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.

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.

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 #_____ AMOUNT OF CHECK
$_____ CHECK DATE_____

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)
_____