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

I. PARTIES

Oaktree Cancer Care, Inc. hereby enters into this Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to ensure compliance by Oaktree, all of its subsidiaries and affiliates, all of their employees, physicians, and other health care professionals, as well as all third parties with whom they may choose to engage to act as billing or coding agents or consultants (hereinafter collectively referred to as "Oaktree") with the requirements of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))(hereinafter collectively referred to as the "Federal health care programs"). Oaktree's compliance with the terms and conditions in this CIA shall constitute an element of its present responsibility with regard to participation in the Federal health care programs.

Contemporaneously with this CIA, Oaktree is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

II. TERM OF THE CIA

The period of the compliance obligations assumed by Oaktree under this CIA shall be five (5) years from the effective date of the CIA (unless otherwise specified). The effective date of the CIA will be the approval date of the Settlement Agreement pursuant to which this CIA is entered ("effective date"). The OIG may terminate this CIA one year after Oaktree provides verified proof to the OIG's reasonable satisfaction that none of the other named defendants in the suit captioned United States *ex rel.* Rahman v. Oncology Associates, P.C., *et al.*, Civil Action No. H-95-2241 (D. MD), nor any member of their immediate families or households (as defined by 42 U.S.C. § 1320a-7(j)) has an ownership or control interest (as defined by 42 U.S.C. § 1320a-3(a)(3)) or is a managing employee (as defined by 42 U.S.C. § 1320a-5(b)) of Oaktree. In addition to this verified

proof, before OIG will consent to such earlier termination of the CIA, OIG must also be reasonably satisfied that Oaktree has policies, procedures, and practices in effect to ensure its compliance with the requirements of Medicare, Medicaid and all other Federal health care programs. OIG agrees to act in good faith with respect to any request made by Oaktree for early termination of the CIA.

III. CORPORATE INTEGRITY OBLIGATIONS

Oaktree shall establish and maintain for the period of this CIA a compliance program that includes the following elements.

A. Compliance Officer. Within sixty (60) days of the effective date of this CIA, Oaktree shall appoint an individual to serve as Compliance Officer, who shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with the requirements of the Federal health care programs. The Compliance Officer shall be a member of senior management of Oaktree, shall make regular (at least quarterly) reports regarding compliance matters directly to the CEO and/or to the Board of Directors of Oaktree, and shall be authorized to report to the Board of Directors at any time. The Compliance Officer shall be responsible for monitoring the day-to-day activities engaged in by Oaktree to further its compliance objectives. The Compliance Officer shall be responsible for any reporting obligations created under this CIA.

In the event a new Compliance Officer is appointed during the term of this CIA, Oaktree shall notify the OIG, in writing, within fifteen (15) days of such a change.

B. Independent Coding Officer. Within sixty (60) days after the effective date of this CIA, Oaktree shall appoint an appropriately qualified Independent Coding Officer ("ICO") who has expertise in the rules governing submissions of claims to Federal health care programs for radiation oncology items and services. The ICO may retain additional personnel, including, but not limited to consultants, if needed to help meet the ICO's obligations under this CIA. Oaktree shall be responsible for all costs reasonably incurred by the ICO in carrying out the responsibilities specified in this CIA, including, but not limited to, travel costs, consultants, administrative personnel, office space and equipment, or additional personnel.

The ICO shall have the sole authority and responsibility to determine which claims for reimbursement for radiation oncology items and services furnished by Oaktree will be submitted to Federal health care programs. The policies, procedures, and rules developed

by the ICO shall be consistent with the final New York Local Medical Review Policy on Radiation Oncology and any subsequently adopted revisions. Oaktree shall be informed in writing of the policies, procedures, and guidelines developed by the ICO.

Oaktree shall bill Federal health care programs for items and services solely in accordance with the ICO's policies, procedures and guidelines. Oaktree will not participate in the ICO's development of these policies, procedures, and guidelines; Oaktree's sole role will be to implement the policies, procedures, and guidelines developed by the ICO.

The ICO shall also be responsible for monitoring the day-to-day activities engaged in by Oaktree to implement the ICO's policies, procedures, and guidelines. As part of that monitoring, the ICO shall at least twice per year conduct audits of Oaktree's compliance with the coding policies, procedures, and guidelines. In the event an ICO audit detects that a claim submitted to a Federal health care program was at variance with the ICO's coding policies and procedures, the ICO shall investigate the discrepancy and require withdrawal of the claim or refund of payment as appropriate. Oaktree shall comply with the ICO's findings. The ICO shall keep documentation of his or her investigations for submission as part of the Annual Report.

To facilitate performance of the ICO's responsibilities, Oaktree shall give the ICO:

i. immediate access to Oaktree's facilities, at any time and without prior notice, to assess compliance with this CIA;

ii. prompt access to any of Oaktree's documents and data requested by the ICO to perform the duties required under this CIA; and

iii. prompt access to Oaktree's staff for interviews outside the presence of supervisory staff or counsel, provided such interviews are conducted in accordance with all applicable laws and the rights of such individuals.

If the ICO resigns for any reason prior to expiration of the CIA, Oaktree shall appoint a replacement within forty-five (45) days of the resignation and shall notify OIG of the identity of the new ICO within fifteen (15) days of such change.

C. Written Standards.

1. *Code of Conduct.* Within ninety (90) days of the effective date of this CIA, Oaktree shall establish a Code of Conduct. The Code of Conduct shall be distributed within ninety (90) days of the effective date of this CIA to all employees, and to all contractors and agents who are involved directly or indirectly in the delivery of patient care and/or in the preparation, coding or submission of claims for reimbursement of such care to any Federal health program. (Those employees, contractors, and agents who are involved directly or indirectly in the delivery of patient care and/or in the preparation, coding or submission of claims for reimbursement of such care to any Federal health program shall hereinafter be referred to collectively as "Program Staff.") Oaktree shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees and Program Staff. The Code of Conduct shall, at a minimum, set forth:

a. Oaktree's commitment to full compliance with all statutes, regulations, and guidelines applicable to Federal health care programs, including its commitment to prepare and submit accurate billings consistent with Federal health care program regulations and procedures or instructions otherwise communicated by the Health Care Financing Administration ("HCFA") (or other appropriate regulatory agencies) and/or its agents;

b. Oaktree's requirement that all of its employees and Program Staff shall comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with Oaktree's own policies and procedures (including the requirements of this CIA);

c. Oaktree's requirement that all of its employees and Program Staff shall be expected to report suspected violations of any statute, regulation, or guideline applicable to Federal health care programs or of Oaktree's own policies and procedures;

d. the possible consequences to both Oaktree, and to employees and Program Staff, of failure to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with Oaktree's own policies and procedures or of failure to report such non-compliance; and

e. the right of all employees and Program Staff to use the confidential disclosure program, as well as Oaktree's commitment to confidentiality and non-retaliation with respect to disclosures.

Within one hundred twenty (120) days of the effective date of the CIA, each employee and Program Staff member shall certify, in writing, that he or she has received, read, understands, and will abide by Oaktree's Code of Conduct.

New employees and Program Staff members shall receive the Code of Conduct and shall complete the required certification within two (2) weeks after the commencement of their employment or contract or within one hundred twenty (120) days of the effective date of the CIA, whichever is later.

Oaktree will annually review the Code of Conduct and will make any necessary revisions. These revisions shall be distributed within thirty (30) days of initiating such a change. Employees and Program Staff shall certify on an annual basis that they have received, read, understand, and will abide by the Code of Conduct.

2. *Policies and Procedures*. Within ninety (90) days of the effective date of this CIA, Oaktree shall develop and put into effect written Policies and Procedures regarding the operation of Oaktree's compliance program and its compliance with all Federal and state health care statutes, regulations, and guidelines, including the requirements of the Federal health care programs. In addition, the Policies and Procedures shall include disciplinary guidelines and methods for employees and Program Staff to make disclosures or otherwise report on compliance issues to Oaktree's management through the Confidential Disclosure Program required by section III.F. Oaktree shall assess and update as necessary the Policies and Procedures at least annually and more frequently, as appropriate. A summary of the Policies and Procedures will be provided to OIG in the Implementation Report. The Policies and Procedures will be available to OIG upon request.

Within ninety (90) days of the effective date of the CIA, Oaktree shall distribute the relevant portions of the Policies and Procedures to all Program Staff. Oaktree will make its compliance staff or supervisors available to explain any and all policies and procedures.

D. Training and Education.

1. *General Training.* Within one hundred twenty (120) days of the effective date of this CIA, Oaktree shall provide at least two (2) hours of training to each employee and Program Staff member. This general training shall explain Oaktree's:

a. Corporate Integrity Agreement requirements;

b. Compliance Program (including the Policies and Procedures as they pertain to general compliance issues); and

c. Code of Conduct.

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

New employees and Program Staff Members shall receive the general training described above within thirty (30) days of the beginning of their employment or within one hundred twenty (120) days after the effective date of this CIA, whichever is later. Employees and Program Staff shall receive such general training on an annual basis.

2. *Specific Training.* Within one hundred fifty (150) days of the effective date of this CIA, all Program Staff shall receive at least four (4) hours of training in addition to the general training required above. This training shall include a discussion of:

a. the submission of accurate bills for services rendered to Medicare and/or Medicaid patients;

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

c. the personal obligation of each individual involved in the coding and billing process to ensure that such codings and billings are accurate;

d. applicable reimbursement rules and statutes;

e. the legal sanctions for improper billings and codings; and

f. examples of proper and improper billing and coding practices.

These training materials shall be made available to OIG, upon request. Persons providing the training must have expertise in the subject area.

New Program Staff shall receive this training within thirty (30) days of the beginning of their employment or within one hundred fifty (150) days of the effective date of this CIA, whichever is later. If a new Program Staff member has any responsibility for the delivery of patient care, the preparation or submission of claims and/or the assignment of procedure codes prior to completing this specific training, a Program Staff member who has completed the substantive training shall review all of the untrained person's work.

Program Staff members shall receive such specific training on an annual basis.

3. *Certification.* Each employee and Program Staff member shall certify, in writing, that he or she has attended the required training. The certification shall specify the type of training received and the date received. The Compliance Officer shall retain the certifications, along with specific course materials. These shall be made available to OIG upon request.

E. Review Procedures. Oaktree shall retain an entity, such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization") to perform review procedures to assist Oaktree in assessing the adequacy of its billing and compliance practices pursuant to this CIA. This shall be an annual requirement and shall cover a twelve (12) month period. The Independent Review Organization must have expertise in the billing, coding, reporting and other requirements of the Federal health care programs from which Oaktree seeks reimbursement. The Independent Review Organization must be retained to conduct the audit of the first year within ninety (90) days of the effective date of this CIA.

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

1. *Billing Engagement.* The billing engagement shall consist of a review of a statistically valid sample of claims that can be projected to the population of claims for the relevant period. The sample size shall be determined through the use of a probe sample. At a minimum, the full sample must be within a ninety (90) percent confidence

level and a precision of twenty-five (25) percent. The probe sample must contain at least thirty (30) sample units and cannot be used as part of the full sample. Both the probe sample and the sample must be selected through random numbers. Oaktree shall use OIG's Office of Audit Services Statistical Sampling Software, also known as "RAT-STATS," which is available through the Internet at "www.hhs.gov".

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

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

b. Billing Engagement Population: Identify the population, which is the group about which information is needed. Explain the methodology used to develop the population and provide the basis for this determination.

c. Sources of Data: Provide a full description of the source of the information upon which the billing engagement conclusions will be based, including the legal or other standards applied, documents relied upon, payment data, and/or any contractual obligations.

d. Sampling Unit: Define the sampling unit, which is any of the designated elements that comprise the population of interest.

e. Sampling Frame: Identify the sampling frame, which is the totality of the sampling units from which the sample will be selected.

As part of the billing engagement, the Independent Review Organization shall report in writing its findings regarding:

a. Oaktree's billing and coding operation (including, but not limited to, the operation of the billing system, strengths and weaknesses of this system, internal controls, and effectiveness of the system);

b. whether Oaktree is submitting accurate claims for services billed to the Federal health care programs.

c. Oaktree's procedures to correct inaccurate billings or codings to the Federal health care programs; and

d. the steps Oaktree is taking to bring their operations into compliance or to correct problems identified by the review.

2. *Compliance Engagement.* As part of the compliance engagement, the Independent Review Organization shall report in writing its findings regarding whether Oaktree's program, policies, procedures, and operations comply with the terms of this CIA. This engagement shall include findings regarding the status of Oaktree's compliance with each section of this CIA. In making its findings, the Independent Review Organization may interview appropriate employees and other individuals, inspect appropriate documents, and take such other actions as are necessary to ascertain the facts.

A complete copy of the Independent Review Organization's billing and compliance engagement shall be included in Oaktree's Annual Reports to OIG.

3. *Verification/Validation.* If the OIG has reason to believe that the billing engagement or compliance engagement fails to conform to the requirements of the CIA or indicates improper submissions not otherwise adequately addressed in the Independent Review Organization's report, it may conduct an independent review to determine whether or the extent to which Oaktree is complying with its obligations under this CIA. Upon identifying the need for an independent review, OIG will notify Oaktree of the basis for its determination and the expected parameters of the review, and will give Oaktree an opportunity to respond to the problems that OIG found with the Independent Review Organization's report. OIG may thereafter permit correction of the Independent Review Organization's report or, in its sole discretion, determine that an independent review is required. Oaktree agrees to pay for the reasonable cost of any such review or engagement by OIG or any of its designated agents.

F. Confidential Disclosure Program. Within ninety (90) days after the effective date of this CIA, Oaktree shall establish a Confidential Disclosure Program, which must include measures (*e.g.*, a toll-free compliance telephone line) to enable Program Staff or other individuals to disclose, to the Compliance Officer or some other person who is not in the reporting individual's chain of command, any suspected violation or irregularity associated with Oaktree's policies, practices or procedures related to any Federal health care program. Oaktree shall publicize the existence of the hotline by means calculated to reach all employees, contractors, agents, and other affected persons (*e.g.*, e-mail to employees or posting the hotline number prominently in common areas).

The Confidential Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communication. Upon receipt of a complaint, the Compliance Officer (or designee) shall gather the information in such a way as to elicit all relevant information from the individual reporting the alleged misconduct. 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, Oaktree 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 shall maintain a confidential disclosure log, which shall include a record and summary of each allegation received, the status of the respective investigations, and any corrective action taken in response to the investigation.

G. Ineligible Persons.

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

2. *Screening Requirements*. Oaktree shall not hire or engage as employees or Program Staff any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Oaktree shall screen all prospective employees and prospective Program Staff members prior to engaging their services by (i) requiring applicants to disclose whether they are Ineligible Persons, and (ii) reviewing 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").

3. *Review and Removal Requirement*. Within ninety (90) days of the effective date of this CIA, Oaktree will review its list of current employees and Program Staff members against the Exclusion Lists. Thereafter, Oaktree will review the list semi-

annually. If Oaktree has notice that an employee or Program Staff member has become an Ineligible Person, Oaktree will remove such person from responsibility for, or involvement with, its 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 Oaktree has notice that an employee or Program Staff member is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion, Oaktree shall take all appropriate actions to ensure that the responsibilities of that employee or Program Staff member have not and will not adversely affect the quality of care rendered to any patient or resident, or the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Proceedings. Within thirty (30) days of discovery, Oaktree shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that Oaktree has committed a crime or has engaged in fraudulent activities or any other knowing misconduct. 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. Oaktree shall also provide written notice to OIG within thirty (30) days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

I. Reporting.

1. *Overpayments*

a. Definition of Overpayments. For purposes of this CIA, an "overpayment" shall mean the amount of money Oaktree has received in excess of the amount due and payable under the Federal health care programs' statutes, regulations or guidelines, including carrier and intermediary instructions. Oaktree may not subtract any underpayments for purposes of determining the amount of relevant "overpayments."

b. Reporting of Overpayments. If, at any time, Oaktree identifies or learns of any billing, coding or other policies, procedures or practices that result in overpayments, Oaktree shall notify the payor (*e.g.*, Medicare fiscal intermediary or

carrier) and repay any overpayments within thirty (30) days of discovery (or such additional time as may be agreed to by the payor) and take remedial steps within sixty (60) days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Notification of overpayment may be done pursuant to a form similar to the Overpayment Refund Form, provided as Attachment # 1 to this CIA.

2. *Material Deficiencies.*

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

(i) a substantial overpayment to Oaktree relating to any Federal healthcare program; OR

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

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

b. Reporting of Material Deficiencies. If Oaktree has reason to believe that there is a material deficiency, Oaktree shall notify OIG within thirty (30) days of making the determination that the Material Deficiency exists. The report to 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 H.1, and shall include all of the information on the Overpayment Refund Form, as well as:

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

(b) the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid/refunded.

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

(iii) a description Oaktree's actions to correct the Material Deficiency; and

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

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event Oaktree purchases or establishes new business units after the effective date of this CIA, Oaktree shall notify OIG of this fact within thirty (30) days of the date of purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Federal health care program provider number(s) (if any), and the corresponding payor(s) (contractor specific) that has issued each provider number. All employees and Program Staff members at such locations shall be subject to the requirements in this CIA that apply to new employees and Program Staff members (*e.g.*, completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

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

1. the name, address, phone number and position description of the Compliance Officer required by section III.A;

2. a copy of Oaktree's Code of Conduct required by section III.C.1;

3. the summary of the Policies and Procedures required by section III.C.2;

4. a description of the training programs required by section III.D including a description of the targeted audiences and a schedule of when the training sessions were held;

5. a certification by the Compliance Officer that:

a. the Policies and Procedures required by section III.C have been developed, are being implemented, and have been distributed to all Program Staff;

b. all employees and Program Staff have completed the Code of Conduct certification required by section III.C.1; and

c. all Program Staff have completed the training and executed the certification required by section III.D;

7. a description of the confidential disclosure program required by section III.F;

8. the identity of the Independent Review Organization(s) and the proposed start and completion date of the first audit;

9. a summary of personnel actions taken pursuant to section III.G;

10. the name, address, phone number and position description of the Independent Coding Officer required by section III.B;

11. a copy of any policies, procedures, and guidelines developed by the ICO in accordance with section III.B;

12. a list of all locations (including locations and mailing addresses) of Oaktree, 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 name, address, and telephone number of the payor (specific contractor) that issued each provider identification number; and

13. a certification by the Independent Coding Officer that the policies, procedures, and guidelines required by section III.B have been developed and implemented; that Oaktree did not participate in or interfere with the development of these policies, procedures, and guidelines; and that Oaktree has cooperated fully with the ICO in implementing these policies, procedures, and guidelines.

B. Annual Reports. Oaktree shall submit to OIG an Annual Report with respect to the status and findings of Oaktree's compliance activities. The Annual Reports shall include:

1. any change in the identity or position description of the Compliance Officer and/or the Independent Coding Officer described in sections III.A-B;

2. a certification by the Compliance Officer that:

   a. all employees and Program Staff have completed the annual Code of Conduct certification required by section III.C.1; and

   b. all Program Staff have completed the training and executed the certification required by section III.D;

3. notification of any changes or amendments to the Policies and Procedures required by section III.C and the reasons for such changes (*e.g.*, change in contractor policy);

4. a complete copy of any and all reports prepared pursuant to the Independent Review Organization's billing and compliance engagements, including a copy of the methodology used;

5. Oaktree's response/corrective action plan to any issues raised by the Independent Review Organization;

6. a summary of Material Deficiencies (as defined in III.I) identified during the reporting period and the status of any corrective and preventative actions relating to the Material Deficiency;

7. a report of the aggregate overpayments that have been returned to the Federal health care programs that were discovered as a direct or indirect result of implementing this CIA. Overpayment amounts should be broken down into the following categories: Medicare, Medicaid (report each applicable state separately) and other Federal health care programs;

8. a copy of the confidential disclosure log required by section III.F;

9. a description of any personnel action (other than hiring) taken by Oaktree as a result of the obligations in section III.G;

10. a summary describing any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that Oaktree has committed a crime or has engaged in fraudulent activities, which have been reported pursuant to section III.F. The statement shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation, legal proceeding or requests for information;

11. a description of all changes to the most recently provided list (as updated) of Oaktree's business units and 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 Federal health care program provider identification number(s), and the name, address, and telephone number of the payor (specific contractor) that issued each provider identification number;

12. copies of any revisions to the policies, procedures and guidelines developed by the ICO pursuant to section III.B;

13. copies of audit findings of the ICO pursuant to section III.B;

14. a certification by the Independent Coding Officer that Oaktree did not participate in or interfere with the development of any revisions to the policies, procedures, and guidelines required by section III.B, and that Oaktree has cooperated fully with the ICO in implementing these policies, procedures, and guidelines.

The first Annual Report shall be received by OIG no later than one year and thirty (30) days after the effective date of this CIA. Subsequent Annual Reports shall be submitted 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) Oaktree 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, upon such inquiry, the information is accurate and truthful.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing subsequent to the effective date of this CIA, all notifications and reports required under this CIA shall be submitted to the entities listed below:

OIG:

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

Oaktree:

Donald Gallo
Corporate Compliance Officer
Oaktree Cancer Care, Inc.
100 Oakhurst Road
Pittsburgh, PA 15215
Phone: 412-781-7070
Fax: 412-781-6662

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 Oaktree's books, records, and other documents and supporting materials and/or conduct onsite reviews of Oaktree's operations for the purpose of verifying and evaluating: (a) Oaktree's compliance with the terms of this CIA; and (b) Oaktree's compliance with the requirements of the Federal health care programs in which they participate. Oaktree shall make available the documentation described above to OIG or its duly authorized representative(s) at reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this

provision, OIG or its duly authorized representative(s) may interview any of Oaktree's employees or Program Staff who consent to be interviewed at the person's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the person and OIG. Oaktree agrees to assist OIG in contacting and arranging interviews with such persons upon OIG's request. Oaktree's employees and Program Staff members may elect to be interviewed with or without a representative of Oaktree present.

VIII. DOCUMENT AND RECORD RETENTION

Oaktree shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs or to compliance with this CIA, one year longer than the term of this CIA (or longer if otherwise required by law).

IX. DISCLOSURES

Subject to HHS' Freedom of Information Act ("FOIA") procedures set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Oaktree prior to any release by OIG of information submitted by Oaktree pursuant to its obligations under this CIA and identified upon submission by Oaktree as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. Oaktree shall refrain from identifying any information as trade secrets, commercial or financial information and privileged and confidential that does not meet the criteria for exemption from disclosure under FOIA.

X. BREACH AND DEFAULT PROVISIONS

Oaktree is expected to fully and timely comply with all of the obligations herein throughout the term of this CIA or other time frames herein agreed to.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Oaktree 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 $2,000 (which shall begin to accrue on the day after the date the obligation became due) for each day, beginning 120 days (150 days regarding requirements in Paragraph III.D.2) after the effective date of this CIA and

concluding at the end of the term of this CIA, Oaktree fails to have in place any of the following:

a. a Compliance Officer required by section III.A;
b. written Code of Conduct required by section III.C.1;
c. written Policies and Procedures required by section III.C.2;
d. training and education programs required by section III.D;
e. a Confidential Disclosure Program required by section III.F;
f. an Independent Coding Officer required by section III.B.

2. A Stipulated Penalty of $2,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Oaktree fails to meet any of the deadlines to submit the Implementation Report or the Annual Reports to the OIG.

3. A Stipulated Penalty of $2,000 (which shall begin to accrue on the date the failure to comply began) for each day Oaktree employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Oaktree'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. (This Stipulated Penalty shall not be demanded for any time period during which Oaktree 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.)

4. A Stipulated Penalty of $1,000 (which shall begin to accrue on the date Oaktree fails to grant access) for each day Oaktree fails to grant access to the information or documentation as required in section VII of this CIA.

5. A Stipulated Penalty of $1,000 (which shall begin to accrue ten (10) days after the date that OIG provides notice to Oaktree of the failure to comply) for each day Oaktree fails to comply with any other obligation of this CIA. In its notice to Oaktree, OIG shall state the specific grounds for its determination that Oaktree has failed to comply with the CIA obligation(s) at issue.

B. Payment of Stipulated Penalties.

1. *Demand Letter*. Upon a finding that Oaktree has failed to comply with any of the obligations described in section X.A and determining that Stipulated Penalties are appropriate, OIG shall notify Oaktree by personal service or certified mail of (a) Oaktree'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").

Within fifteen (15) days of the date of the Demand Letter, Oaktree 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.D. In the event Oaktree elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Oaktree cures, to OIG's satisfaction, the alleged breach in dispute; provided, however, that no Stipulated Penalties shall be warranted if the ALJ overrules, reverses or vacates the OIG's determination of noncompliance. 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.C.

2. *Timely Written Requests for Extensions*. Oaktree may 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 Oaktree fails to meet the revised deadline as agreed to by the OIG-approved extension. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until two (2) business days after Oaktree receives OIG's written denial of such request. A "timely written request" is defined as a request in writing received by OIG at least five (5) business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

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 otherwise noted, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's determination that Oaktree has materially breached this CIA, which decision shall be made at OIG's discretion and governed by the provisions in section X.C, below.

C. Exclusion for Material Breach of this CIA

1. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA shall constitute an independent basis for Oaktree's exclusion from participation in the Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). Upon a determination by OIG that Oaktree has materially breached this CIA and that exclusion should be imposed, OIG shall notify Oaktree by certified mail of (a) the facts alleged to constitute the 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").

2. *Opportunity to Cure.* Oaktree shall have thirty-five (35) days from the date of the Notice of Material Breach and Intent to Exclude Letter to demonstrate to OIG's satisfaction that:

a. Oaktree is in full compliance with this CIA;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 35-day period, but that: (i) Oaktree has initiated action to cure the material breach, (ii) Oaktree is pursuing such action with due diligence, and (iii) Oaktree has provided to OIG a reasonable timetable for curing the material breach.

3. *Exclusion Letter.* If at the conclusion of the thirty five (35) day period, Oaktree fails to satisfy the requirements of section X.C.2, OIG may exclude Oaktree from participation in the Federal health care programs. OIG will notify Oaktree in writing of its determination to exclude (hereinafter the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.D, below, the exclusion shall go into effect thirty (30) days after the date of the Exclusion Letter. The exclusion shall have national effect and will also apply to all other federal procurement and non-procurement programs. Oaktree may seek reinstatement pursuant to the provisions at 42 C.F.R. §§1001.3001-.3004.

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

a. a failure by Oaktree to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.E;

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

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section X.B above;

d. a failure to retain and use an Independent Review Organization for review purposes in accordance with the requirements set forth in section III.E;

e. a failure to retain and use an Independent Coding Officer in accordance with the requirements set forth in section III.B.

D. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Oaktree of a Demand Letter or an Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this CIA, Oaktree shall be afforded certain review rights comparable to those provided in 42 U.S.C. §1320a-7(f) and 42 C.F.R. §1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§1005.2-1005.21. Notwithstanding the language in 42 C.F.R. §1005.2(c), the request for a hearing involving stipulated penalties shall be made within fifteen (15) days of the date of the Demand Letter and the request for a hearing involving exclusion shall be made within thirty (30) days of the date 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 Oaktree was in full and timely compliance with the obligations of this CIA for which OIG

demands payment; and (b) the period of noncompliance. Oaktree shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ finds for OIG with regard to a finding of a breach of this CIA and orders payment of stipulated penalties, such stipulated penalties shall become due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that Oaktree may request review of the ALJ decision by the DAB.

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 Oaktree was in material breach of this CIA; (b) whether such breach was continuing on the date of the Exclusion Letter; and (c) where applicable, whether it has been shown that although the alleged material breach cannot be cured within the 35 day period, (i) action has been initiated to cure the material breach, (ii) such corrective action is being pursued with due diligence, and (iii) OIG has been provided a reasonable timetable for curing the material breach. For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision that is favorable to OIG. Oaktree's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Oaktree upon the issuance of the ALJ's decision. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect twenty (20) days after the ALJ issues such a decision, notwithstanding that a timely request is made for review of the ALJ decision by the DAB.

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, Oaktree and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns and transferees of Oaktree.

B. This CIA shall be binding upon Oaktree and shall become final and binding on the date the final signature is obtained on the CIA.

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

D. The undersigned signatories for Oaktree 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 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

DATE 7/10/00

ON BEHALF OF OAKTREE CANCER CARE, INC.

DONALD GALLO
President

7/10/00
DATE