INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
KERLAN-JOBE ORTHOPAEDIC CLINIC, A MEDICAL GROUP, INC.

I. PREAMBLE

Kerlan-Jobe Orthopaedic Clinic, A Medical Group, Inc. ("KJOC") hereby enters into this Integrity Agreement ("Agreement") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance with the statutes, regulations, program requirements, 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") by KJOC. Separate from this Agreement, KJOC has entered into a Settlement Agreement with the United States.

Prior to execution of this Agreement, KJOC established a compliance program ("Compliance Program"). The Compliance Program includes: written policies and procedures; an education and training component; mechanisms for the ongoing monitoring and auditing of KJOC's claims to assess compliance; a mechanism for employees to anonymously report incidents of noncompliance; a system for responding to violations of policies and procedures, and Federal laws, rules or regulations; and oversight of the Compliance Program by an Administrator, Compliance Contact, Compliance Committee, and Executive Committee. KJOC agrees to continue the operation of the Compliance Program as appropriate, but, at a minimum, KJOC shall ensure that it complies with the integrity obligations enumerated in this Agreement.

II. TERM AND SCOPE OF THE AGREEMENT

A. The period of the compliance obligations assumed by KJOC under this Agreement shall be 3 years from the effective date of this Agreement ("Effective Date") (unless otherwise specified). The Effective Date shall be the date on which the final signatory of this Agreement executes this Agreement. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

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

C. The scope of this Agreement shall be governed by the following definition:

1. "Covered Persons" includes:

a. all officers, directors, associates, and employees of KJOC ("KJOC Covered Persons"); and

b. all contractors and agents that provide patient care items or services or that perform billing or coding functions on behalf of KJOC ("Contractor Covered Persons").

III. INTEGRITY OBLIGATIONS

KJOC hereby agrees to maintain a Compliance Program that, at minimum, includes the following elements:

A. Compliance Contact

To the extent KJOC has not already done so, within 30 days after the Effective Date, KJOC shall designate a person to be the Compliance Contact for purposes of developing and implementing policies, procedures, and practices designed to ensure compliance with the obligations herein and with Federal health care program requirements. In addition, the Compliance Contact is responsible for responding to questions and concerns from Covered Persons and the OIG regarding compliance with the Agreement obligations. The name and phone number of the Compliance Contact shall be included in the Implementation Certification. In the event a new Compliance Contact is appointed during the term of this Agreement, KJOC shall notify the OIG, in writing, within 15 days of such a change.

B. Posting of Notice

Within the first 30 days following the Effective Date, KJOC shall post in a prominent place accessible to all patients and Covered Persons a notice detailing KJOC's commitment to comply with all Federal health care program requirements in the conduct

of its business. This notice shall include a means (i.e., telephone number, address, etc.) by which instances of misconduct may be reported anonymously. A copy of this notice shall be included in the Annual Report.

C. Written Policies and Procedures

To the extent not already accomplished, within 90 days after the Effective Date, KJOC agrees to develop, implement, and make available to all Covered Persons written policies that address the following:

1. KJOC's commitment to operate its business in full compliance with all Federal health care program requirements;

2. KJOC's requirement that all Covered Persons shall be expected to comply with all Federal health care program requirements and with KJOC's own Policies and Procedures, as implemented pursuant to Section III.C (including the requirements of this Agreement);

3. The requirement that all of KJOC's Covered Persons shall be expected to report to KJOC or the Compliance Contact suspected violations of any Federal health care program requirements or KJOC's own Policies and Procedures. Any Covered Person who makes an inquiry regarding compliance with Federal health care program requirements shall be able to do so without risk of retaliation or other adverse effect.

4. The requirement that KJOC shall ensure that all owners, officers, directors, employees, contractors, and agents of KJOC are not Ineligible Persons. For purposes of this Agreement, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or (ii) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible. To prevent hiring, contracting, or engaging with any Ineligible Person, KJOC shall check all prospective owners, officers, directors, employees, contractors, and agents prior to engaging their services against the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov) and the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov). In addition to prospective checks, KJOC shall conduct annual checks of all employees against each exclusion list.

5. The commitment of KJOC to remain current with all Federal health care program requirements by obtaining and reviewing program memoranda, newsletters, and any other correspondence from the carrier related to Federal health care program requirements.

6. The proper procedures for the accurate preparation and submission of claims in accordance with Federal health care program requirements; and

7. The proper documentation of services and billing information and the retention of such information in a readily retrievable form.

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

Within 90 days after the Effective Date, each Covered Person shall certify in writing that he or she has received, read, understood, and will abide by KJOC's Policies and Procedures. New Covered Persons shall review the Policies and Procedures and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

Copies of the written policies and procedures shall be included in the Annual Report. Copies of any written policies and procedures that are subsequently revised shall be included in the Annual Report.

D. Training and Certification

Within 90 days following the Effective Date and at least once each year thereafter, KJOC Covered Persons involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program shall receive at least 4 hours of training. The training shall be conducted by an individual or entity with expertise in the relevant subject areas, e.g., preparation or submission of claims to Federal health care programs for the types of services provided by KJOC.

New KJOC Covered Persons involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any

Federal health care program shall receive the training described above within 30 days after becoming a KJOC Covered Person or within 90 days after the Effective Date, whichever is later. The training for new KJOC Covered Persons may either be provided internally by Covered Persons who have completed the required annual training or externally by a qualified individual or entity. Until they have received the requisite training, such new KJOC Covered Persons shall work under the direct supervision of a Covered Person who has received such training.

At a minimum, the annual and new KJOC Covered Person training sessions shall cover the following topics:

1. Federal health care program requirements related to the proper submission of accurate bills for services rendered and/or items provided to Federal health care program patients;

2. the written Policies and Procedures developed pursuant to Section III.C, above;

3. the legal sanctions for improper billing or other violations of the Federal health care program requirements; and

4. Examples of proper and improper billing practices.

Each KJOC Covered Person shall annually 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. KJOC shall retain the certifications, along with the training course materials. The training course materials shall be provided in the Annual Report.

KJOC shall require each Contractor Covered Person to certify to KJOC at least once per year that his/hers/its employees and agents who perform work for KJOC have received training of at least four hours per year on the subjects set forth in topics 1, 3, and 4 above, as well as the particular written KJOC Policies and Procedures which directly relate to the work which he/she/it has been contracted to perform (which KJOC shall furnish to the Contractor Covered Person on an annual basis). KJOC shall retain the certifications and provide them to OIG upon request.

E. Annual Review Procedures

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days after the Effective Date, KJOC shall retain a person or entity, such as a nurse reviewer, an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist KJOC in assessing and evaluating its billing and coding practices. Each IRO retained by KJOC shall have expertise in the billing, coding, reporting, and other requirements of physician practices and in the general requirements of the Federal health care program(s) from which KJOC seeks reimbursement. Each IRO shall assess, along with KJOC, whether it can perform the IRO review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist. The IRO(s) review shall address and analyze KJOC's billing and coding to the Federal health care programs ("Claims Review") and shall analyze whether KJOC 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 Reporting Periods. The IRO(s) shall perform all components of each annual Claims Review.

c. Frequency of Unallowable Cost Review. The IRO shall perform the Unallowable Cost Review for the first Reporting Period, if applicable.

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

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

a. Discovery Samples. The IRO shall randomly select and review two samples of 50 Medicare Paid Claims submitted by or on behalf of KJOC. One sample shall be composed of 50 Paid Claims for Evaluation and Management services and the second sample shall be composed of 50 Paid Claims for Surgical services. The Paid Claims shall be reviewed based on the supporting documentation available at KJOC or under KJOC'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 a Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The threshold listed above does not imply that this is an acceptable error rate. Accordingly, KJOC should, as appropriate, further analyze any errors identified in the Discovery Samples. KJOC recognizes that OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority, may also analyze or review Paid Claims included, or errors identified, in the Discovery Samples.)

ii. If a 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 Medicare Paid Claims using commonly accepted sampling methods and in accordance with Appendix A. The Full Sample shall be designed to (i) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate; and (ii) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be

reviewed based on supporting documentation available at KJOC or under KJOC'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, KJOC 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. OIG, in its full discretion, may refer the findings of the Full Sample (and any related workpapers) received from KJOC 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 either Discovery Sample identifies an Error Rate of 5% or greater, KJOC's IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO shall perform a "walk through" of the system(s) and process(es) that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and process(es) that generated the claim.

d. Repayment of Identified Overpayments. In accordance with Section III.F.1, KJOC shall repay 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. KJOC shall make available to OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor.

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

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

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

6. *Validation Review.* In the event OIG has reason to believe that: (a) KJOC's Claims Review or Unallowable Cost Review fails to conform to the requirements of this Agreement; or (b) the IRO's findings or Claims Review results are inaccurate, 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 Agreement and/or the findings or Claims Review results are inaccurate ("Validation Review"). KJOC shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents so long as it is initiated within one year after KJOC's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify KJOC of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, KJOC may request a meeting with 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; present a corrected Claims Review; or propose alternatives to the proposed Validation Review. KJOC shall provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Claims Review or Unallowable Cost Review with KJOC prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

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

F. Reporting of Overpayments and Material Deficiencies

1. *Overpayments*

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

b. Reporting of Overpayments. If, at any time, KJOC identifies or learns of any overpayments, KJOC shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayments from recurring. Also, within 30 days after identification of the Overpayment, KJOC shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, KJOC 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, shall include the information contained

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

2. *Material Deficiencies.*

a. Definition of Material Deficiency. For purposes of this Agreement, 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 KJOC determines, by any means, that there is a Material Deficiency, KJOC shall notify OIG, in writing, within 30 days after 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.F.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 KJOC's actions taken to correct the Material Deficiency; and

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

G. Notification of Government Investigations or Legal Proceedings

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

IV. New Business Units or Locations

In the event that, after the Effective Date, KJOC changes locations or sells, closes, purchases, or establishes a new business related to the furnishing of items or services that may be reimbursed by Federal health care programs, KJOC shall notify OIG of this fact as soon as possible, but no later than within 30 days after 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 or supplier 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 Agreement (e.g., completing certifications and undergoing training).

V. REPORTS

A. Implementation Certification

Within 120 days after the Effective Date, KJOC shall submit a written certification to OIG summarizing the status of its implementation of the requirements of this Agreement. This submission, known as the "Implementation Certification," shall include:

1. A certification signed by the Compliance Contact attesting that the Policies and Procedures are being implemented and have been made available to all Covered Persons; and

2. A certification signed by the Compliance Contact attesting that all employees have completed the initial training required by Section III.D and have executed the required certifications.

B. Annual Reports

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

Each Annual Report shall include:

1. Any change in the name, address, or phone number of KJOC's Compliance Contact;

2. A copy of the notice KJOC posted in its office as described in Section III.B and a description of where and when the notice has been posted;

3. A copy of the written policies and procedures required by Section III.C of this Agreement; In subsequent years, if revisions were made to the written policies and procedures developed pursuant to Section III.C of this Agreement, a copy of any policies and procedures that were revised;

4. A certification by the Compliance Contact that all Covered Persons have executed the annual Policies and Procedures certification required by Section III.C;

5. A copy of all training materials used for the training required by Section III.D, a description of the training, including a summary of the topics covered, the length of the session(s) and a schedule of when the training session(s) were held;

6. A certification signed by the Compliance Contact certifying that he or she is maintaining written certifications from all Covered Persons that they received training pursuant to the requirements set forth in Section III.D of this Agreement;

7. The name and qualifications of the IRO, a summary/description of all engagements between KJOC 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 KJOC;

9. A complete copy of all reports prepared pursuant to the IRO's Claims Review and Unallowable Costs review, including the Claims Review Report, along with a copy of the IRO's engagement letter;

10. KJOC's response and corrective action plan(s) related to any issues raised or recommendations made by the IRO;

11. A summary of Material Deficiencies (as defined in Section III.F) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;

12. 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;

13. A certification signed by KJOC certifying that all prospective employees and contractors are being screened against the HHS/OIG List of Excluded Individuals/Entities and the General Services Administration's List of Parties Excluded from Federal Programs;

14. A list of all KJOC'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 KJOC currently submits claims; and

15. A certification signed by KJOC's compliance contact, certifying that he or she has reviewed the Annual Report, he or she has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated subsequent to the execution of this Agreement, all notifications and reports required under the terms of this Agreement shall be submitted to the following:

OIG:
Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Phone: 202-619-2078
Fax: 202-205-0604

KJOC:
Ralph A. Gambardella, M.D.
Kerlan-Jobe Orthopaedic Clinic
6801 Park Terrace, Suite 500
Los Angeles, California 90045
Phone: 310-665-7235
Fax: 310-665-7296

Unless otherwise specified, all notifications and reports required by this Agreement 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 KJOC's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of KJOC's locations for the purpose of verifying and evaluating: (a) KJOC's compliance with the terms of this Agreement; and (b) KJOC's compliance with the requirements of the Federal health care programs in which KJOC participates. The documentation described above shall be made available by KJOC 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 KJOC'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. KJOC agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. KJOC's employees may elect to be interviewed with or without a representative of KJOC present. Nothing in this CIA, or any other communication or report made pursuant to this CIA, shall constitute or require a waiver by KJOC of its attorney-client, attorney work-product, or other applicable privileges. Notwithstanding that fact, the existence of any such privilege shall not be used by KJOC to avoid its obligations to comply with the provisions of this CIA.

VIII. DOCUMENT AND RECORD RETENTION

KJOC shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this Agreement, for four 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 KJOC prior to any release by OIG of information submitted by KJOC pursuant to its obligations under this Agreement and identified upon submission by KJOC as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, KJOC shall have the rights set forth at 45 C.F.R. § 5.65(d). KJOC 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

Full and timely compliance by KJOC is expected throughout the duration of this Agreement with respect to all of the obligations herein agreed to by KJOC.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, KJOC and OIG hereby agree that failure to comply with certain obligations set forth in this Agreement 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 KJOC fails to have in place any of the obligations described in Section III:

   a. a Compliance Contact;

   b. a written Code of Conduct;

   c. written Policies and Procedures;

   d. a requirement that Covered Persons be trained; and

   e. 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 KJOC fails to retain an IRO, as required in Section III.E.

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 KJOC fails to meet any of the deadlines for the submission of the Implementation Certification 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 KJOC has an owner, officer, director, employee, contractor, or agent who is an Ineligible Person and that person: (a) has responsibility for, or involvement with, KJOC's business operations related to the Federal

health care programs; or (b) 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 Subsection shall not be demanded for any time period during which KJOC can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry as to the status of the person).

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

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

7. A Stipulated Penalty of $1,000 for each day KJOC fails to comply fully and adequately with any obligation of this Agreement. In its notice to KJOC, OIG shall state the specific grounds for its determination that KJOC has failed to comply fully and adequately with the Agreement obligation(s) at issue and steps KJOC shall take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after KJOC receives notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.

B. Timely Written Requests for Extensions

KJOC 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 Agreement. 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 KJOC 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 KJOC 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 KJOC 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 KJOC of: (a) KJOC's failure to comply; and (b) 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 after the receipt of the Demand Letter, KJOC shall respond by either: (a) curing the breach to OIG's satisfaction and paying the applicable Stipulated Penalties; or (b) sending in writing to OIG a request for 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 KJOC elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until KJOC 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 Agreement 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 KJOC has materially breached this Agreement, 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 Agreement

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

a. a failure by KJOC to report a Material Deficiency, take corrective action and make the appropriate refunds, as required in Section III.F;

b. a repeated or flagrant violation of the obligations under this Agreement, 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.E.

2. *Notice of Material Breach and Intent to Exclude*. The parties agree that a material breach of this Agreement by KJOC constitutes an independent basis for KJOC's exclusion from participation in the Federal health care programs. Upon a determination by OIG that KJOC has materially breached this Agreement and that exclusion should be imposed, OIG shall notify KJOC of: (a) KJOC'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*. KJOC 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. KJOC is in compliance with the obligations of the Agreement 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) KJOC has begun to take action to cure the material breach; (ii) KJOC is pursuing such action with due diligence; and (iii) KJOC has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter*. If at the conclusion of the 30-day period, KJOC fails to satisfy the requirements of Section X.D.3, OIG may exclude KJOC from participation in the Federal health care programs. OIG will notify KJOC in writing of its determination to exclude KJOC (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, KJOC wishes to apply for reinstatement, KJOC 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 KJOC of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this Agreement, KJOC 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 Agreement. 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 Agreement shall be: (a) whether KJOC was in full and timely compliance with the obligations of this Agreement for which OIG demands payment; and (b) the period of noncompliance. KJOC 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 Agreement and orders KJOC to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless KJOC 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 Agreement shall be:

a. whether KJOC was in material breach of this Agreement;

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) KJOC had begun to take action to cure the material breach within that period; (ii) KJOC has pursued and is pursuing such action with due diligence; and (iii) KJOC provided to OIG within that period a reasonable timetable for curing the material breach and KJOC 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 KJOC, only after a DAB decision in favor of OIG. KJOC's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude KJOC upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that KJOC 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. KJOC agrees to waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of KJOC, KJOC will be reinstated effective on the date of the original exclusion.

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

XI. EFFECTIVE AND BINDING AGREEMENT

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

A. This Agreement shall be binding on the successors, assigns, and transferees of KJOC;

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

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

D. OIG may agree to a suspension of KJOC's obligations under this Agreement in the event of KJOC's cessation of participation in Federal health care programs. If KJOC withdraws from participation in Federal health care programs and is relieved from its Agreement obligations by the OIG, KJOC agrees to notify the OIG 30 days in advance of KJOC'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 Agreement should be reactivated or modified.

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

IN WITNESS WHEREOF, the parties hereto affix their signatures:

KERLAN-JOBE ORTHOPAEDIC CLINIC

4-15-04
Date

Ralph A. Gambardella, M.D.
Chairman and President
Kerlan-Jobe Orthopaedic Clinic,
a Medical Group, Inc.
6801 Park Terrace Drive, Suite 500
Los Angeles, California 90045

Approved as to form and content:

4/15/04
Date

Ronald J. Nessim
Bird, Marella, Boxer & Wolpert
Counsel for Kerlan-Jobe Orthopaedic Clinic

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

April 22, 2004
Date

Larry J. Goldberg
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services

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 KJOC has received in excess of the amount due and payable under any Medicare 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 KJOC and for which KJOC has received reimbursement from Medicare.

d. Population: All Items for which KJOC has submitted a code or line item and for which KJOC has received reimbursement from Medicare (i.e., a Medicare Paid Claim) as a primary payor 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 net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample or Full Sample (as applicable) shall be included as part of the net Overpayment calculation.)

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

2. *Other Requirements.*

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

KJOC cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by KJOC 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.

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. *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, if applicable.

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

3. *Claims Review Findings.*

a. Narrative Results.

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

ii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any) with the gross Overpayment amount, the net Overpayment amount, and the corresponding Error Rate(s) related to the net Overpayment.

b. Quantitative Results.

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

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

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

iv. Error Rate in the sample.

v. 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), and dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)

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

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

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

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

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

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

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

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

REFUND INFORMATION

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

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

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

For Institutional Facilities Only:
Cost Report Year(s) _____
(If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)

For OIG Reporting Requirements:
Do you have a Corporate Integrity Agreement with OIG? _____Yes _____No

Reason Codes:

Billing/Clerical Error	MSP/Other Payer Involvement	Miscellaneous
01 - Corrected Date of Service Documentation	08 - MSP Group Health Plan Insurance	13 - Insufficient
02 - Duplicate HMO	09 - MSP No Fault Insurance	14 - Patient Enrolled in an
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		17 - Other (Please Specify)
06 - Billed in Error	12 - Veterans Administration	_____
07 - Corrected CPT Code		