

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

I. PREAMBLE

GAMBRO Healthcare, Inc. ("GAMBRO") and GAMBRO Healthcare Laboratory Services, Inc. ("GHLSI") hereby enter 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 by their officers, directors, employees, contractors and agents of GHLSI and all third parties engaged to bill/submit reimbursement claims for ESRD laboratory services, and all other individuals responsible for the provision, marketing or such documentation as the laboratory is required to generate and/or maintain regarding ESRD laboratory items or services reimbursable by Federal health care programs, or in the preparation of claims, reports or other requests for reimbursement for such items or services ("Covered Persons") 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 and GHLSI are entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

The requirements of this CIA shall apply to any and all ESRD laboratories owned or operated by GAMBRO during the term of this CIA. Currently, GAMBRO's ESRD laboratory services are performed exclusively by its subsidiary, GHLSI. Accordingly, the requirements of this CIA are written in direct reference to GHLSI. However, should GAMBRO own or operate any ESRD laboratory outside of GHLSI, GAMBRO agrees that the requirements of this CIA shall apply to any such laboratory. GAMBRO shall notify the OIG within fifteen (15) days of initiating the ownership or operation of any ESRD laboratory outside of GHLSI.

II. TERM OF THE CIA

The period of the compliance obligations assumed by GAMBRO and GHLSI under this CIA shall be five (5) years from the effective date of this CIA (unless otherwise specified). The effective date of this CIA shall be the date on which the final signatory of this CIA executes this CIA.

Sections VII, VIII, IX, X and XI shall remain in effect until GHLSI submits all information required by OIG as part of the final Annual Report.

III. CORPORATE INTEGRITY OBLIGATIONS

GHLSI has instituted a voluntary compliance program known as the Laboratory Continuous Compliance Understanding Plan. To the extent that the compliance obligations under this CIA conflict with the requirements of the Laboratory Continuous Compliance Understanding Plan, GHLSI hereby agrees that the requirements of the CIA shall control and GHLSI shall amend the Laboratory Continuous Compliance Understanding Plan to conform to the requirements of this CIA. These requirements are as follows:

A. Compliance Officer and Committee.

1. *Compliance Officer.* GHLSI has appointed an individual to serve as its Compliance Officer. For at least the duration of this CIA, GHLSI shall continue to employ an individual to serve as Compliance Officer, who 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 GHLSI, shall make periodic (at least quarterly) reports regarding compliance matters directly to the President and/or to the Board of Directors of GHLSI, and shall be authorized to report on such matters to the Board of Directors of GHLSI and of GAMBRO at any time. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by GHLSI as well as for any reporting obligations created under this CIA.

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, must be reported to OIG, in writing, within fifteen (15) days of such a change.

2. Compliance Committee. GHLSI has appointed a Compliance Committee known as the Laboratory Compliance Group. For at least the duration of this CIA, GHLSI shall continue to maintain a Compliance Committee that shall, at a minimum, include the Compliance Officer and any other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of each major department, such as billing, clinical, human resources, audit, marketing, and operations). The Compliance Officer shall chair the Compliance Committee and the 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).

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, must be reported to OIG, in writing, within fifteen (15) days of such a change.

B. Written Standards.

1. Code of Ethics. GAMBRO has established a written code of business ethics applicable to all employees, including those of GHLSI. Within 90 days of the effective date of this CIA, GHLSI shall review its Code of Ethics and, if necessary to comply with the requirements of this CIA, will amend that Code. The revised Code of Ethics shall be distributed to all Covered Persons within 90 days of the effective date of this CIA. GHLSI shall make the promotion of, and adherence to, the revised Code of Ethics an element in evaluating the performance of all employees. The revised Code of Ethics shall, at a minimum, set forth:

- a. GHLSI'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. GHLSI's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with GHLSI's own Policies and Procedures as

implemented pursuant to section III.B (including the requirements of this CIA);

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

d. the possible consequences to both GHLSI and Covered Persons of failure to comply with all Federal health care program requirements and with GHLSI's own Policies and Procedures or of failure to report such non-compliance; and

e. the right of all individuals to use the Confidential Disclosure Program described in section III.E, and GHLSI's commitment to maintain confidentiality, as appropriate, and non-retaliation with respect to disclosures.

Within ninety (90) days of the effective date of the CIA, each Covered Person shall certify, in writing, that he or she has received, read, understood, and will abide by GHLSI's revised Code of Ethics. New Covered Persons shall receive the revised Code of Ethics and shall complete the required certification within two weeks after becoming a Covered Person or within ninety (90) days of the effective date of the CIA, whichever is later.

GHLSI shall annually review the revised Code of Ethics to determine if further revisions are appropriate and shall make any necessary revisions based on such a review. Any such re-revised Code of Ethics shall be distributed within thirty (30) days of finalizing such changes. Covered Persons shall certify that they have received, read, understood and will abide by the re-revised Code of Ethics within thirty (30) days of the finalization of such revisions.

~~2. Policies and Procedures.~~ Within ninety (90) days of the effective date of this CIA, GHLSI shall implement written Policies and Procedures regarding the operation of GHLSI'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 revised Code of Ethics identified in section III.B.1;
- b. the proper coding methodology for laboratory services;
- c. the billing requirements for routine ESRD laboratory tests (e.g., tests that are included in the composite rate), including the policy against billing separately for tests that are already reimbursed through the composite rate;
- d. the billing requirements for non-routine ESRD laboratory tests (e.g., tests that are billed separately from the composite rate);
- e. the policy against the misuse of standing orders and the procedures to foster individualized creation and use of physician laboratory orders;
- f. the policy to promote awareness of HCFA's 50/50 rule; and
- g. the policy against receiving kickbacks (e.g., swapping discounts¹ on routine ESRD laboratory tests in exchange for non-routine ESRD laboratory business).

The Policies and Procedures shall be available to OIG, upon request.

Within ninety (90) days of the effective date of the CIA, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions are related to those Policies and Procedures. Appropriate and knowledgeable staff should be available to explain the Policies and Procedures.

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

¹ E.g., a discount that is not commercially reasonable in the absence of other, non-discounted business. See, OIG Advisory Opinion 99-13, OIG Advisory Opinion 99-2.

C. Training and Education.

1. *General Training.* Within ninety (90) days of the effective date of this CIA, GHLSI shall provide at least two (2) hours of general training to each Covered Person. This training shall explain GHLSI's:

- a. CIA requirements; and
- b. Compliance Program (including the revised Code of Ethics and the Policies and Procedures as they pertain to general compliance issues).

All training materials shall be made available to OIG, upon request.

New Covered Persons shall receive the general training described above within thirty (30) days of becoming a Covered Person or within ninety (90) days after the effective date of this CIA, whichever is later. After receiving the initial training described above, each Covered Person shall receive at least one (1) hour of general training annually.

2. *Specific Training.* Within ninety (90) days of the effective date of this CIA, each Covered Person who is involved in the preparation or submission of claims for reimbursement from any Federal health care program (hereinafter referred to as "Relevant Covered Persons") shall receive at least six (6) hours of specific training in addition to the general training required above. This specific training shall include a discussion of:

- a. ~~the submission of accurate~~ bills for services rendered to Federal health care program patients;
- b. ~~policies, procedures and other~~ requirements applicable to the billing of laboratory services;
- c. ~~the personal obligation of each individual~~ involved in the billing process to ensure that such billings are accurate;
- d. ~~applicable reimbursement~~ statutes, regulations, and program requirements and directives;

- e. the legal sanctions for improper billings; and
- f. examples of proper and improper billing practices.

All training materials shall be made available to OIG, upon request. Persons providing the training must be knowledgeable about the subject area.

Relevant Covered Persons shall receive this training within thirty (30) days of the beginning of their employment or becoming Relevant Covered Persons or within ninety (90) days of the effective date of this CIA, whichever is later. A GHLSI employee who has completed the specific training shall review a new Relevant Covered Person's work, to the extent that the work relates to the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes applicable training.

After receiving the initial training described in this section, every Relevant Covered Person shall receive at least four (4) hours of specific training annually.

3. *Certification.* Each individual who is required to attend training shall certify, in writing, 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 his or her designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

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Nationally Known
organization.

D. Review Procedures

GHLSI shall retain an entity, such as an accounting, auditing, consulting firm or other independent consultants (hereinafter "Independent Review Organization"), to perform review procedures to assist GHLSI in assessing the adequacy of its billing and compliance practices pursuant to this CIA. This shall be an annual requirement and shall cover a twelve (12) month period. The Independent Review Organization must have expertise in the billing, coding, reporting and other requirements of the Federal health care programs from which GHLSI seeks reimbursement. The Independent Review Organization must be retained to conduct the audit of the first year within one-hundred and twenty (120) days of the effective date of this CIA.

The Independent Review Organization will conduct two separate engagements. One will be an analysis of GHLSI's billing to the Federal health care programs to assist GHLSI and OIG in determining compliance with all applicable statutes, regulations, and directives/guidance ("billing engagement"). The second engagement will determine whether GHLSI is in compliance with this CIA ("compliance engagement").

1. *Billing Engagement.* The billing engagement shall consist of a review of a statistically valid sample of beneficiaries that can be projected to the population of claims for the relevant period. The sample size shall be determined through the use of a probe sample. At a minimum, the full sample must be within a ninety (90) percent confidence level and a precision of twenty-five (25) percent. The probe sample must contain at least thirty (30) sample units and cannot be used as part of the full sample. Both the probe sample and the sample must be selected through random numbers. GHLSI shall use OIG's Office of Audit Services Statistical Sampling Software, also known as "RAT-STATS," which is available through the Internet at "www.hhs.gov/progorg/oas/ratstat.html".

Each annual billing engagement analysis shall include the following components in its methodology:

- a. **Billing Engagement Objective:** A statement stating clearly the objective intended to be achieved by the billing engagement and the procedure or combination of procedures that will be applied to achieve the objective.
- b. **Billing Engagement Population:** Identify the population,

which is the group about which information is needed. Explain the methodology used to develop the population and provide the basis for this determination.

- c. **Sources of Data:** Provide a full description of the source of the information upon which the billing engagement conclusions will be based, including the legal or other standards applied, documents relied upon, payment data, and/or any contractual obligations.
- d. **Sampling Unit:** Define the sampling unit, which is any of the designated elements that comprise the population of interest. Under this CIA, the sampling unit will be defined by beneficiary patient quarter, i.e., claims grouped by beneficiary for each quarter.
- e. **Sampling Frame:** Identify the sampling frame, which is the totality of the sampling units from which the sample will be selected.

The billing engagement shall provide:

- i. findings regarding GHLSI's billing and coding operation (including, but not limited to, the operation of the billing system, strengths and weaknesses of this system, internal controls, effectiveness of the system);
- ii. findings regarding GHLSI's procedures to correct inaccurate billings or codings to the Federal health care programs;
- iii. findings regarding whether GHLSI is submitting accurate claims for services billed to the Federal health care programs;
- iv. findings regarding whether GHLSI is submitting accurate claims for routine ESRD laboratory tests (e.g., not billing separately for tests that are already reimbursed through the composite rate);

- v. findings regarding whether GHLSI is submitting accurate claims for non-routine ESRD laboratory tests (e.g., accurate billing for tests reimbursed separately from the composite rate);
- vi. findings regarding whether GHLSI's use of standing orders is proper and whether it employs procedures to foster the individualized creation and use of physician laboratory orders;
- vii. findings regarding whether GHLSI is submitting accurate claims for automated blood chemistry tests;
- viii. findings regarding GHLSI's compliance with the Anti-Kickback Statute, 42 U.S.C. §1320a-7b(b); and
- ix. findings regarding the steps GHLSI is taking to bring its operations into compliance or to correct problems identified by the audit.

2. Compliance Engagement. An Independent Review Organization shall also conduct a compliance engagement, that shall provide findings regarding whether GHLSI's program, policies, procedures, and operations comply with the terms of this CIA. This engagement shall include section by section findings regarding the requirements of this CIA.

A complete copy of the Independent Review Organization's billing and compliance engagement reports to GHLSI and/or ~~GAO~~ shall be included in each of GHLSI's Annual Reports to OIG.

3. ~~Verification~~ Validation. In the event that the OIG determines that it is necessary to conduct an independent review to determine whether or the extent to which GHLSI is complying with its obligations under this CIA, GHLSI agrees to pay for the reasonable cost of any such review or engagement by the OIG or any of its designated agents.

Current investigation fall under purview of the CIA Verification / Validation Independent Review

E. Confidential Disclosure Program.

GAMBRO maintains a toll free hotline number for its employees to report misconduct. Within 90 days after the effective date of this CIA, GHLSI shall establish a Confidential Disclosure Program, which must include 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 GHLSI's policies, 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. GHLSI shall publicize the existence of the confidential disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Confidential Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communications. 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, GHLSI shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or his or her designee) shall maintain a confidential disclosure log, which shall include a record and summary of each disclosure received, the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The confidential disclosure log shall be available to OIG, upon request.

F. Ineligible Persons.

1. Definition. For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (a) is currently excluded, debarred or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or (b) has been convicted of a criminal offense related to the provision of health care items or services or patient abuse or neglect, but has not yet been excluded, debarred or otherwise declared ineligible.

2. Screening Requirements. GHLSI shall not hire or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, GHLSI shall screen all prospective employees and prospective contractors prior to engaging their service by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>) and the OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.gov/oig>) (these lists will hereinafter be referred to as the "Exclusion Lists").

3. Review and Removal Requirement. Within ninety (90) days of the effective date of this CIA, GHLSI shall review its list of current employees and contractors against the Exclusion Lists. Thereafter, GHLSI shall review the list annually. In addition, GHLSI shall require employees and contractors to disclose immediately any debarment, exclusion or other event that makes the employee an Ineligible Person.

If GHLSI has notice that an employee or contractor has become an Ineligible Person, GHLSI shall remove such person from responsibility for, or involvement with, GHLSI's business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. Pending Charges and Proposed Exclusions. If GHLSI has notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract, GHLSI shall take all appropriate actions to ensure that the responsibilities of that employee or contractor 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.

G. Notification of Government Investigation or Legal Proceedings.

Within thirty (30) days of discovery, GHLSI shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that GHLSI 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. GHLSI shall also provide written notice to OIG within thirty (30) days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

H. Reporting.

1. Overpayments

a. Definition of Overpayments. For purposes of this CIA, an "overpayment" shall mean the amount of money GHLSI has received in excess of the amount due and payable under any Federal health care program requirements. GHLSI may not subtract any underpayments for purposes of determining the amount of relevant "overpayments."

b. Reporting of Overpayments. If, at any time, GHLSI identifies or learns of any overpayments, GHLSI shall notify the payor (e.g., Medicare fiscal intermediary or carrier) and repay any identified overpayments within thirty (30) days of discovery and take remedial steps within sixty (60) days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Notification and repayment to the contractor should be done in accordance with the contractor policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Attachment A to this CIA.

2. Material Deficiencies.

a. Definition of Material Deficiency. For purposes of this CIA, a "Material Deficiency" means anything that involves:

(i) a substantial overpayment; or

(ii) a matter that a reasonable person would consider a potential violation of criminal, civil, or administrative laws

applicable to any Federal health care program for which penalties or exclusion may be authorized.

A Material Deficiency may be the result of an isolated event or a series of occurrences.

b. Reporting of Material Deficiencies. If GHLSI determines that there is a Material Deficiency, GHLSI shall notify OIG, in writing, within thirty (30) days of making the determination that the Material Deficiency exists. The report to the OIG shall include the following information:

(i) If the Material Deficiency results in an overpayment, the report to the OIG shall be made at the same time as the notification to the payor required in section III.H.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) on which the overpayment was repaid/refunded;

(ii) a complete description of the Material Deficiency, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

(iii) a description of GHLSI's actions taken to correct the Material Deficiency; and

(iv) any further steps GHLSI plans to take to address the Material Deficiency and prevent it from recurring.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the effective date of this CIA, GHLSI changes locations or purchases or establishes new business units related to the furnishing of items or services that may be reimbursed by Federal health care programs, GHLSI shall notify OIG of this fact as soon as possible, but no later than within thirty (30) days of the date of change of location, purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Medicare provider number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare provider number. All Covered Persons at such locations shall be subject to the applicable requirements in this CIA (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within one hundred and fifty (150) days after the effective date of this CIA, GHLSI shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:

1. the name, address, phone number and position description of the Compliance Officer required by section III.A;
2. the names and positions of the members of the Compliance Committee required by section III.A;
3. a copy of GHLSI's revised Code of Ethics required by section III.B.1;
4. the summary of the Policies and Procedures required by section III.B.2;
5. a description of the training required by section III.C, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;
6. a certification by the Compliance Officer that:

- a. the Policies and Procedures required by section III.B have been developed, are being implemented, and have been distributed to all appropriate Covered Persons;
- b. all Covered Persons have completed the revised Code of Ethics certification required by section III.B.1; and
- c. all Covered Persons have completed the applicable training and executed the certification(s) required by section III.C.;

The documentation supporting this certification shall be available to OIG, upon request.

- 7. a description of the Confidential Disclosure Program required by section III.E;
- 8. the identity of the Independent Review Organization(s) and the proposed start and completion dates of the first annual review;
- 9. a summary of personnel actions taken pursuant to section III.F.;
- 10. a list of all of GHLSI'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 identification number(s) and the contractor's name and address that issued each provider identification number; and
- 11. To the extent not already furnished to OIG, or if modified, a description of GHLSI's corporate structure, including identification of any parent and sister companies, subsidiaries and their respective lines of business.

B. Annual Reports. GHLSI shall submit to OIG Annual Reports with respect to the status of and findings regarding of GHLSI's compliance activities for each of the five one-year periods beginning on the effective date of the CIA. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period").

Each Annual Report shall include:

1. any change in the identity or position description of the Compliance Officer and/or members of the Compliance Committee described in section III.A;

2. a certification by the Compliance Officer that:

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

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

c. GHLSI has complied with its obligations under the Settlement Agreement: (i) 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; and (ii) not to charge to or otherwise seek payment from Federal or state payors for unallowable costs (as defined in the Settlement Agreement) and to identify and adjust any past charges or claims for unallowable costs;

The documentation supporting this certification shall be available to OIG, upon request.

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);

4. a description of the training required by section III.C conducted during the Reporting Period, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

5. a complete copy of all reports prepared pursuant to the Independent Review Organization's billing and compliance engagements, including a copy of the methodology used, along with a copy of the Independent Review Organization's engagement letter;

6. GHLSI's response and corrective action plan(s) related to any issues raised by the Independent Review Organization(s);
7. a summary of Material Deficiencies (as defined in III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;
8. a report of the aggregate overpayments that have been returned to the Federal health care programs. Overpayment amounts should be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately) and other Federal health care programs;
9. a summary of the disclosures in the confidential disclosure log required by section III.E that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;
10. a description of any personnel actions (other than hiring) taken by GHLSI as a result of the obligations in section III.F, and the name, title, and responsibilities of any person that falls within the ambit of section III.F.4, and the actions taken in response to the obligations set forth in that section;
11. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to section III.G. 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; and
12. a description of all changes to the most recently provided list (as updated) of GHLSI's locations (including locations and mailing addresses) as required by section V.A.10, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program provider identification number(s), and the contractor name and address that issued each provider identification number.

The first Annual Report shall be received by the OIG no later than one year and sixty (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) except as otherwise described in the applicable report, GHLSI is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information is accurate and truthful.

D. Designation of Information: GHLSI 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 exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. GHLSI 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 of this CIA, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

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

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GHLSI:

Judith A. Waltz
Foley & Lardner
One Maritime Plaza, Sixth Floor
San Francisco, CA 94111-3404
Tel. 415/438-6412
Fax 415/434-4507
Internet jwaltz@foleylaw.com

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

VIII. DOCUMENT AND RECORD RETENTION

GHLSI shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for five (5) 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, the OIG shall make a reasonable effort to notify GHLSI prior to any release by OIG of information submitted by GHLSI pursuant to its obligations under this CIA and identified upon submission by GHLSI as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, GHLSI shall have the rights set forth at 45 C.F.R. § 5.65(d). GHLSI shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA.

X. BREACH AND DEFAULT PROVISIONS

GAMBRO and GHLSI are expected to fully and timely comply with all of their CIA obligations.

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

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day GHLSI fails to have in place any of the following:

- a. a Compliance Officer as described by section III.A.1;
- b. a Compliance Committee as described by section III.A.2;
- c. a written Code of Ethics as described by section III.B.1;
- d. written Policies and Procedures as described by section III.B.2;
- e. a requirement that Covered Persons be trained as described in section III.C; and

f. a Confidential Disclosure Program as described in section III.E.

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 GHLSI fails to retain an Independent Review Organization, as required in section III.D.

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 GHLSI fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

4. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day GHLSI employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, GHLSI's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which GHLSI can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person).

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

6. A Stipulated Penalty of \$1,000 for each day GAMBRO or GHLSI fails to comply fully and adequately with any obligation of this CIA not already covered in paragraphs 1-5. In its notice to GAMBRO or GHLSI, OIG shall state the specific grounds for its determination that GAMBRO or GHLSI has failed to comply fully and adequately with the CIA obligation(s) at issue and steps GAMBRO or GHLSI must take to comply with the CIA. (This Stipulated Penalty shall begin to accrue ten (10) days after the date that OIG provides notice to GAMBRO or GHLSI of the failure to comply.)

B. Timely Written Requests for Extensions. GAMBRO or GHLSI 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 or GHLSI 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 two business days after GAMBRO or GHLSI 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 (5) 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 or GHLSI 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 or GHLSI of: (a) GAMBRO or GHLSI's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within ten (10) days of the receipt of the Demand Letter, GAMBRO or GHLSI 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 or GHLSI elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until GAMBRO or GHLSI cures, to OIG's satisfaction, the alleged breach in dispute. If the ALJ overturns the OIG's imposition of Stipulated Penalties, then any amounts collected in payment of Stipulated Penalties shall be returned to GAMBRO or GHLSI. 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 or GHLSI 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 GHLSI to report a material deficiency, take corrective action and make the appropriate refunds, as required in section III.H;
- 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 retain and use an Independent Review Organization in accordance with section III.D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by GAMBRO or GHLSI constitutes an independent basis for exclusion of the party in breach from participation in the Federal health care programs. Upon a determination by OIG that GAMBRO or GHLSI has materially breached this CIA and that exclusion should be imposed, OIG shall notify GAMBRO or GHLSI of: (a) GAMBRO's or GHLSI'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 or GHLSI shall have thirty (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 or GHLSI is in full compliance with this CIA;
- b. the alleged material breach has been cured; or

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

4. *Exclusion Letter.* If at the conclusion of the thirty (30) day period, GAMBRO or GHLSI fails to satisfy the requirements of section X.D.3, OIG may exclude the party in breach from participation in the Federal health care programs. OIG will notify GAMBRO or GHLSI in writing of its determination to exclude GAMBRO or GHLSI (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 thirty (30) days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, GAMBRO or GHLSI wishes to apply for reinstatement, GAMBRO or GHLSI must submit 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 or GHLSI 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 or GHLSI 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 ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within ten (10) days of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within twenty five (25) days of receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether

GAMBRO or GHLSI was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. GAMBRO or GHLSI shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders GAMBRO or GHLSI to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision unless GAMBRO or GHLSI 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 twenty (20) days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

- a. whether GAMBRO or GHLSI 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 thirty (30) day period, but that:
 - (i) GAMBRO or GHLSI had begun to take action to cure the material breach within that period;
 - (ii) GAMBRO or GHLSI has pursued and is pursuing such action with due diligence; and
 - (iii) GAMBRO or GHLSI provided to OIG within that period a reasonable timetable for curing the material breach and GAMBRO or GHLSI 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 GHLSI, only after a DAB decision in favor of OIG. GAMBRO or GHLSI's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude GAMBRO or GHLSI upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination

of the OIG and determines that exclusion is authorized, such exclusion shall take effect twenty (20) days after the ALJ issues such a decision, notwithstanding that GAMBRO or GHLSI 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 twenty (20) days after the DAB decision.

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, GHLSI and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of GAMBRO and GHLSI;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA; and
- D. The undersigned GAMBRO and GHLSI 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.

BRAD NUTTER
Chief Executive Officer
GAMBRO Healthcare, Inc.

DATE

On Behalf of GAMBRO Healthcare Laboratory Services, Inc.

NANCY F. DANVERS
President
GAMBRO Healthcare Laboratory Services, Inc.

DATE

Counsel for GAMBRO and GHLSI

JUDITH A. WALTZ
Foley & Lardner, P.A.
Counsel for Defendants

DATE

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



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

7/3/00
DATE