INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
RICHARD ROTHMAN, M.D. AND
RECONSTRUCTIVE ORTHOPEDIC ASSOCIATES II

I. PREAMBLE

Richard Rothman, M.D. ("Dr. Rothman") and Reconstructive Orthopedic Associates II ("ROA II") hereby enter 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 Dr. Rothman's and ROA II's 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 Agreement applies to Dr. Rothman, ROA II, their employees, and all third parties involved directly or indirectly with delivery of patient care or with billing or coding for purposes of claiming reimbursement from the Federal health care programs for Dr. Rothman or ROA II ("Covered Persons"). Though Dr. Rothman is currently employed by ROA II, the obligations set forth in this Agreement shall apply to Dr. Rothman wherever he may practice during the term of the Agreement. Contemporaneously with this Agreement, Dr. Rothman and ROA II are 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 Dr. Rothman and ROA II under this Agreement shall be five years from the Effective Date of this Agreement. The Effective Date of this Agreement shall be the date on which the final signatory executes this Agreement.

Sections VII, VIII, IX, X and XI shall remain in effect until OIG has completed its review of the final annual report and any additional materials submitted by Dr. Rothman and ROA II pursuant to OIG's request, but in no event later than 120 days after the OIG's

receipt of (1) Dr. Rothman's and ROA II's final annual report; or (2) any additional materials submitted by Dr. Rothman or ROA II pursuant to the OIG's request, whichever is later.

III. INTEGRITY OBLIGATIONS

Dr. Rothman and ROA II hereby agree to establish and maintain a Compliance Program that, at minimum, includes the following elements:

A. Compliance Contact

Within 60 days after execution of this Agreement, Dr. Rothman and ROA II 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, Dr. Rothman and ROA II shall notify the OIG, in writing, within 15 days after such a change.

B. Posting of Notice

Within the first 30 days following the Effective Date of this Agreement, Dr. Rothman and ROA II 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 their 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 90 days after the Effective Date of this Agreement, Dr. Rothman and ROA II agree to develop, implement, and make available to all Covered Persons written policies that address the following:

1. Dr. Rothman's and ROA II's commitment to operate their business in full compliance with all Federal health care program requirements;

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

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

4. The requirement that all Covered Persons shall be expected to report to Dr. Rothman or ROA II or the Compliance Contact suspected violations of any Federal health care program requirements or Dr. Rothman's or ROA II'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;

5. The requirement that Dr. Rothman and ROA II not hire as employees 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, suspended or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services, but has not yet been excluded, debarred, suspended or otherwise declared ineligible. To prevent hiring or contracting with any Ineligible Person, Dr. Rothman and ROA II shall check all prospective employees and other Covered Persons prior to engaging their services against the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov) and the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and, as appropriate, the state list of exclusions from Medicaid or Medical Assistance programs;

6. The commitment of Dr. Rothman and ROA II to remain current with all applicable 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 and by attending appropriate training sessions geared to the practice of Dr. Rothman and ROA II;

7. The requirement that, with respect to services for which reimbursement is sought from Federal health care programs, Dr. Rothman and every other

physician who is a Covered Person provide appropriate documentation of the nature of the services they render and/or observe in the operating room consistent with the Federal health care program statutes, regulations, guidelines and directives in effect at the time of the procedure, including but not limited to, documentation that he or she was physically present during the critical or key portion(s) of all procedures for which he or she requests reimbursement, and that describes, at a minimum, the service furnished to the patient, the critical portion(s) thereof, the participation of the teaching physician in providing the service, and states that the teaching physician was physically present during the critical portion(s), and, if the teaching physician is not present during the non-critical or non-key portions of the first procedure and is at that time participating in a second surgical procedure, identifies the surgeon who could assist the resident in the first case should the need arise; and

8. The requirement that a daily log be kept that sets forth each surgical procedure performed by each physician who is a covered person; the date, approximate starting and stopping time, and operating room in which it was performed; and the patient's name.

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

Within 90 days after the Effective Date of the Agreement and annually thereafter, each Covered Person shall certify in writing that he or she has read, understood, and will abide by Dr. Rothman's and ROA II'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 90 days after 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 90 days following the Effective Date of this Agreement and at least once each year thereafter, Dr. Rothman and Covered Persons shall receive at least two hours of training from an individual or entity other than Dr. Rothman 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 Dr. Rothman and ROA II. All covered person who, within six months prior to the Effective Date of this Agreement, participated in training that met the requirements of this section shall not be required to take the first year of such training.

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 60 days after becoming a Covered Person or within 90 days after the Effective Date of this Agreement, 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 Covered Person training sessions shall cover the following topics:

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

2. The written Policies and Procedures developed pursuant to Section III.C., above, including the requirement set forth in Section III.C.7 that with respect to services for which reimbursement is sought from Federal health care programs, Dr. Rothman and every other physician who is a Covered Person provide appropriate documentation of the nature of the services they render and/or observe in the operating room;

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

4. Examples of proper and improper billing practices.

Each 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. Dr. Rothman and ROA II shall retain the certifications, along with the training course materials. The training course materials shall be provided in the Annual Report.

E. Third Party Billing

Dr. Rothman and ROA II represent that they presently do not contract with a third party billing company to submit claims for surgical procedures to the Federal health care programs. In the event that Dr. Rothman or ROA II contracts with a third party billing company to submit claims for services of any kind to any Federal health care programs during the term of this Agreement, then within 30 days thereafter, Dr. Rothman and ROA II shall obtain and include in the Annual Report a certification from the third party billing company that (i) it is presently in compliance with all Federal health care program requirements as they relate to submission of claims to the Federal health care programs; (ii) it has a policy of not knowingly employing any person who has been excluded, debarred, suspended or declared ineligible to participate in Medicare or other Federal health care programs, and who has not yet been reinstated to participate in those programs; and (iii) it provides the required training in accordance with section III.D. of the Agreement for those Covered Persons involved in the preparation and submission of claims to Federal health care programs. With respect to third party billing companies with whom Dr. Rothman or ROA II entered into a contract prior to the Effective Date of this Agreement, Dr. Rothman and ROA II shall obtain the certification from them within 30 days after the Effective Date of this Agreement to the extent allowable by the pre-existing contract. If Dr. Rothman or ROA II contracts with a new third party billing company during the term of this Agreement, Dr. Rothman or ROA II shall, within 30 days after entering into such contract, obtain and send to OIG the certification described in this paragraph.

F. Annual Review Procedures

1. *Retention of Independent Review Organization.* Within 90 days after the Effective Date of this Agreement, Dr. Rothman and ROA II shall retain a person or entity, such as a nurse reviewer, an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform billing engagements to assess Dr. Rothman's, ROA II's, and other Covered Persons' billing and coding practices ("Billing Engagement"). The Independent Review Organization retained by Dr. Rothman

and ROA II shall have expertise in the billing, coding, reporting and other requirements of the particular section of the health care industry pertaining to this Agreement and in the Federal health care program requirements. The IRO shall assess, along with Dr. Rothman and ROA II, whether it can perform the Billing Engagement in a professionally independent fashion, taking into account any other business relationships or other engagements that may exist.

2. *Frequency of the Billing Engagement.* Each component of the Billing Engagement shall be performed at least annually and shall cover each of the one-year periods beginning with the Effective Date of this Agreement. The IRO shall perform each Billing Engagement in accordance with the procedures detailed in section II.F of this CIA and in Appendix A to this Agreement, which is incorporated by reference into this Agreement. The IRO shall prepare a report for each Billing Engagement in accordance with the guidelines set forth in Appendix A.

3. *Description of the Billing Engagement.* The IRO shall perform the Billing Engagement described as follows. The objective of the Billing Engagement is twofold: (1) to ensure that Dr. Rothman rendered the services billed and that Dr. Rothman's inpatient surgical services were performed, coded, billed, and reimbursed in accordance with the appropriate Medicare statutes, regulations, program requirements and written directives, including but not limited to those applicable to concurrent procedures and a physician's presence in the operating room; and (2) to ensure that a Covered Person who billed for a surgery actually performed the procedure, as opposed to Dr. Rothman performing the procedure. For purposes of ensuring that a Covered Person who billed for a surgery actually performed the surgery, the IRO need only review surgeries performed by Covered Persons that have the same code as the surgeries performed by Dr. Rothman within the 12 months being reviewed (*e.g.*, knee replacement, knee revision, hip replacement, hip revision). While the Billing Engagement concerns only inpatient surgical procedures, the IRO may review outpatient records and any other records relevant to performing the Billing Engagement.

The population for the Billing Engagement shall consist of all calendar days on which Dr. Rothman performed three or more surgeries ("Surgical Calendar Days"). From this population the IRO shall randomly select 15 Surgical Calendar Days using RAT-STATS, the OIG's statistical sampling software. The IRO shall review all of Dr. Rothman's surgical procedures on the selected Surgical Calendar Days in accordance with the first objective of this Billing Engagement. In accordance with the second objective of the Billing Engagement, the IRO shall review the surgical procedures performed by every other Covered Person on the selected Surgical Calendar Days (limited to codes used by Rothman in the review period), regardless of whether a claim was submitted and

regardless of the identity of the payor.

If the IRO determines that there were billings in violation of the Medicare statutes, regulations, program requirements or written directives applicable to the objectives of this Billing Engagement that involve Dr. Rothman, the IRO will consider such procedures to be overpayments. In determining whether there were such billing violations, the IRO will be guided in part by the CMS regulations in effect as well as the public comment thereto, including, but not limited to the Medicare Carriers' Manual, which currently provides in part that the teaching physician determines the key or critical portion or portions of the procedure performed under his or her supervision. For example, if the IRO determines that a surgery billed by another Covered Person was in fact performed by Dr. Rothman, the IRO will consider this procedure to have been performed by Dr. Rothman for purposes of determining if there were billings in violation of the Medicare statutes, regulations, program requirements and written directives applicable to concurrent procedures and physicians' presence, and therefore this procedure shall be considered an overpayment. Any claim for which Dr. Rothman and ROA II cannot produce documentation sufficient to support the claim shall be considered an error and the total reimbursement received by Dr. Rothman or ROA II for such claim shall be considered an overpayment.

The IRO shall identify the total paid Medicare dollars associated with the population, the total paid Medicare dollars associated with the sample, the total Medicare dollar overpayment in the sample, and any Medicare dollar underpayments in the sample. If the IRO identifies a Medicare service that was not billed, this claim may be submitted to the appropriate Medicare contractor, in accordance with Medicare guidelines, for a payment determination. If the Medicare contractor determines that this claim should be paid, the amount Medicare reimburses shall be considered an underpayment so long as it does not violate any of the Medicare statutes, regulations, program requirements and written directives that are being examined in this Billing Engagement. For calculation purposes, the IRO may net the Medicare overpayments and the Medicare underpayments, regardless of Medicare's underpayment resubmission timelines. The net result shall be divided by the total paid Medicare dollars associated with the sample. This calculation yields the Medicare financial error rate. The Medicare financial error rate shall be multiplied by the total paid Medicare dollars in the population. This result yields the projected overpayment amount. Dr. Rothman and ROA II agree to voluntarily refund the projected overpayment amount to the appropriate Medicare contractor within 30 days after determination of the amount due. Included in each Annual Report shall be the IRO's Billing Engagement Report findings presented in accordance with the guidelines set forth in Appendix A.

4. *Retention of Records.* The IRO and Dr. Rothman and ROA II shall retain and make available to the OIG upon request all work papers, supporting documentation, correspondence, and draft reports related to the engagements.

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

6. *Validation Review.* In the event the OIG has reason to believe that: (a) any of the Billing Engagements fail to conform to the requirements of this Agreement; or (b) any of the findings or Billing Engagement results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Billing Engagement complies with the requirements of the Agreement and/or the findings or Billing Engagement results are inaccurate. Dr. Rothman and ROA II agree to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after the final Annual Report is submitted and received by the OIG. To the extent consistent with the requirements of the Freedom of Information Act (FOIA), Dr. Rothman and ROA II may request copies of any work papers underlying the validation review.

Prior to initiating a Validation Review, the OIG shall notify Dr. Rothman and ROA II of its intent to do so and provide an explanation for believing why such a review is necessary. In order to resolve any concerns raised by the OIG, Dr. Rothman and ROA II may request a meeting with the OIG to discuss the results of any Engagement submissions or any Billing Engagement findings; present any additional or relevant information to clarify the results of the Engagements or to correct the inaccuracy of the Billing Engagement(s); and/or propose alternatives to the proposed Validation Review. Dr. Rothman and ROA II agree 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 Billing Engagement issues with Dr. Rothman and ROA II 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. If the Validation Review concludes that Dr. Rothman's and ROA II's Billing Engagement(s) conformed to the requirements of this Agreement and that the findings or Billing Engagement results are accurate, then Dr. Rothman and ROA II will not pay for the cost of the Validation Review.

G. 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 Dr. Rothman or ROA II has received in excess of the amount due and payable under any Federal health care program requirements. Dr. Rothman and ROA II 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, Dr. Rothman or ROA II identifies or learns of any overpayments, they shall notify the payor within 30 days after identification of the overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Also, within 30 days after identification of the overpayment, Dr. Rothman and ROA II shall repay the overpayment to the appropriate payor to the extent such overpayment has been quantified. If not yet quantified, within 30 days after identification, Dr. Rothman and ROA II shall notify the payor of their efforts to quantify the overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the contractor should be done in accordance with the contractor policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix B to this Agreement. Nothing set forth herein prevents Dr. Rothman and ROA II from subtracting underpayments for purposes of determining the amount of repayment for any Overpayment, consistent with the instructions of his Medicare contractor.

2. *Material Deficiencies.*

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

(i) a substantial overpayment; or

(ii) a matter that a reasonable person would consider a

potential violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.

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

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

(i) If the Material Deficiency results in an overpayment, the report to the OIG shall be made at the same time as the notification to the payor required in section III.F.1, and shall include all of the information on the Overpayment Refund Form, as well as:

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

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

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

(iii) a description of Dr. Rothman's and ROA II's actions taken to correct the Material Deficiency; and

(iv) any further steps Dr. Rothman and ROA II plan to take to address the Material Deficiency and prevent it from recurring.

H. Notification of Government Investigations or Legal Proceedings

Within 30 days after discovery, Dr. Rothman and ROA II 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 Dr. Rothman or ROA II 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. Dr. Rothman and ROA II shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date of this Agreement, Dr. Rothman or ROA II changes locations or purchases or establishes a new business related to the furnishing of items or services that may be reimbursed by Federal health care programs, they shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change of location, purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Medicare provider 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 120 days after the Effective Date of this Agreement, Dr. Rothman and ROA II 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 and phone number of Dr. Rothman's and ROA II's Compliance Contact;

2. A copy of the notice Dr. Rothman and ROA II posted in their offices 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 Dr. Rothman attesting that the Policies and

Procedures are being implemented and have been made available to all Covered Persons;

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

6. A certification signed by Dr. Rothman attesting that all Covered Persons have completed the initial training required by Section III.D. and have executed the required certifications;

7. A copy of the certification from the third party billing company, if any, as required by Section III.E of the Agreement;

8. The name and qualifications of the IRO Dr. Rothman and ROA II have retained to conduct the billing engagement and the proposed start and completion dates of the first annual review;

9. A certification from the IRO regarding its professional independence and/or objectivity from Dr. Rothman and ROA II;

10. A list of all Dr. Rothman's and ROA II's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare provider identification number(s) and the contractor's name and address that issued each provider identification number; and

11. A certification from Dr. Rothman stating that he has reviewed the Implementation Report, he has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

B. Annual Reports

Dr. Rothman and ROA II shall submit to OIG Annual Reports with respect to the status of and findings regarding Dr. Rothman's and ROA II's compliance activities for each of the five 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 90 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 Dr. Rothman 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 Dr. Rothman certifying that he 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 prepared pursuant to the IRO's Billing Engagement, along with a copy of the IRO's engagement letter;

6. Dr. Rothman's and ROA II's response and corrective action plan(s) related to any issues raised or recommendations made by the IRO;

7. A summary/description of all engagements between Dr. Rothman, ROA II and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting;

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

9. A summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to section III.H. 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;

10. A certification signed by Dr. Rothman certifying that all prospective employees and other Covered Persons 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

11. A certification signed by Dr. Rothman certifying that he has reviewed the Annual Report, he has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

If to the 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
330 Independence Avenue, SW
Cohen Building, Room 5527
Washington, DC 20201
Ph. 202.619.2078
Fax 202.205.0604

If to Dr. Rothman: Richard Rothman, M.D.
925 Chestnut Street
Philadelphia, PA 19101
Ph: 215.955.6315
Fax: 215.503.0571

If to ROA II: Reconstructive Orthopedic Associates, P.C.- Compliance Contact
925 Chestnut Street
Philadelphia, PA 19101

Ph: 215.955.6315
Fax: 215.503.0571

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

VIII. DOCUMENT AND RECORD RETENTION

Dr. Rothman and ROA II 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).

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 Dr. Rothman and ROA II prior to any release by OIG of information submitted by Dr. Rothman and ROA II pursuant to its obligations under this Agreement and identified upon submission by Dr. Rothman and ROA II as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Dr. Rothman and ROA II shall have the rights set forth at 45 C.F.R. § 5.65(d). Dr. Rothman and ROA II shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA. The OIG shall protect confidential information under the FOIA rules to the greatest extent allowed by law.

X. BREACH AND DEFAULT PROVISIONS

Full and timely compliance by Dr. Rothman and ROA II shall be expected throughout the duration of this Agreement with respect to all of the obligations herein agreed to by Dr. Rothman and ROA II.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Dr. Rothman, ROA II 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 Dr. Rothman or ROA II:

   a. Fails to have in place a Compliance Contact as required in section III.A;

   b. Fails to post the notice required in section III.B;

c. Fails to have in place the Policies and Procedures required in section III.C;

d. Fails to require that each applicable Covered Person attends the training required by section III.D. of the Agreement within the time frames required in that section;

e. Fails to retain an IRO within the timeframe required in section III.F.1, as required in section III.F and Appendix A; or or

f. Fails to 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 Dr. Rothman or ROA II employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Dr. Rothman's or ROA II'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 Dr. Rothman and ROA II can demonstrate that they 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 Dr. Rothman or ROA II 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 they fail to grant access.)

4. A Stipulated Penalty of $750 for each day Dr. Rothman or ROA II fails to comply fully and adequately with any obligation of this Agreement. In its notice to Dr. Rothman and ROA II, OIG shall state the specific grounds for its determination that Dr. Rothman or ROA II has failed to comply fully and adequately with the Agreement obligation(s) at issue and the steps Dr. Rothman and ROA II must take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to Dr. Rothman and ROA II of the failure to comply.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under paragraphs 1-3 of this section.

B. Timely Written Requests for Extensions

Dr. Rothman and ROA II 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 Dr. Rothman or ROA II 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 Dr. Rothman and ROA II receive 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 Dr. Rothman or ROA II 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 Dr. Rothman and ROA II of: (a) Dr. Rothman's or ROA II's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Dr. Rothman and ROA II shall respond by either: (a) curing the breach to OIG's satisfaction, notifying OIG of their corrective actions, 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 Dr. Rothman or ROA II elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Dr. Rothman or ROA II cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this Agreement and shall be grounds for exclusion under section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in section VI.

4. *Independence from Material Breach Determination.* Except as set forth in section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Dr. Rothman or ROA II 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 Dr. Rothman or ROA II to report a material deficiency, take corrective action and make the appropriate refunds, as required in section III.G;

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

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

d. a failure to retain and use an Independent Review Organization in accordance with section III.D.

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

4. *Exclusion Letter.* If at the conclusion of the 30-day period, Dr. Rothman and ROA II fail to satisfy the requirements of section X.D.3, OIG may exclude Dr. Rothman and ROA II from participation in the Federal health care programs. OIG will notify Dr. Rothman and ROA II in writing of its determination to exclude Dr. Rothman and ROA II (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, Dr. Rothman or ROA II wishes to apply for reinstatement, they 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 Dr. Rothman and ROA II 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, Dr. Rothman and ROA II 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 after the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after 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 Dr. Rothman and ROA II were in full and timely compliance with the obligations of this Agreement for which OIG demands payment; and (b) the period of noncompliance. With respect to the Stipulated Penalties set forth in sections X.A.1, X.A.2, and X.A.3, Dr. Rothman and ROA II shall have the burden of proving his full and timely compliance and the steps taken to cure the noncompliance, if any. With respect to the Stipulated Penalty set forth in section X.A.4, the OIG shall have the burden of proving non-compliance and Dr. Rothman and ROA II shall have the burden of proving the steps taken to cure the noncompliance, if any. If the ALJ agrees with OIG with regard to a finding of a breach of this Agreement and orders Dr. Rothman or ROA II to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Dr. Rothman or ROA II 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 Dr. Rothman or ROA II 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) Dr. Rothman and ROA II had begun to take action to cure the material breach within that period;

(ii) Dr. Rothman and ROA II have pursued and are pursuing such action with due diligence; and

(iii) Dr. Rothman and ROA II provided to OIG within that period a reasonable timetable for curing the material breach and they have 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 Dr. Rothman and ROA II, only after a DAB decision in favor of OIG. Dr. Rothman's and ROA II's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Dr. Rothman or ROA II 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 Dr. Rothman or ROA II 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. Dr. Rothman and ROA II agree to waive their right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ

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, Dr. Rothman, ROA II and the OIG agree as follows:

1. This Agreement shall be binding on the successors, assigns and transferees of Dr. Rothman and ROA II;

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; and

4. Dr. Rothman and ROA II represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever, and acknowledges that he has been represented by and has had the full advice of his counsel prior to executing this Agreement. The undersigned OIG signatory represents that he is signing this Agreement in his official capacity and that he is authorized to execute this Agreement.

IN WITNESS WHEREOF, the parties hereto affix their signatures:

RICHARD ROTHMAN, M.D.

April 14, 2003
Date

Richard Rothman, M.D.

April 14, 2003
Date

Counsel for Dr. Rothman

RECONSTRUCTIVE ORTHOPEDIC ASSOCIATES II

April 14, 2003
Date

BY: Richard Rothman, M.D.
President

April 14 2003
Date

Counsel for ROAII

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

4/8/03
Date

BY: Larry Goldberg, Esquire
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

APPENDIX A

A. Claims Review.

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

a. Claims Review Sample: A statistically valid, randomly selected, sample of items selected for appraisal in the Claims Review.

b. Item: Any discrete unit that can be sampled (e.g., code, line item, beneficiary, patient encounter, etc.). For purposes of this Billing Engagement, the term "Item" refers to a Surgical Calendar Day as defined in the CIA.

c. Overpayment: Consistent with the definition of Overpayment as articulated in section III.H.1.a of the CIA, the amount of money Dr. Rothman or ROA II has received in excess of the amount due and payable under any Federal health care program requirements.

d. Population: The population shall consist of all calendar days in which Dr. Rothman performed three or more surgeries ("Surgical Calendar Days").

e. RAT-STATS: OIG's Office of Audit Services Statistical Sampling Software. RAT-STATS is publicly available to download through the Internet at "www.hhs.gov/oig/oas/ratstat.html".

B. Billing Engagement Report. The IRO shall prepare a separate report for each Billing Engagement. All Billing Engagement reports shall be included in the submission of the Annual Report. The following information shall be included in each Billing Engagement Report, unless otherwise specified:

1. ***Billing Engagement Methodology***

a. Objective: A clear statement of the objective(s) intended to be achieved by the Billing Engagement.

b. Sampling Unit: A description of the Item as that term is utilized for the Billing Engagement. For purposes of the Billing Engagement, the sampling unit is a Surgical Calendar Day, as defined in section II.F.3.a of the CIA and in section A.1.b above.

c. Billing Engagement Population: A description of the Population subject to the Billing Engagement. For purposes of the Billing Engagement, the Population shall consist of all of Dr. Rothman's Surgical Calendar Days for the reporting period.

d. Sampling Frame: A description of the sampling frame, which is the totality of Items from which each sample has been selected and an explanation of the methodology used to identify the sampling frame. In most circumstances, the sampling frame will be identical to the Population.

e. Sources of Data: A description of the documentation relied upon by the IRO when performing the Billing Engagement (e.g., medical records, physician orders, surgical log, local medical review policies, CMS program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).

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

2. ***Statistical Sampling Documentation***

a. The number of Items appraised in each Billing Engagement Sample.

b. A copy of the RAT-STATS printout of the random numbers generated by the "Random Numbers" function for each Billing Engagement performed.

c. If applicable, a copy of the RAT-STATS printout of the "Sample Size Estimators" results used to calculate the minimum number of claims for

inclusion in the Full Claims Review Sample.

d. If applicable, a copy of the RAT-STATS printout of the "Variable Appraisals", "Difference Values Only" function results for the 30 Claim Review Sample, including a copy of the data file.

e. The Sampling Frame used in any of the Billing Engagements shall be available to the OIG upon request.

3. ***Billing Engagement Results***. Each Billing Engagement Report shall contain the following components unless otherwise specified:

a. Total number and percentage of instances in which the IRO determined that the claim submitted by Dr. Rothman, ROA II or other Covered Persons ("Claim Submitted") differed from what should have been the correct claim to have been submitted ("Correct Claim"), regardless of the effect on the payment.

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

c. The total dollar amount of all Medicare paid claims in each Billing Engagement and the total dollar amount of Overpayments associated with the Medicare paid claims in the sample.

e. A spreadsheet of the Billing Engagement results that includes the following information for each Medicare paid claim reviewed: beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor, the correct allowed amount, and comments. (See Attachment 1 to this Appendix.) If a claim is disallowed due to a concurrency or presence issue, the IRO shall note in the comments field of this spreadsheet all other claims associated with the concurrency or presence issue (e.g., claim was disallowed because both this claim and claim XXX were billed as if Dr. Rothman performed the surgeries).

f. Please specify the following information: the total Medicare dollars in

the sample, the total Medicare dollar underpayment in the sample, the Medicare financial error rate, and the Medicare dollar projected amount that is being refunding to the appropriate Medicare contractor.

4. ***Credentials.*** The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Billing Engagement; and (2) performed the Billing Engagement.