EXHIBIT A

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

I. PREAMBLE

Renal Care Group, Inc. ("Renal Care Group") and RenaLab, Inc. ("RenaLab") 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 RenaLab and all third parties engaged to bill or submit reimbursement claims for ESRD laboratory services, and all individuals responsible for the provision or marketing of ESRD laboratory items or services reimbursable by Federal health care programs, the submission to Federal health care programs of such documentation as the lab is required to generate or maintain, or 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, Renal Care Group and RenaLab 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 Renal Care Group during the term of this CIA. Currently, Renal Care Group's ESRD laboratory services are performed exclusively by its subsidiary, RenaLab. Accordingly, the requirements of this CIA are written in direct reference to RenaLab. However, should Renal Care Group own or operate any ESRD laboratory outside of RenaLab, Renal Care Group agrees that the requirements of this CIA shall apply to any

such laboratory. Renal Care Group shall notify the OIG within fifteen (15) days of obtaining ownership or initiating operation of any ESRD laboratory outside of RenaLab.

Prior to the Effective Date (as defined below) of this CIA, Renal Care Group has provided to the OIG a copy of Renal Care Group's compliance materials, including *Renal Care Group, Standards of Conduct and Business Ethics*; and *Compliance Manual–Statement of Policies of Renal Care Group, Inc., and its Affiliated Organizations Regarding Compliance with Laws, Business Ethics, and Standards of Conduct for Associates and Related Professionals (Final Draft Pending Approval)*. Renal Care Group represents that these materials, as modified by a separate set of policies and procedures applicable specifically to RenaLab, attached hereto as Appendix C, constitute the RenaLab compliance program (the "RenaLab Compliance Program"). RenaLab and the OIG agree that RenaLab may utilize and adapt any components of the RenaLab Compliance Program existing at the time of execution of this CIA as necessary to be in compliance with the corporate integrity obligations assumed by RenaLab pursuant to this CIA. To the extent that the existing RenaLab Compliance Program can not be adapted or maintained to meet the corporate integrity obligations of this CIA, RenaLab shall adopt new components to the existing RenaLab Compliance Program, or create a new compliance program, so that RenaLab will meet the corporate integrity obligations assumed by RenaLab pursuant to this CIA.

II. TERM OF THE CIA

The period of the compliance obligations assumed by Renal Care Group and RenaLab under this CIA shall be three (3) 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 expire no later than 120 days from the OIG's receipt of: (1) RenaLab's final annual report; or (2) any additional materials submitted by RenaLab pursuant to this CIA upon the OIG's request, whichever is later.

III. CORPORATE INTEGRITY OBLIGATIONS

Renal Care Group and RenaLab hereby agree to maintain a Compliance Program for and any and all ESRD laboratories owned or operated by Renal Care Group that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* At all times during the term of this CIA, RenaLab shall have in place an individual serving as its Compliance Officer. 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 RenaLab, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of RenaLab, and shall be authorized to report on such matters to the President and/or the Board of Directors of Renal Care Group and RenaLab at any time. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by RenaLab as well as for any reporting obligations created under this CIA.

RenaLab shall report to the 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 of such a change.

2. *Compliance Committee.* At all times during the term of this CIA, RenaLab shall have in place a Laboratory Compliance Committee. The Laboratory Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Laboratory Compliance Committee, and the Laboratory 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).

RenaLab shall report to the OIG, in writing, any changes in the composition of the Laboratory Compliance Committee, or any actions or changes that would affect the Laboratory Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA within 15 days of such a change.

B. Written Standards.

1. *Code of Conduct.* At all times during the term of this CIA, RenaLab shall have in effect a written Code of Conduct. The Code of Conduct shall be distributed to all Covered Persons who have not already received it within 120 days of the Effective Date of this CIA. RenaLab shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

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

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

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

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

Within 120 days of the Effective Date of the CIA, each Covered Person who has not already done so shall certify, in writing, that he or she has received, read, understood, and will abide by RenaLab's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days of the Effective Date of the CIA, whichever is later.

RenaLab shall annually review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Code of Conduct shall be distributed within 30 days of finalizing such changes. Covered Persons shall certify that they have received, read, understood and will abide by the revised Code of Conduct within 30 days of the distribution of such revisions.

2. *Policies and Procedures*. Within 120 days of the effective date of this CIA, RenaLab shall have in place written Policies and Procedures regarding the operation of RenaLab'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 Code of Conduct 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 a 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. a policy against the misuse of standing orders and the procedures to foster individualized creation and use of physician laboratory orders.

Within 120 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), RenaLab shall assess and update as necessary the Policies and Procedures. Within 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.

C. Training and Education.

1. *General Training.* Within 120 days of the Effective Date of this CIA, RenaLab shall provide reasonable and appropriate general training to each Covered Person. This training, at a minimum, shall explain:

a. This CIA's requirements; and

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

New Covered Persons shall receive the general training described above within 60 days of becoming a Covered Person or within 120 days after the Effective Date of this CIA, whichever is later. After receiving the initial training described above, each Covered Person shall receive such reasonable and appropriate general training annually. General compliance training (as described above) provided to Covered Persons by RenaLab during the six months immediately prior to the execution of this CIA may be credited towards the training time requirements set forth in this section III.C.1, however, RenaLab shall meet the requirements of this section by updating any such training, as appropriate, via e-mail, newsletter, flyer, or other appropriate medium.

2. *Specific Training.* Within 120 days of the Effective Date of this CIA, each Covered Person who is involved directly or in a supervisory role in the preparation or submission of claims for reimbursement for laboratory services 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 beneficiaries;

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.

Persons providing the training must be knowledgeable about the subject area.

Relevant Covered Persons shall receive this training within 60 days of the beginning of their employment or becoming Relevant Covered Persons or within 120 days of the Effective Date of this CIA, whichever is later. A RenaLab 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 his/her 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 certifications shall be made available to OIG, upon request.

D. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 120 days of the effective date of this CIA, RenaLab shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist RenaLab in assessing and evaluating its billing and coding practices and certain compliance obligations pursuant to this CIA and the Settlement Agreement. Each IRO retained by RenaLab shall have expertise in the billing, coding, reporting and other requirements applicable to ESRD laboratory services and in the general requirements of the Federal health care program(s) from which RenaLab seeks reimbursement. Each IRO shall assess, along with RenaLab, whether it can perform the IRO review in a professionally independent fashion taking into account any other business relationships or other engagements that may exist. The IRO(s) review shall address and analyze RenaLab's billing and coding to the Federal health care programs ("Claims Review") and shall analyze whether RenaLab sought payment for certain unallowable costs ("Unallowable Cost Review").

b. Frequency of Claims Review. The Claims Review shall be performed annually and shall cover each of the one-year periods of the CIA beginning with the effective date of this CIA. The IRO(s) shall perform all components of each annual Claims Review.

c. Frequency of Unallowable Cost Review. The Unallowable Cost Review shall be performed by the IRO for the first one-year reporting period beginning with the effective date of the CIA.

d. Retention of Records. The IRO and RenaLab shall retain and make available to the OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and RenaLab 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 A to this CIA, which is incorporated by reference.

a. Discovery Sample. The IRO shall randomly select and review a sample of 50 Medicare Paid Claims submitted by or on behalf of RenaLab. The Paid Claims shall be reviewed based on the supporting documentation available at RenaLab or under RenaLab's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted and reimbursed.

i. If the Error Rate (as defined in Appendix A) for the Discovery Sample is less than 5%, no additional sampling is required, and no Systems Review shall be required. (Note: The threshold listed above does not imply that this is an acceptable error rate. Accordingly, RenaLab should, as appropriate, further analyze any errors identified in the Discovery Sample. RenaLab recognizes that the 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.)

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.D.2.a, the IRO shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance

with Appendix A. The Full Sample should be designed to (1) 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 (2) 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 RenaLab or under RenaLab's control and applicable billing and coding regulations and guidance to determine whether the claim submitted 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, RenaLab may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 50 Items, as part of its Full Sample. The OIG, in its full discretion, may refer the findings of the Full Sample (and any related workpapers) received from RenaLab to the appropriate Federal health care program payor, including the Medicare contractor (*e.g.*, carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

c. Systems Review. If RenaLab's Discovery Sample identifies an Error Rate of 5% or greater, RenaLab'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 should 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 to RenaLab 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.H.1 of the CIA, RenaLab agrees to 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. RenaLab agrees to make available to the OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor and the associated documentation.

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

4. *Unallowable Cost Review.* The IRO shall conduct a review of RenaLab's compliance with the unallowable cost provisions of the Settlement Agreement.

a. The IRO shall determine whether Renal Care Group and RenaLab have complied with their obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and their 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 Renal Care Group or any of its subsidiaries, and to request, and agree, that such cost reports, cost statements, information reports or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. 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. The IRO shall prepare a report based upon the Unallowable Cost Review performed. The Unallowable Cost Review Report shall include:

a. the IRO's findings and supporting rationale regarding the Unallowable Costs Review and whether Renal Care Group and RenaLab have complied with their 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. *Validation Review.* In the event the OIG has reason to believe that: (a) RenaLab's Claims Review or Unallowable Cost Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review or Unallowable Cost Review complied with the requirements of the CIA and/or the findings or Claims Review results are inaccurate ("Validation Review"). RenaLab agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after RenaLab's final submission (as described in section II) is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify RenaLab of its intent to do so and provide a written explanation of why the OIG believes such a review is necessary. To resolve any concerns raised by the OIG, RenaLab may request a meeting with the OIG to discuss the results of any Claims Review or Unallowable Cost Review submissions or findings; present any additional or relevant information to clarify the results of the Claims Review or Unallowable Cost Review to correct the inaccuracy of the Claims Review; and/or propose alternatives to the proposed Validation Review. RenaLab agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Claims Review or Unallowable Cost Review with RenaLab 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 the OIG.

7. *Independence Certification.* The IRO shall include in its report(s) to RenaLab a certification or sworn affidavit that it has evaluated its professional independence with regard to the Claims Review or Unallowable Cost Review and that it has concluded that it was, in fact, independent.

E. Disclosure Program.

At all times during the term of this CIA, RenaLab shall maintain a Disclosure Program, similar to that described in the Renal Care Group Standards of Conduct and Business Ethics and Compliance Manual, that 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 RenaLab'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. RenaLab 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 non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality will 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, RenaLab 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 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 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 that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred or otherwise declared ineligible.

2. *Screening Requirements*. RenaLab shall not hire as employees or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, RenaLab shall screen all prospective employees and prospective contractors prior to engaging their services by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) querying the General Services

Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.hhs.gov/oig) (these lists will hereinafter be referred to as the "Exclusion Lists"). Nothing in this section affects the responsibility of (or liability for) RenaLab to refrain from billing Federal health care programs for services of the Ineligible Person.

3. *Review and Removal Requirement.* Within 120 days of the Effective Date of this CIA, RenaLab shall review its list of current employees and contractors against the Exclusion Lists. Thereafter, RenaLab shall review its list of current employees and contractors against the Exclusion Lists annually. In addition, RenaLab shall require employees and contractors to disclose immediately any debarment, exclusion, or other event that makes the employee an Ineligible Person.

If RenaLab has actual notice that an employee or contractor has become an Ineligible Person, RenaLab shall remove such person from responsibility for, or involvement with, RenaLab'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 RenaLab has actual 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 term, RenaLab 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 30 days of discovery, RenaLab shall notify OIG, in writing, of any ongoing investigation known to RenaLab or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that RenaLab 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. RenaLab shall also provide written notice to OIG within 30 days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

H. Reporting.

1. *Overpayments*

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

b. Reporting of Overpayments. If, at any time, RenaLab identifies or learns of any overpayments, RenaLab shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of identification of the overpayment and take remedial steps within 60 days of identification (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. Also, within 30 days of identification of the overpayment, RenaLab shall repay the overpayment to the appropriate payor to the extent such overpayment has been quantified. If not yet quantified, within 30 days of identification, RenaLab 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 should be done in accordance with the payor's policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix B 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 (e.g., credit balances) should be handled in accordance with such policies and procedures.

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 probable 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 RenaLab determines through any means that there is a Material Deficiency, RenaLab shall notify OIG, in writing, within 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) by 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 RenaLab's actions taken to correct the Material Deficiency; and

(iv) any further steps RenaLab 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, RenaLab changes locations or sells, closes, purchases or establishes new business units related to the furnishing of items or services that may be reimbursed by Federal health care programs, RenaLab shall notify OIG of this fact as soon as possible, but no later than within 30 days of the date of change of location, sale, closure, 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 150 days after the Effective Date of this CIA, RenaLab 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, and a summary of other non-compliance 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 copy of RenaLab's revised Code of Conduct required by section III.B.1 or a certification by the Compliance Officer that the documents included in Appendix C constitute the required materials;

4. a summary of all Policies and Procedures required by section III.B.2 or a certification by the Compliance Officer that the documents included in Appendix C constitute the required materials;

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 Code of Conduct certification required by section III.B.1;

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

    d. the Disclosure Program required by Section III.E is in place.

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

7. the identity of the IRO(s), a summary/description of all engagements between RenaLab and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, and the proposed start and completion dates of the first annual review;

8. a certification from the IRO regarding its professional independence from RenaLab;

9. a summary of personnel actions (other than hiring) taken pursuant to section III.F.;

10. a list of all of RenaLab'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 name and address of the Medicare contractor to which RenaLab currently submits claims;

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

12. the certification required by section V.C.

B. Annual Reports. RenaLab shall submit to OIG Annual Reports with respect to the status of, and findings regarding, RenaLab's compliance activities for each of the three 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, position description, or other non-compliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in section III.A;

2. a certification by the Compliance Officer that:

   a. all Covered Persons have completed any Code of Conduct certifications 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. RenaLab 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; (ii) not to charge to or otherwise seek payment from Federal or State payors for Unallowable Costs (as defined in the Settlement Agreement); and (iii) 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); copies of any compliance-related Policies and Procedures shall be available to OIG upon request;

4. a description of all training materials used for the training required by section III.C (to the extent it has not already been provided as part of the Implementation Report), 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 IRO's billing and compliance engagements, including a copy of the methodology used, along with a copy of the IRO's engagement letter;

6. RenaLab's response and corrective action plan(s) related to any issues raised by the IRO(s);

7. a revised summary/description of all engagements between RenaLab and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, if different from what was submitted as part of the Implementation Report;

8. a certification from the IRO regarding its professional independence from RenaLab;

9. 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;

10. 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, non-hospital patient, 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 (e.g., credit balances) do not need to be included in this aggregate overpayment report;

11. a summary of the disclosures in the disclosure log required by section III.E that relate to Federal health care programs;

12. a description of any personnel actions (other than hiring) taken by RenaLab 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;

13. 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;

14. a description of all changes to the most recently provided list (as updated) of RenaLab's locations (including locations and mailing addresses) as required by section V.A.11, 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; and

15. the certification required by section V.C.

The first Annual Report shall be received by the 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) except as otherwise described in the applicable report, RenaLab 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: RenaLab 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. RenaLab 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
Telephone: (202) 619-2078
Facsimile: (202) 205-0604

Renal Care Group or RenaLab:

Doug Chappell
General Counsel
Renal Care Group, Inc.
2100 West End Avenue, Suite 800
Nashville, TN 37203
Telephone: (615) 345-5526
Facsimile: (615) 345-5503

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 RenaLab's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of RenaLab's locations for the purpose of verifying and evaluating: (a) RenaLab's compliance with the terms of this CIA; and (b) RenaLab's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by RenaLab 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 RenaLab'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. RenaLab agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Notwithstanding such agreement, OIG recognizes that employees have the right to refuse to submit to interviews, and RenaLab shall not be obligated to require their employees to submit to interviews. In those instances where RenaLab is involved in ongoing litigation with the United States, or is under a government investigation manifested by the issuance of a subpoena, Civil Investigative Demand, Authorized Investigative Demand, or other formal civil or criminal request from HHS or any other Government agency for records at the RenaLab, RenaLab retains the discretion (in accordance with the law) to prevent interviews sought pursuant to this paragraph of any officer or employee of RenaLab. Subject to the above, employees of the RenaLab may elect to be interviewed with or without a representative of RenaLab present.

Nothing in this CIA, or any communication or report made pursuant to this CIA, shall constitute a waiver of, or be construed to require RenaLab to waive, RenaLab's attorney-client, work product, or other applicable privileges. Notwithstanding that fact, the existence of any such privilege does not affect RenaLab's obligation to comply with the provisions of this CIA, e.g., by providing all documents necessary to determine whether RenaLab is in compliance with the terms of the CIA.

VIII. DOCUMENT AND RECORD RETENTION

RenaLab shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for four (4) 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 RenaLab prior to any release by OIG of information submitted by RenaLab pursuant to its obligations under this CIA and identified upon submission by RenaLab as trade secrets, or information that is

commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, RenaLab shall have the rights set forth at 45 C.F.R. § 5.65(d). RenaLab 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

Renal Care Group and RenaLab are 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, Renal Care Group, RenaLab, 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 RenaLab fails to have in place any of the obligations described in section III:

a. a Compliance Officer;

b. a Compliance Committee;

c. a written Code of Conduct;

d. written Policies and Procedures;

e. a requirement that Covered Persons be trained; and

f. a Disclosure Program.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day RenaLab fails to retain an IRO, 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 RenaLab 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 RenaLab employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, RenaLab'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 RenaLab 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 RenaLab 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 RenaLab fails to grant access.)

6. A Stipulated Penalty of $1,000 for each day Renal Care Group or RenaLab fails to comply fully and adequately with any obligation of this CIA. In its notice to Renal Care Group or RenaLab, OIG shall state the specific grounds for its determination that Renal Care Group or RenaLab has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Renal Care Group or RenaLab must take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the Renal Care Group or RenaLab receives notice from the OIG of the failure to comply.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under paragraphs 1-5 of this section.

B. Timely Written Requests for Extensions. Renal Care Group or RenaLab 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 Renal Care Group or RenaLab 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 Renal Care Group or RenaLab 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 Renal Care Group or RenaLab 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 Renal Care Group or RenaLab of: (a) Renal Care Group's or RenaLab'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 10 days of the receipt of the Demand Letter, Renal Care Group or RenaLab 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 Renal Care Group or RenaLab elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Renal Care Group or RenaLab 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 Renal Care Group or RenaLab 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 RenaLab 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 Renal Care Group or RenaLab constitutes an independent basis for the exclusion of the party in material breach from participation in the Federal health care programs. Upon a determination by OIG that Renal Care Group or RenaLab has materially breached this CIA and that exclusion should be imposed, OIG shall notify Renal Care Group or RenaLab of: (a) Renal Care Group's or RenaLab'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.* Renal Care Group or RenaLab 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. Renal Care Group or RenaLab is in compliance with the obligations of the CIA cited by the 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) Renal Care Group or RenaLab has begun to take action to cure the material breach; (ii) Renal Care Group or RenaLab is pursuing such action with due diligence; and (iii) Renal Care Group or RenaLab has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If at the conclusion of the 30-day period, Renal Care Group or RenaLab fails to satisfy the requirements of section X.D.3, OIG may exclude the party in material breach from participation in the Federal health care programs. OIG will notify Renal Care Group or RenaLab in writing of its determination to exclude the party in material breach (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 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, Renal Care Group or RenaLab wishes to apply for reinstatement, then the party that was excluded 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 Renal Care Group or RenaLab 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, Renal Care Group or RenaLab 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 of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 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 Renal Care Group or RenaLab was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. Renal Care Group or RenaLab shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. The 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 Renal Care Group or RenaLab to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Renal Care Group or RenaLab 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 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 Renal Care Group or RenaLab 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) Renal Care Group or RenaLab had begun to take action to cure the material breach within that period;

(ii) Renal Care Group or RenaLab has pursued and is pursuing such action with due diligence; and

(iii) Renal Care Group or RenaLab provided to OIG within that period a reasonable timetable for curing the material

breach and Renal Care Group or RenaLab 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 Renal Care Group or RenaLab, only after a DAB decision in favor of OIG. Renal Care Group or RenaLab's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Renal Care Group or RenaLab 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 20 days after the ALJ issues such a decision, notwithstanding that Renal Care Group or RenaLab 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. Renal Care Group and RenaLab agree to waive their rights 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 Renal Care Group or RenaLab, Renal Care Group or RenaLab will be reinstated effective on the date of the original exclusion.

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, Renal Care Group, RenaLab, and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of Renal Care Group and RenaLab;

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;

D. OIG may agree to a suspension of Renal Care Group's or RenaLab's obligations under the CIA in the event of Renal Care Group's or RenaLab's cessation of participation in Federal health care programs. If Renal Care Group or RenaLab withdraws from participation in Federal health care

programs and is relieved from its CIA obligations by the OIG, Renal Care Group or RenaLab agrees to notify OIG 30 days in advance of Renal Care Group's or RenaLab's intent to reapply as a participating provider or supplier with the Federal health care programs. Upon receipt of such notification, OIG will evaluate whether the CIA should be reactivated or modified.

E. The undersigned Renal Care Group and RenaLab 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 RENAL CARE GROUP, INC.

R. DIRK ALLISON
Executive Vice President and
Chief Financial Officer

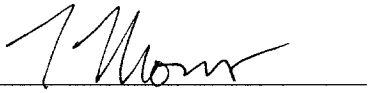
01/03/02
DATE

ON BEHALF OF RENALAB, INC.

GARY R. BRUKARDT
Vice President

01/03/02
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

12/18/01
DATE

APPENDIX A

A. Claims Review.

1. **Definitions**. For the purposes of the Claims Review the following definitions shall be used:

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

b. Item: Any discrete unit that can be sampled (e.g., code, line item, beneficiary, patient encounter, etc.).

c. Paid Claim: A code or line item submitted by or on behalf of RenaLab for items or services provided by RenaLab and for which Renal Care Group or RenaLab has received reimbursement from the Medicare program.

d. Population: All Items for which Renal Care Group or RenaLab has submitted a code or line item for items or services provided by RenaLab and for which Renal Care Group or RenaLab has received reimbursement from the Medicare program (i.e., a Paid Claim) during the 12-month period covered by the Claims Review. To be included in the Population, an Item must have resulted in at least one Paid Claim.

e. Error Rate: The Error Rate shall be the percentage of net overpayments identified in the sample. 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 Items included in the Claims Review, any Paid Claim for which RenaLab cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by RenaLab for such Paid Claim shall be deemed an Overpayment.

Replacement sampling for Paid Claims with missing documentation is not permitted.

b. 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 associated with the Items selected in each first sample (or first sample for each strata, if applicable) shall be used. In other words, 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 Item as that term is utilized for the Claims Review. For purposes of this Claims Review, the term "Item" may refer to any discrete unit that can be sampled (e.g., claim, line item, beneficiary, patient encounter, etc.).

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 totality of Items 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. In most circumstances, the sampling frame will be identical to the Population.

e. Source of Data: A description of the 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, CMS program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).

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

2. **Claims Review Findings.**

a. a description of RenaLab's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing;

b. the IRO's findings, supporting rationale, and a summary of such findings and rationale regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any) with the gross Overpayment amount, the net Overpayment amount, and the corresponding Error Rate(s) related to the net Overpayment. Note: for the purpose of this reporting, 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 or Full Sample (as applicable) shall be included as part of the net Overpayment calculation; and

c. the IRO's findings and recommendations concerning the Systems Review (if any).

3. **Statistical Sampling Documentation.**

a. The number of Items 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 Items are to be included in the Full Sample.

d. A description or identification of the statistical sampling software package used to conduct the sampling.

4. **Claims Review Results.**

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

b. 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 RenaLab.

c. Total dollar amount of paid Items included in the sample and the net Overpayment associated with the sample.

d. Error Rate in the sample.

e. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, 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.)

5. **Systems Review.** Observations and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s) in the sample Population.

6. **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.

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 reaso
n 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	MSP/Other Payer Involvement	Miscellaneous
01 - Corrected Date of Service	08 - MSP Group Health Plan Insurance	13 - Insufficient Documentation
02 - Duplicate	09 - MSP No Fault Insurance	14 - Patient Enrolled in an HMO
03 - Corrected CPT Code	10 - MSP Liability Insurance	15 - Services Not Rendered
04 - Not Our Patient(s)	11 - MSP, Workers Comp.(Including Black Lung	16 - Medical Necessity
05 - Modifier Added/Removed	12 - Veterans Administration	17 - Other (Please Specify)
06 - Billed in Error		_____
07 - Corrected CPT Code		

Attachment 1

Claim 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