

**INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ONCOLOGY ASSOCIATES, LLP**

I. PREAMBLE

Oncology Associates, LLP (“OA”) 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”). This commitment to promote compliance applies to any entities that OA owns or in which OA has a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), and OA’s and any such entity’s officers, directors and employees, and any agents, contractors and all third parties with whom OA or such entity may choose to engage to act as billing or coding consultants for purposes of claiming reimbursement from the Federal health care programs (“Covered Persons”). For the purposes of this Integrity Agreement, the definition of “Covered Persons” excludes administrative and clerical staff that neither provide patient care items or services nor perform billing or coding functions on behalf of OA. Contemporaneously with this Agreement, OA is entering into a Settlement Agreement with the United States, and this Agreement is incorporated by reference into the Settlement Agreement.

II. TERM OF THE AGREEMENT

Except as otherwise provided, the period of compliance obligations assumed by OA under this Agreement shall be 3 years from the Effective Date of this Agreement (unless otherwise specified). The “Effective Date” shall be the date on which the final signatory of this Agreement executes this Agreement.

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

III. INTEGRITY OBLIGATIONS

OA hereby agrees to establish a Compliance Program that, at minimum, includes the following elements:

A. Compliance Contact

Within 30 days after execution of this Agreement, OA 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 Report. In the event a new Compliance Contact is appointed during the term of this Agreement, OA shall notify the OIG, in writing, within 30 days of such a change.

B. Posting of Notice

Within the first 30 days following the Effective Date, OA shall post in a prominent place accessible to all patients and Covered Persons a notice detailing their commitment to comply with all Federal health care program requirements in the conduct of the 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 Implementation Report.

C. Written Policies and Procedures

Within 120 days after the Effective Date, OA agrees to develop, implement, and make available to all Covered Persons written policies that address the following:

1. OA's commitment to operate their business in full compliance with all Federal health care program requirements;
2. OA's requirement that all Covered Persons shall be expected to comply with all Federal health care program requirements and with OA's own Policies and Procedures as implemented pursuant to section III.C (including the requirements of this Agreement);

3. The requirement that all of OA's Covered Persons shall be expected to report to OA or the Compliance Contact suspected violations of any Federal health care program requirements or OA'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 OA not hire, employ or engage as contractors any Ineligible Person. For purposes of this Agreement, 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 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, or otherwise declared ineligible. To prevent hiring or contracting with any Ineligible Person, OA shall check all prospective employees and contractors prior to engaging their services against the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.hhs.gov/oig>) 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, OA shall conduct annual checks of all employees against each exclusion list.
5. The commitment of OA 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 commitment to comply with 42 U.S.C. § 1320a-7b(b) (the "Anti-Kickback Statute") and 42 U.S.C. § 1395nn (the "Stark Law"), and the regulations and to be aware of and to review other guidance documents related to these statutes.
7. The commitment to avoid business or financial arrangements or contracts that induce the unlawful referral of Federal health care program beneficiaries in violation of the Anti-Kickback Statute or the Stark Law.
8. The proper procedures for the accurate preparation and submission of claims in accordance with Federal health care program requirements;

9. The proper documentation of services and billing information and the retention of such information in a readily retrievable form;
10. The proper documentation of services and billing procedures for physician office visits.

At least annually (and more frequently if appropriate), OA 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 150 days after the Effective Date and annually thereafter, each Covered Person shall certify in writing that he or she has read, understood, and will abide by OA's Policies and Procedures. New Covered Persons shall review the Policies and Procedures and shall complete the required certification within two weeks after becoming a Covered Person or within 150 days of the effective date of the Agreement, whichever is later.

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

D. Training and Certification

Within 150 days following the Effective Date and at least once each year thereafter, OA and 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 two hours of training from an individual or entity, other than OA or another Covered Person. The training shall be conducted by individuals 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 OA.

New 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 Covered Person or within 150 days after the Effective Date, whichever is later. The training for New 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 Covered Persons shall work under the direct supervision of a Covered Person who has received such training.

At a minimum, the annual and new employee 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;
4. Examples of proper and improper billing practices;
5. Examples of violations of the Anti-Kickback Statute and Stark Law;
6. Proper coding and billing procedures for physician services; and
7. The statutory requirements of 42 U.S.C. § 1320a-7b(b) (the “Anti-Kickback Statute”) and 42 U.S.C. § 1395nn (the “Stark Law”), and the regulations and other guidance documents related to these statutes.

Each 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. OA shall retain the certifications, along with the training course materials. The training course materials shall be provided in the Annual Report.

E. Annual Review Procedures

1. General Description.

- a. Scope. This Section shall apply to every arrangement or transaction that: (1)(a) involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and (b) is

between OA and any actual or potential source of health care business or referrals to OA or any actual or potential recipient of health care business or referrals from OA. The term “source” shall mean any physician, contractor, vendor, or agent and the term “health care business or referrals” shall be read to include referring, recommending, arranging for, ordering, leasing, or purchasing of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program; or (2)(a) is between a third party and a physician (or a physician’s immediate family member (as defined at 42 C.F.R. § 411.351)); and (b) where the physician makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to a third party for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)), collectively, “Arrangements.” The other party to an Arrangement shall be referred to herein as a “contractor.”

b. Retention of Records. Subject to Section III(E)(2)(b)(4) below regarding non-waiver of any applicable privileges, OA shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports related to the reviews.

2. *Arrangements Review*

a. Implementation. Within 120 days after the Effective Date, OA shall create procedures reasonably designed to ensure that each Arrangement does not violate the Anti-Kickback Statute and the Stark Law, and shall implement procedures to evaluate all existing Arrangements, to the extent not already so evaluated, to determine whether such Arrangements violate the Anti-Kickback Statute and/or the Stark Law. OA shall summarize all Arrangements in the form provided at Appendix A. OA shall update the summary at Appendix A annually and shall submit the summary with each Annual Report.

b. Requirements. OA shall ensure that all new and/or renewed (*i.e.*, at renewal date) Arrangements are in compliance with the Anti-Kickback Statute and Stark Law and the regulations related to these statutes, and comply with the following requirements:

1. The Arrangement shall include a provision that all Covered Persons shall comply with OA's Compliance Program, including the training related to the Anti-Kickback Statute and the Stark Law. Additionally, OA will provide each Covered Person contractor with a copy of its Code of Conduct and Stark and Anti-Kickback Policies and Procedures;
2. OA shall certify and shall require the Covered Person contractor to certify, at the time of signing the Arrangement and annually thereafter, that the Arrangement is not intended to generate referrals for services or supplies for which payment may be made in whole or in part under any Federal health care program; and
3. OA shall require the Covered Person contractor to certify, at the time of signing the Arrangement, that the contractor shall comply with OA's compliance program and with the Anti-Kickback Statute and the Stark Law.
4. OA shall retain and make available to OIG, upon request, copies of all Arrangements subject to this Section and, to the extent available, all non-privileged communications related to the Arrangements and the actual performance of the duties under the Arrangements. Nothing in this CIA or any other communication or report made pursuant to this CIA, shall constitute a waiver by OA 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 OA to avoid its obligations to comply with the provisions of this CIA.

3. *Validation Review.* In the event the OIG has reason to believe that:
(a) OA's Arrangements Review fails to conform to the requirements of this Agreement;
or (b) the Arrangements Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Arrangements Review complied with the requirements of the Agreement and/or the findings or Arrangements Review results are inaccurate ("Validation Review"). OA shall pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated

before one year after OA's final submission (as described in Section II) is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify OA of its intent to do so and provide a written explanation of why the OIG believes such a review is necessary. To resolve any concerns raised by the OIG, OA may request a meeting with the OIG to discuss the results of any submissions or findings; present any additional or relevant information to clarify the results of the Arrangements Review to correct the inaccuracy of the Arrangements Review; and/or propose alternatives to the proposed Validation Review. OA agrees to provide any additional information as may be requested by the OIG under this Section in an expedited manner. The OIG will attempt in good faith to resolve any Arrangements Review with OA prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG.

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 OA has received from any Federal health care program in excess of the amount due and payable under such program's requirements. OA 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, OA identifies or learns of any Overpayments, OA shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of identification of the Overpayment and take remedial steps within 60 days of identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayments from recurring. Also, within 30 days of identification of the Overpayment, OA shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days of identification, OA shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when

such work is expected to be completed. Notification and repayment to the payor should be done in accordance with the payor's policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix B to this 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;
- (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; or

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

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

- (i) If the Material Deficiency results in an Overpayment, the report to the OIG shall be made at the same time as the notification to the payor required in section III.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 OA's actions taken to correct the Material Deficiency; and

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

G. Notification of Government Investigations or Legal Proceedings

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

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, from the Effective Date of this Agreement, OA changes locations, 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, or ceases to participate in federal health care programs, OA shall notify OIG of this fact as soon as possible, but no later than within 30 days of the date of change of location, sale, closure, purchase, establishment, or change in status of participation in Federal health care programs. 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 Report

Within 180 days after the Effective Date, OA shall submit a written report to OIG summarizing the status of its implementation of the requirements of this Agreement. This report, known as the "Implementation Report," shall include:

1. The name, address and phone number of OA's Compliance Contact;
2. A copy of the notice OA 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;
4. A certification signed by OA attesting that the Policies and Procedures are being implemented and have been made available to all Covered Persons;
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 OA attesting that all Covered Person employees have completed the initial training required by Section III.D. and have executed the required certifications;
7. A list of all OA'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 OA currently submits claims; and
8. A certification from the OA stating that it has reviewed the Implementation Report, it has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

B. Annual Reports

OA shall submit to OIG Annual Reports with respect to the status of and findings regarding OA's compliance activities for each of the three one-year periods beginning on the Effective Date of the Agreement. (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. 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;
2. A certification by OA that all Covered Persons have executed the annual Policies and Procedures certification required by section III.C.;
3. A schedule, topic outline and copies of the training materials for the training programs attended in accordance with section III.D. of this Agreement;
4. A certification signed by OA certifying that it 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;
5. A complete copy of all reports and work papers prepared pursuant to the Arrangement Review, including the Arrangement Review Report at Appendix A;
6. OA's response and corrective action plan(s) related to any issues raised or recommendations arising out of the Arrangement Review;
7. A summary of Material Deficiencies (as defined in III.F.) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;

8. 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;
9. A certification signed by OA 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; and
10. A certification signed by OA certifying that it has reviewed the Annual Report, they have 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, SW
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

OA: Dr. Larry Ebbert
Oncology Associates, LLP
353 Fairmont Blvd.
Rapid City, SD 57701
Telephone: 605.719.2301
Facsimile: 605.719.4588

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

VIII. DOCUMENT AND RECORD RETENTION

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

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, OA 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 \$1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day OA fails to:

- a. have in place a Compliance Contact as required in section III.A;
- b. post the notice required in section III.B;
- c. implement and make available the Policies and Procedures required in section III.C;
- d. require that Covered Persons attend the training required by section III.D. of the Agreement within the time frames required in that section;
- e. to submit the annual Arrangement Review Report as required in section III.E and Appendix A; or
- f. meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

2. A Stipulated Penalty of \$750 (which shall begin to accrue on the date the failure to comply began) for each day OA employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, OA’s business operations related to the Federal health care programs; or (ii) is in a position for which the person’s salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period

during which OA can demonstrate that OA did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.C.5) as to the status of the person).

3. A Stipulated Penalty of \$750 for each day OA fails to grant access to the information or documentation as required in section VII of this Agreement. (This Stipulated Penalty shall begin to accrue on the date OA fails to grant access.)

4. A Stipulated Penalty of \$750 for each day OA fails to comply fully and adequately with any obligation of this Agreement. In its notice to OA, OIG shall state the specific grounds for its determination that OA has failed to comply fully and adequately with the Agreement obligation(s) at issue and steps the OA must take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date OA receives notice from the OIG of the failure to comply unless OIG determines that such failure was cured prior to the beginning of the 10-day accrual period.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under paragraphs 1-3 of this section.

B. Timely Written Requests for Extensions

OA 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 OA 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 OA 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 OA 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 OA of: (a) OA'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 of the receipt of the Demand Letter, OA 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 OA elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until OA cures, to OIG’s satisfaction, the alleged breach in dispute; provided that if the ALJ determines that OA was not in breach, no Stipulated Penalties shall be imposed. 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 OA 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 OA 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 conduct an Arrangement Review 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 OA constitutes an independent basis for OA's exclusion from participation in the Federal health care programs. Upon a determination by OIG that OA has materially breached this Agreement and that exclusion should be imposed, OIG shall notify OA of: (a) OA'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.* OA 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. OA 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) OA has begun to take action to cure the material breach; (ii) OA is pursuing such action with due diligence; and (iii) OA has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If at the conclusion of the 30-day period, OA fails to satisfy the requirements of section X.D.3, OIG may exclude OA from participation in the Federal health care programs. OIG will notify OA in writing of its determination to exclude OA (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, OA wishes to apply for reinstatement, OA 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 OA 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, OA 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 OA was in full and timely compliance with the obligations of this Agreement for which OIG demands payment; and (b) the period of noncompliance. OA 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 OA to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless OA 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 OA 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) OA had begun to take action to cure the material breach within that period;

(ii) OA has pursued and is pursuing such action with due diligence; and

(iii) OA provided to OIG within that period a reasonable timetable for curing the material breach and OA 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 OA, only after a DAB decision in favor of OIG. OA's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude OA 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 OA 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. OA agrees to waive their rights to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of OA, OA 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, OA and the OIG agree as follows:

1. This Agreement shall be binding on the successors, assigns and transferees of OA;
2. This Agreement shall become final and binding on the date the final signature is obtained on the Agreement;
3. Any modifications to this Agreement shall be made with the prior written consent of the parties to this Agreement;

4. OIG may agree to a suspension of OA's obligations under this Agreement in the event of OA's cessation of participation in Federal health care programs. If OA withdraws from participation in Federal health care programs and is relieved from its Agreement obligations by the OIG, OA agrees to notify the OIG 30 days in advance of OA's intent to reapply as a participating provider or supplier with the Federal health care programs. Upon receipt of such notification, OIG will evaluate whether the CIA should be reactivated or modified.

5. The undersigned OA 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.

FROM FAEGRE & BENSON

(THU) 12:19'02 8:34/ST. 8:27/NO. 4864296427 P 23
(WED) 12:18'02 10:57/ST. 10:49/NO. 4864296426 P 24

IN WITNESS WHEREOF, the parties hereto affix their signatures:

ONCOLOGY ASSOCIATES, LLP

12/19/02

Date

12-19-02

Date

[Signature]
Larry Ebert, MD

[Signature]
Counsel for Oncology Associates

Oncology Associates Integrity Agreement
December 2002

12/18/02 WED 15:20 [TX/RX NO 8445]

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PAGE 03

IN WITNESS WHEREOF, the parties hereto affix their signatures:

ONCOLOGY ASSOCIATES, LLP

Date


Larry Ebbert, MD

Date

Counsel for Oncology Associates

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

12/19/02
Date



Lewis Morris, Esquire
Chief Counsel to the Inspector General
Office of Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services

NOTICE

Oncology Associates, LLP

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**Oncology Associates, LLP
353 Fairmont Blvd.
Rapid City, SD 57701**