevant Arrangements entered into by or on behalf of the Gambro Clinic to determine Gambro's compliance with the Anti-Kickback Statute. This investigation shall not be limited to a review of the documents and shall include interviews of relevant persons (including Contractors and outside parties) and any other means of gathering

information Gambro deems necessary to determine the intentions of Gambro in negotiating, effectuating, maintaining, and, if applicable, ending the Relevant Arrangement and the means by which Gambro fulfilled those intentions.

GAMBRO HEALTHCARE, INC. CORPORATE INTEGRITY AGREEMENT
APPENDIX C
INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.E of the CIA.

A. IRO Engagement.

Gambro shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and/or objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Gambro if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Gambro may continue to engage the IRO.

If Gambro engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Gambro shall submit the information identified in Section V.A.8 to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Gambro if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Gambro may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Claims Review, the Unallowable Cost Review, and the Stat Lab Billing Review engagements who have expertise in the billing, coding, reporting, and other requirements of the Medicare end-stage renal disease benefit and in the general requirements of the Federal health care program(s) from which Gambro seeks reimbursement;

2. assign individuals to design and select the Claims Review sample who are knowledgeable about the appropriate statistical sampling techniques;

3. assign individuals to conduct the coding review portions of the Claims Review who have a nationally recognized coding certification (*e.g.*, CCA, CCS, CCS-P, CPC, RRA, etc.) and who have maintained this certification (*e.g.*, completed applicable continuing education requirements);

4. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each Claim Review, the Unallowable Cost Review, and the Stat Lab Systems Review in accordance with the specific requirements of the CIA;

2. follow all applicable Medicare rules and reimbursement guidelines in making assessments in the Claims Review, and Stat Lab Systems Review;

3. if in doubt of the application of a particular Medicare policy or regulation, request clarification from the appropriate authority (*e.g.*, fiscal intermediary or carrier);

4. respond to all OIG inquires in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendixes D and E.

D. IRO Independence/Objectivity.

The IRO must perform all reviews in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Gambro.

E. IRO Removal/Termination.

1. *Provider.* If Gambro terminates its IRO during the course of the engagement, Gambro must submit a notice explaining its reasons to OIG no later than 30 days after termination. Gambro must engage a new IRO in accordance with Paragraph A of this Appendix.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Gambro to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring Gambro to engage a new IRO, OIG shall notify Gambro of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Gambro may request a meeting with

OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. Gambro shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Gambro prior to requiring Gambro to terminate the IRO. However, the final determination as to whether or not to require Gambro to engage a new IRO shall be made at the sole discretion of OIG.

GAMBRO HEALTHCARE, INC. CORPORATE INTEGRITY AGREEMENT
APPENDIX D
CLAIMS REVIEW

A. Claims Review.

1. *Definitions.* For the purposes of the Claims Review, the terms defined in the CIA shall retain the same meanings here. In addition, the following definitions shall be used:

a. Overpayment: The amount of money Gambro has received in excess of the amount due and payable under any Federal health care program requirements.

b. Paid Claim: A code or line item submitted by and for which Gambro has received reimbursement from the Medicare program.

c. Population: The Population shall be defined as all Clinics.

d. Sampling Frame: The Portion of the Population from which the sample is drawn. The Sampling Frame shall consist of the top 10% of Clinics with the highest billings per patient for separately billable drugs and non-laboratory diagnostic tests (*e.g.*, electrocardiograms).

e. Sample Unit: The Sample Unit shall be a Beneficiary Paid Claim.

f. Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample shall be included as part of the net Overpayment calculation.)

The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Items in the sample.

2. *Other Requirements.*

a. Paid Claims without Supporting Documentation. For the purpose of appraising Paid Claims included in the Claims Review, any Paid Claim for

which Gambro cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Gambro for such Paid Claim shall be deemed an Overpayment. Replacement sampling is not permitted.

b. Replacement Sampling. Considering the Sample Unit shall consist only of Paid Claims and that Paid Claims with missing documentation cannot be replaced, there is no need to utilize alternate or replacement sampling units.

c. Use of First Samples Drawn. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, the Paid Claims selected in each first sample shall be used (*i.e.*, it is not permissible to generate more than one list of random samples and then select one for use with the Discovery Sample or Full Sample).

B. Claims Review Report. The following information shall be included in the Claims Review Report for each Discovery Sample and Full Sample (if applicable).

1. *Claims Review Methodology.*

a. Sampling Unit. A description of the Beneficiary Paid Claim as that term is utilized for the Claims Review.

b. Claims Review Population. A description of the Population subject to the Claims Review.

c. Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.

d. Sampling Frame. A description of the Sampling Frame, which is the portion of the Population from which the Discovery Sample and, if any, Full Sample has been selected and an explanation of the methodology used to identify the Sampling Frame.

e. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Claims Review (*e.g.*, medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).

f. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.

2. *Statistical Sampling Documentation.*

a. The number of Paid Claims appraised in the Discovery Sample and, if applicable, in the Full Sample.

b. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.

c. A copy of the statistical software printout(s) estimating how many Beneficiary Paid Claims are to be included in the Full Sample, if applicable.

d. A description or identification of the statistical sampling software package used to select the sample and determine the Full Sample size, if applicable.

3. *Claims Review Findings.*

a. Narrative Results.

i. A description of Gambro's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.

ii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any).

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by Gambro (Claim Submitted) differed from what should have been the correct claim (Correct Claim), regardless of the effect on the payment.

ii. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to Gambro.

iii. Total dollar amount of all Overpayments in the sample.

iv. Total dollar amount of Paid Claims included in the sample and the net Overpayment associated with the sample.

v. Error Rate in the sample.

vi. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)

4. *Systems Review.* Observations, findings, and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s).

5. *Credentials.* The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review; and (2) performed the Claims Review.

Attachment 1

Claims Review Results

Federal Health Care Program Billed	Bene HIC #	Date of Service	Procedure Code Submitted	Procedure Code Reimbursed	Allowed Amount Reimbursed	Correct Procedure Code (IRO determined)	Correct Allowed Amt Reimbursed (IRO determined)	Dollar Difference between Amt Reimbursed and Correct Allowed Amt

GAMBRO HEALTHCARE, INC. CORPORATE INTEGRITY AGREEMENT
APPENDIX E
STAT LAB SYSTEMS REVIEW

A. Stat Lab Systems Review.

1. *Definitions*. For the purposes of the Stat Lab Systems Review, the terms defined in the CIA shall retain the same meanings here. In addition, the following definitions shall be used:

a. Stat Lab Test: A laboratory test that must be performed immediately or on an urgent basis, and which is performed by a non-Gambro lab.

b. Stat Lab Requisition: The form documenting the physician's order for the Stat Lab test which is provided to the Stat Lab with the patient specimen.

d. Population: The Population shall be defined as all Gambro Clinics.

e. Sampling Frame: The Portion of the Population from which the sample is drawn. The Gambro Clinics shall be ranked according to the number of Stat Lab Requisitions during the 12-month period under review. The Sampling Frame shall consist of 50 Gambro Clinics, in the following strata:

Top 50 Clinics	20 Sampling Units
Next 100 Clinics	20 Sampling Units
Remaining 400	10 Sampling Units

f. Sample Unit: The Sample Unit shall be a Stat Lab Requisition.

g. Stat Lab Files: Records associated with the Stat Lab Requisition including instructions for billing, test results, indication of billing by the Stat Lab to Gambro and Stat Lab agreements, where available.

h. Deficiency: Any Stat Lab Requisition for which Gambro cannot produce Stat Lab Files in accordance with its policies and procedures.

2. *Other Requirements*.

a. Root Cause Analysis. The root cause of any Deficiencies shall be identified, and a corrective action plan shall be implemented.

b. Replacement Sampling. Considering the Sample Unit shall consist only of Requisitions and that Requisitions with missing documentation cannot be replaced, there is no need to utilize alternate or replacement-sampling units.

B. Stat Lab Systems Review Report. The following information shall be included in the Stat Lab Systems Review Report.

1. *Stat Lab Systems Review Methodology.*

a. Sampling Unit. A description of the Stat Lab Requisition as that term is utilized for the Stat Lab Systems Review.

b. Stat Lab Systems Review Population. A description of the Population subject to the Stat Lab Systems Review.

c. Stat Lab Systems Review Objective. A clear statement of the objective intended to be achieved by the Stat Lab Systems Review.

d. Sampling Frame. A description of the Sampling Frame, which is the portion of the Population from which the Sample has been selected and an explanation of the methodology used to identify the Sampling Frame.

e. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Stat Lab Systems Review (*e.g.*, requisitions, instructions for billing, resulting tests, indication of billing by the stat lab to Gambro, and applicable Gambro policies and procedures).

f. Review Protocol. A narrative description of how the Stat Lab Systems Review was conducted and what was evaluated.

2. *Statistical Sampling Documentation.*

a. The number of Stat Lab Requisitions appraised in the Sample.

b. A description or identification of the statistical sampling software package used to select the sample.

3. *Stat Lab Systems Review Findings.*

a. Narrative Results.

i. A description of Gambro's Stat Lab Requisition process.

ii. A summary of Gambro's Stat Lab policy and procedures.

iii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for Deficiencies, patterns noted, etc.) regarding the Stat Lab Systems Review, including the results of the Sample.

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined Deficiencies.

ii. Observations, findings, recommendations, and corrective action plan on possible improvements to the system(s) and process(es) that generated the Deficiencies (Root Cause Analysis).

5. *Credentials*. The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review; and (2) performed the Stat Lab Systems Review.

APPENDIX F

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

Date:_____
Contractor Deposit Control #_____ Date of Deposit: _____
Contractor Contact Name:_____ Phone #_____
Contractor Address:_____
Contractor Fax:

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.

PROVIDER/PHYSICIAN/SUPPLIERNAME_____
ADDRESS_____
PROVIDER/PHYSICIAN/SUPPLIER #_____ CHECK NUMBER#_____
CONTACT PERSON:_____ PHONE #_____
$_____ CHECK DATE_____ AMOUNT OF CHECK

REFUND INFORMATION

For each Claim, provide the following:
Patient Name_____ HIC #_____
Medicare Claim Number_____ Claim Amount Refunded $_____
Reason Code for Claim Adjustment:_____ (Select reason code from list below. Use one reason per claim)

(Please list all claim numbers involved. Attach separate sheet, if necessary)

*Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling, please indicate methodology and formula used to determine amount and reason for overpayment:*_____

For Institutional Facilities Only:
Cost Report Year(s) _____
(If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)
For OIG Reporting Requirements:
Do you have a Corporate Integrity Agreement with OIG? Yes No

Reason Codes:

Billing/Clerical Error
01 - Corrected Date of Service
02 - Duplicate
03 - Corrected CPT Code
04 - Not Our Patient(s)
05 - Modifier Added/Removed
06 - Billed in Error
07 - Corrected CPT Code

MSP/Other Payer Involvement
08 - MSP Group Health Plan Insurance
09 - MSP No Fault Insurance
10 - MSP Liability Insurance
11 - MSP, Workers Comp.(Including Black Lung
12 - Veterans Administration

Miscellaneous
13 - Insufficient Documentation
14 - Patient Enrolled in an HMO
15 - Services Not Rendered
16 - Medical Necessity
17 - Other (Please Specify)
_____