

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ORTHOLOGIC CORP.**

I. PREAMBLE

OrthoLogic Corp. ("OrthoLogic") hereby enters into this Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance by its officers, directors, employees, and contractors and agents who have any responsibility for activities related to the marketing of or billing for medical devices to Federal health care programs or their beneficiaries ("Covered Persons") with the statutes, regulations and written directives of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) ("Federal health care program requirements"). Contemporaneously with this CIA, OrthoLogic is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement. Previously, effective August 17, 1998, OrthoLogic and OIG entered into a prior CIA ("August 17, 1998 CIA"). The Parties to this CIA acknowledge that OrthoLogic has on an ongoing basis been implementing and otherwise satisfying the requirements of the August 17, 1998 CIA. Therefore, the obligations set forth in this CIA will reflect and incorporate these ongoing efforts. Notwithstanding, this CIA upon its execution shall supersede the August 17, 1998 CIA, and all requirements contained therein shall terminate upon execution of this CIA.

Prior to the execution of this CIA, OrthoLogic established a compliance program (the "Compliance Program"). This Compliance Program provides for policies and procedures and, as represented by OrthoLogic in this CIA, is aimed at ensuring that its participation in the Federal health care programs is in conformity with the statutes, regulations and other directives applicable to those programs. Therefore, pursuant to this CIA, OrthoLogic hereby agrees to maintain in full operation the Compliance Program for



the term of this CIA. The Compliance Program may be modified by OrthoLogic as appropriate but, at a minimum, shall comply with the integrity obligations enumerated in this CIA.

II. TERM OF THE CIA

The period of the compliance obligations assumed by OrthoLogic under this CIA shall be three (3) years from the effective date of this CIA (unless otherwise specified).

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 OrthoLogic pursuant to OIG's request. However, Sections VII, VIII, IX, X and XI shall expire no later than 120 days from OIG's receipt of (1) OrthoLogic's final Annual Report or (2) any additional materials submitted by OrthoLogic pursuant to OIG's request, whichever is later.

III. CORPORATE INTEGRITY OBLIGATIONS

OrthoLogic hereby agrees to maintain its Compliance Program which, at a minimum, shall include the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* OrthoLogic represents that it has appointed an individual to serve as its Compliance Officer. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of OrthoLogic's management, shall make periodic (at least quarterly) reports regarding compliance matters directly to the CEO, President and/or the Board of OrthoLogic (or a committee thereof), and shall be authorized to report on such matters to the Board of Directors (or a committee thereof) at any time. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by OrthoLogic as well as for any reporting obligations created under this CIA.



Any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, must be reported to OIG, in writing, within 15 days of such a change.

2. *Compliance Committee.* OrthoLogic represents that it has appointed a Compliance Committee. The Compliance Committee shall, at a minimum, continue to include the Compliance Officer and any other members of management necessary to meet the requirements of this CIA (e.g., individuals of each major department, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

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

B. Written Standards.

1. *Code of Ethics.* OrthoLogic shall maintain its Code of Ethics established pursuant to its Compliance Program. The Code of Ethics shall be distributed to any Covered Person who has not received to date a copy of the Code of Ethics within 90 days of the effective date of this CIA. OrthoLogic shall continue to make the promotion of, and adherence to, the Code of Ethics an element in evaluating the performance of all employees. OrthoLogic represents that the Code of Ethics sets forth:

- a. OrthoLogic's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;
- b. OrthoLogic's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program



requirements and with OrthoLogic's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);

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

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

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

Within 120 days of the effective date of the CIA, to the extent not already performed, each Covered Person shall certify, in writing, that he or she has received, read, understood, and will abide by OrthoLogic's Code of Ethics. New Covered Persons shall receive the Code of Ethics and shall complete the required certification within two weeks after becoming a Covered Person or within 120 days of the effective date of the CIA, whichever is later.

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

2. *Policies and Procedures.* OrthoLogic shall maintain its written Policies and Procedures implemented under the August 17, 1998 CIA regarding the operation of



OrthoLogic's Compliance Program and its compliance with Federal health care program requirements. OrthoLogic represents that such written Policies and Procedures shall, at a minimum, continue to address:

- a. the subjects relating to the Code of Ethics identified in Section III.B.1;
- b. the prohibition against the routine waiver of copayments and deductibles; and.
- c. the marketing of and billing for medical devices.

To the extent not already done, within 120 days of the effective date of the CIA, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions are related to those Policies and Procedures. Appropriate and knowledgeable staff should be available to explain the Policies and Procedures.

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

C. Training and Education.

1. *General Training.* Within 120 days of the effective date of this CIA, OrthoLogic shall provide at least one hour of general training to each Covered Person. This training, at a minimum, shall explain OrthoLogic's:

- a. CIA requirements; and
- b. Compliance Program (including the Code of Ethics and the Policies and Procedures as they pertain to general compliance issues).



New Covered Persons shall receive the general training described above within 30 days of becoming a Covered Person or within 120 days after the effective date of this CIA, whichever is later. After receiving the initial training described above, each Covered Person shall receive at least one hour of general training annually.

2. *Specific Training.* Within 120 days of the effective date of this CIA, each Covered Person who is 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 (hereinafter referred to as "Relevant Covered Persons") shall receive at least three hours of specific training in addition to the general training required above. This specific training shall include a discussion of:

- a. the submission of accurate bills for services rendered to Federal health care program beneficiaries;
- b. policies, procedures and other requirements applicable to the documentation of medical records;
- c. the personal obligation of each individual involved in the billing process to ensure that such billings are accurate;
- d. applicable reimbursement statutes, regulations, and program requirements and directives;
- e. the legal sanctions for improper billings, including the routine waiver of copayments and deductibles; and
- f. examples of proper and improper billing practices.

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

Relevant Covered Persons shall receive this training within 30 days of the beginning of their employment or becoming Relevant Covered Persons or within 120 days of the effective date of this CIA, whichever is later. An OrthoLogic employee who has completed the specific training shall review a new Relevant Covered Person's work,



to the extent that the work relates to the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes applicable training.

After receiving the initial training described in this Section, every Relevant Covered Person shall receive at least three hours of specific training annually.

3. *Certification.* Each individual who is required to attend training shall certify, in writing, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or his or her designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request. For the purposes of meeting the obligations under this Section III.C, for the term of the first Annual Report under this CIA, OIG shall credit OrthoLogic's training and education activities carried out pursuant to the Compliance Program within the twelve months prior to the effective date of this CIA to the extent such training satisfies the requirements set forth above. Also, for the purposes of meeting the obligations under this Section III.C, the training requirements of this CIA do not apply to agents and independent contractors in the case of short-term workers who are not reasonably expected to work more than thirty (30) days, except to the extent that such individual actually works in excess of thirty (30) days during a twelve-month period.

D. Review Procedures.

1. *Review of Practices.* For three years from the effective date of this CIA, OrthoLogic will have an experienced attorney with knowledge of the Federal health care program statutes, regulations, policies, procedures, and guidelines, including those issued by the Health Care Financing Administration (HCFA) and its contractors: (i) review any proposed changes to OrthoLogic's policies and procedures related to the marketing of or billing for medical devices to Federal health care programs or their beneficiaries prior to any implementation of such changes by OrthoLogic, and (ii) annually review all of OrthoLogic's practices related to the marketing of or billing for medical devices to Federal health care programs or their beneficiaries. The underlying documentation OrthoLogic used in the reviews described in this Section shall be maintained and

available for OIG review and inspection for a minimum of four years.

2. *Retrospective Claims Review.* OrthoLogic shall designate one or more billing compliance auditors (the "Billing Compliance Auditors") to conduct retrospective reviews of claims submitted by OrthoLogic to the Medicare program (the "Retrospective Claims Reviews"). Each Billing Compliance Auditor must have expertise in the billing, coding, reporting, and other requirements of the Medicare program. These Billing Compliance Auditors must not have been involved in the billing, coding or any other aspect of the claims submission process.

The Retrospective Claims Reviews shall be performed in accordance with an audit work plan ("Audit Work Plan"). The Audit Work Plan shall utilize an audit methodology to review claims that have been paid by the Medicare program. The Audit Work Plan shall be forwarded to OIG for review at least 30 days in advance of the first Retrospective Claims Review performed pursuant to this CIA. OIG may review and offer comments to the Audit Work Plan. However, such review by OIG shall not be considered OIG approval and does not preclude OIG from further comments, inquiries, and making recommendations after receiving the results. The Retrospective Claims Reviews shall be capable of being extrapolated.

The Retrospective Claims Review shall be performed annually and shall cover each year of the term of the CIA, beginning with the twelve-month period that begins on the effective date of this CIA. The Retrospective Claims Reviews and the Claims Review Reports shall be completed within 120 days of the end of the twelve-month period under review. The universe for each Retrospective Claims Review shall consist of paid units from each of OrthoLogic's product lines. The sampling unit for these reviews shall be by beneficiary during the twelve-month period covered by the review. Each Retrospective Claims Review shall consist of reviewing a statistically valid sample of sampling units from each universe (i.e., each sampling unit has a non-zero probability of being selected in the sample). The reviews shall be performed in accordance with the following guidelines:

- a. OrthoLogic's Billing Department shall categorize sampling units by product line (e.g., Fracture Healing, OrthoRehab and Ancillary Products). Each Medicare beneficiary who had at least one paid item



or service during the twelve-month period under review shall be included in the universe of the product line for which the service received was paid. Therefore, each beneficiary is included in each product line from which he or she received items or services and for which at least one claim was paid by Medicare. Every Medicare beneficiary for whom a claim was paid by Medicare must be included in at least one product line.

- b. OrthoLogic shall use RAT-STATS random number generator to randomly select a minimum of 25 beneficiaries from each product line. All claims for each beneficiary selected that relate to the product line and within the audit timeframe will be reviewed.
- c. For each product line sample of beneficiaries, the Billing Compliance Auditors shall request from OrthoLogic's Reimbursement Department the complete patient files relating to that product line, as well as any other documentation that supports the claim.
- d. For each product line sample of beneficiaries, the Billing Compliance Auditors shall, at a minimum, review the following information:
 - i. Written physician orders, and CMNs where required, had been received and were accurately completed prior to the submission of any claim to the Medicare program of any items and services so ordered;
 - ii. All claims for each beneficiary who received items or services from OrthoLogic met the medical necessity, coverage (or if not, that OrthoLogic used the GA modifier on the claim form to notify the DMERC that it believed the claim to be non-covered), utilization, documentation, delivery and other applicable Medicare program requirements. Claims will also be reviewed to ensure that reasonable efforts were undertaken



by OrthoLogic after receipt of payment from Medicare to obtain from the secondary payor (e.g., Medigap), if any, or, if there is no secondary payor payment, the beneficiary, any coinsurance amounts owed to OrthoLogic. For the purposes of this Section, unless the patient otherwise qualifies for a lawful coinsurance waiver (e.g., financial hardship) reasonable patient collection efforts will include: the issuance of a bill and any subsequent billings by OrthoLogic to the beneficiary; collection letters, telephone calls or personal contacts with the beneficiary in which OrthoLogic requests payment from the beneficiary.

For the first audit period, claims with dates of service within the first six months of the audit period (in order to allow sufficient time for attempts to collect coinsurance) will be examined. For the second audit period, claims from the second six months of the first audit period and claims from the first six months of the second audit period will be reviewed. For the third audit period, claims from the second six months of the second audit period and claims from the full year of the third audit period will be reviewed, but coinsurance will be reviewed only for the first six months of the third audit period;

- iii. All items and services furnished to each beneficiary conformed with the quantity, type, and frequency requested by the ordering physician;
- iv. Each Medicare claim form (e.g., HCFA 1500) submitted for items or services furnished to each beneficiary had been accurately completed, and is in compliance with the Medicare requirements for that claim according to the supporting documentation (e.g., physician orders, CMNs, the items and services furnished by OrthoLogic, the diagnosis of the specific beneficiary, and any other relevant information); and



- v. The amount of reimbursement received by OrthoLogic for each item or service furnished to the beneficiary was correct and payable in accordance with all applicable Medicare program requirements.
- e. For each claim for which the Billing Compliance Auditors are unable to verify each of the items set forth above, the Billing Compliance Auditors shall consider such items to have been billed in error and shall determine the amount of the overpayment (as that term is defined in Section III.H.1) received by OrthoLogic in association with that beneficiary.

3. *Retrospective Claims Review Report.* OrthoLogic shall provide OIG with a report of each Retrospective Claims Review (the "Retrospective Claims Review Report") for each product line. Each Retrospective Claims Report shall include the following:

- a. *Retrospective Claims Review Methodology*
 - i. Retrospective Claims Review Objective: A clear statement of the objective intended to be achieved by the Retrospective Claims Review;
 - ii. Sampling Unit: A description of the Item as that term is utilized for the Retrospective Claims Review. In this review, the term "Item" refers to "beneficiary," the discrete unit that is being sampled;
 - iii. Retrospective Claims Review Population: A description of the Population (*i.e.*, Medicare beneficiaries for each product line) subject to the Claims Review;
 - iv. Sampling Frame: A description of the sampling frame (*i.e.*, Medicare beneficiaries for each product line), which is the



totality of Items from which the Retrospective Claims Review Sample have been selected and an explanation of the methodology used to identify the sampling frame. In this circumstance, the sampling frame is identical to the Population;

- v. Sources of Data: A description of the documentation relied upon by OrthoLogic when performing the Retrospective Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies, HCFA program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations or directives); and
- vi. Review Protocol: A narrative description of how the Retrospective Claims Review was conducted and what was evaluated.

b. *Statistical Sampling Documentation*

- i. The number of Items appraised in the Sample(s) and in the Retrospective Claims Review Sample;
- ii. A copy of the RAT-STATS printout of the random numbers generated by the "Random Numbers" function; and
- iii. The Sampling Frame (i.e., the Medicare beneficiaries) used in the Retrospective Claims Review Sample will be available to the OIG upon request.

c. *Retrospective Claims Review Results*

- i. Total number and percentage of instances in which it is determined that the Paid Claims submitted by OrthoLogic (“Claim Submitted”) differed from what should have been the correct claim (“Correct Claim”), regardless of the effect on the payment;
- ii. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to OrthoLogic;
- iii. The total dollar amount of all Paid Claims in the Retrospective Claims Review Sample and the total dollar amount of Overpayments associated with the Paid Claims identified by the Retrospective Claims Review. (This is the total dollar amount of the Overpayments identified in Section III.D.3.c.ii, above.) OrthoLogic may identify underpayments, but any underpayments identified during the Retrospective Claims Review shall not be offset or “netted out” of the total dollar amount of Paid Claims or of the Overpayments when reporting these amounts in the Retrospective Claims Review Report to OIG;
- iv. The level of precision achieved by the Retrospective Claims Review at a 90% confidence level; and
- v. A spreadsheet of the Retrospective Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by OrthoLogic), correct allowed amount (as determined by OrthoLogic), dollar difference between allowed amount

reimbursed by payor and the correct allowed amount. (See Appendix A to this CIA.)

- d. *Credentials.* The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Retrospective Claims Review; and (2) performed the Retrospective Claims Review.

4. *Verification Review.* OrthoLogic shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO") to verify ("Verification Review") OrthoLogic's audit results for the first and third Retrospective Claims Reviews. The IRO performing the Verification Reviews must have expertise in the billing, coding, reporting, and other Medicare program requirements applicable to OrthoLogic. OrthoLogic shall require the IRO to produce a report for each of the product lines that details its findings. In performing the Verification Reviews, the IRO shall randomly select from the sampled beneficiaries at least five (5) beneficiaries from each product line.

A complete copy of each Retrospective Claims Review Report and the IRO's reports of findings regarding OrthoLogic's Retrospective Claims Review shall be submitted with OrthoLogic's Annual Report to OIG for the year which includes the time period covered by the Retrospective Claims Review. All workpapers and supporting documentation relating to the Retrospective Claims Review shall be retained by OrthoLogic for the duration of this CIA, and shall be furnished to OIG upon request. All workpapers and supporting documentation relating to the Verification Reviews shall be retained by the IRO for the duration of this CIA, and shall also be available to OIG upon request.

Based upon, but not limited to, the results of the first Verification Review, OIG may, at its sole discretion, reduce or dismiss OrthoLogic's obligation to retain an IRO to perform a Verification Review of OrthoLogic's third Retrospective Claims Review.

5. *Validation Review.* In the event OIG has reason to believe that: (a) OrthoLogic's Retrospective Claims Review fails to conform to the requirements of this CIA; or (b) the findings or Retrospective Claims Review results are inaccurate, OIG may,



at its sole discretion, conduct its own review to determine whether the Retrospective Claims Review complies with the requirements of the CIA and/or the findings or Retrospective Claims Review results are inaccurate. OrthoLogic agrees to pay for the reasonable cost of any such review performed by OIG or any of its designated agents so long as it is initiated before one year after OrthoLogic's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify OrthoLogic 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 OIG, OrthoLogic may request a meeting with OIG to discuss the results of any submissions or any Retrospective Claims Review findings; present any additional or relevant information to clarify the results of the submissions or to correct the inaccuracy of the Retrospective Claims Review; and/or propose alternatives to the proposed Validation Review. OrthoLogic agrees to provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any issues with OrthoLogic prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

6. *Independence Certification.* The IRO shall include in its report(s) to OrthoLogic a certification or sworn affidavit that it has evaluated its professional independence with regard to the Verification Review(s) referenced in Section III.D.4 above and has concluded that it was, in fact, independent.

E. Disclosure Program.

OrthoLogic shall maintain its Compliance Assistance Communication System established pursuant to its Compliance Program, which includes a toll-free compliance telephone line to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with OrthoLogic's policies, conduct, practices, or procedures with respect to a Federal health care program, believed by the individual to be a potential violation of criminal, civil or administrative law. OrthoLogic shall continue to appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).



The Compliance Assistance Communication System shall continue to emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communications. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, OrthoLogic shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or his or her designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be available to OIG, upon request.

F. Ineligible Persons.

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

2. *Screening Requirements.* OrthoLogic shall continue not to hire as employees or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, OrthoLogic shall screen all prospective employees and prospective contractors prior to engaging their services by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the



Internet at <http://epls.arnet.gov>) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.hhs.gov/oig>) (these lists will hereinafter be referred to as the "Exclusion Lists").

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

If OrthoLogic has notice that an employee or contractor has become an Ineligible Person, OrthoLogic shall remove such person from responsibility for, or involvement with, OrthoLogic's business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If OrthoLogic has notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract, OrthoLogic shall take all appropriate actions to ensure that the responsibilities of that employee or contractor have not and shall not adversely affect the quality of care rendered to any beneficiary, patient or resident, or the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

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

H. Reporting.

1. *Overpayments.*

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

b. *Reporting of Overpayments.* If, at any time, OrthoLogic identifies or learns of any overpayments, OrthoLogic shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of discovering credible evidence 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, OrthoLogic 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, OrthoLogic 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 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 CIA.

Notwithstanding the above, notification and repayment of any

overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

2. *Material Deficiencies.*

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

- i. a substantial overpayment; or
- ii. a matter that a reasonable person would consider a 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 OrthoLogic determines through any means that there is a Material Deficiency, OrthoLogic shall notify OIG, in writing, within 30 days of making the determination that the Material Deficiency exists. The report to OIG shall include the following information:

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

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

(B) the date of the check and identification number (or

electronic transaction number) 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 OrthoLogic's actions taken to correct the Material Deficiency; and
- iv. Any further steps OrthoLogic plans to take to address the Material Deficiency and prevent it from recurring.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the effective date of this CIA, OrthoLogic changes locations or purchases or establishes new business units related to the furnishing of items or services that may be reimbursed by Federal health care programs, OrthoLogic shall notify OIG of this fact as soon as possible, but no later than within 30 days of 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 number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare provider number. All Covered Persons at such locations shall be subject to the applicable requirements in this CIA (e.g., completing certifications and undergoing training). This notification requirement shall not apply to new locations used solely for manufacturing or warehousing purposes.

V. ANNUAL REPORTS


A. Annual Reports. OrthoLogic shall submit to OIG Annual Reports with respect to the status of, and findings regarding, OrthoLogic's compliance activities for each of the three one-year periods beginning on the effective date of the CIA. The one-year period covered by each Annual Report shall be referred to as "the Reporting Period."

Each Annual Report shall include:

1. any change in the identity, position description, or other non-compliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in Section III.A;
2. a certification by the Compliance Officer that:
 - a. all Covered Persons have completed any Code of Ethics certifications required by Section III.B.1;
 - b. all Covered Persons have completed the applicable training and executed the certification(s) required by Section III.C; and
 - c. if applicable, OrthoLogic has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (ii) not to charge to or otherwise seek payment from Federal or State payors for unallowable costs (as defined in the Settlement Agreement); and (iii) to identify and adjust any past charges or claims for unallowable costs;

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

3. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy) and copies of any compliance-related Policies and Procedures to the extent not already submitted to OIG;
4. a copy of all training materials used for the training required by Section III.C, a description of such training conducted during the Reporting Period, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a



schedule of when the training sessions were held;

5. a complete copy of all reports prepared pursuant to the IRO's Verification Review(s), including a description of the methodology used, along with a copy of the IRO's engagement letter;

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

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

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

9. a report of the aggregate overpayments that have been returned to the Federal health care programs. Overpayment amounts should be broken down into the following categories: inpatient Medicare (if applicable), outpatient Medicare, Medicaid (report each applicable state separately) and other Federal health care programs;

10. a summary of the disclosures in the disclosure log required by Section III.E that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;

11. a description of any personnel actions (other than hiring) taken by OrthoLogic as a result of the obligations in Section III.F, and the name, title, and responsibilities of any person that falls within the ambit of Section III.F.4, and the actions taken in response to the obligations set forth in that Section;

12. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary

shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

13. a list of all of OrthoLogic's locations (including locations and mailing addresses) or, in subsequent Annual Reports, a description of all changes to the most recently provided list (as updated) of OrthoLogic's locations, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program provider identification number(s), and the contractor name and address that issued each provider identification number; and

14. the certification required by Section V.C.

The first Annual Report shall be received by the OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

B. Initial Report. Within 120 days of the effective date of this CIA, OrthoLogic shall provide OIG in writing the identity of the IRO(s) and the proposed start and completion dates of the first Verification Review.

C. Certifications. The Annual Reports shall include a certification by the Compliance Officer that: (1) except as otherwise described in the applicable report, OrthoLogic is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information is accurate and truthful.

D. Designation of Information: OrthoLogic shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. OrthoLogic shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

OIG:

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

OrthoLogic:

Ruben Chairez, Ph.D
Vice President of Medical, Regulatory and Compliance
OrthoLogic Corp.
1275 West Washington
Tempe, AZ 85282
Phone 602-286-5507
FAX 602-470-7080

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

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

VIII. DOCUMENT AND RECORD RETENTION

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

OrthoLogic is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, OrthoLogic and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day OrthoLogic fails to have in place any of the obligations described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a written Code of Ethics;
- d. written Policies and Procedures;
- e. a requirement that Covered Persons be trained; and
- f. the Compliance Assistance Communication System.

2. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day OrthoLogic fails to retain an IRO, as required in Section III.D.

3. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day OrthoLogic fails to meet any of the deadlines for the submission of Annual Reports to OIG.

4. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the date the failure to comply began) for each day OrthoLogic employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with,



OrthoLogic'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 OrthoLogic can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in Section III.F) as to the status of the person).

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

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

B. Timely Written Requests for Extensions. OrthoLogic may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after OrthoLogic 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 OrthoLogic 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 OrthoLogic 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 OrthoLogic of: (a) OrthoLogic'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, OrthoLogic shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event OrthoLogic elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until OrthoLogic cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

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

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that OrthoLogic has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA

1. *Definition of Material Breach.* A material breach of this CIA means:
 - a. a failure by OrthoLogic to report a Material Deficiency, take corrective action and make the appropriate refunds, as required in

Section III.H;

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

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

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

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by OrthoLogic constitutes an independent basis for OrthoLogic's exclusion from participation in the Federal health care programs. Upon a determination by OIG that OrthoLogic has materially breached this CIA and that exclusion should be imposed, OIG shall notify OrthoLogic of: (a) OrthoLogic'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.* OrthoLogic 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. OrthoLogic is in compliance with the obligations of the CIA cited by the OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) OrthoLogic has begun to take action to cure the material breach; (ii) OrthoLogic is pursuing such action with due diligence; and (iii) OrthoLogic has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If at the conclusion of the 30-day period, OrthoLogic fails to satisfy the requirements of Section X.D.3, OIG may exclude OrthoLogic from participation in the Federal health care programs. OIG will notify OrthoLogic in writing of its determination to exclude OrthoLogic (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, OrthoLogic wishes to apply for reinstatement, OrthoLogic 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 OrthoLogic of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, OrthoLogic shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether OrthoLogic was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. OrthoLogic shall have the burden of proving its full and timely compliance and 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 CIA and orders OrthoLogic to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless OrthoLogic requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

- a. whether OrthoLogic was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that:
 - (i) OrthoLogic had begun to take action to cure the material breach within that period;
 - (ii) OrthoLogic has pursued and is pursuing such action with due diligence; and
 - (iii) OrthoLogic provided to OIG within that period a reasonable timetable for curing the material breach and OrthoLogic has followed the timetable.

For the purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for OrthoLogic, only after a DAB decision in favor of OIG. OrthoLogic's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude OrthoLogic 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 OrthoLogic 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. OrthoLogic agrees to waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB.

XI. EFFECTIVE AND BINDING AGREEMENT

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

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

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA or the date of the Court's entry of the Stipulation and Order of Settlement, whichever is later;

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

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

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

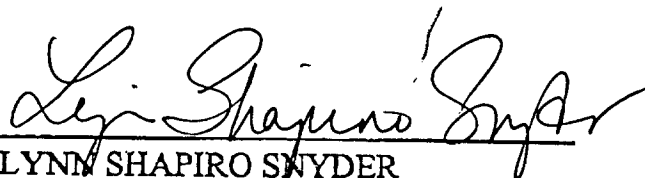


ON BEHALF OF ORTHOLOGIC CORP.



THOMAS R. TROTTER
President and CEO
OrthoLogic Corp.

06/07/2001
DATE



LYNN SHAPIRO SNYDER
Epstein Becker & Green, P.C.
Counsel to OrthoLogic Corp.

6/18/2001
DATE



CARRIE VALIANT
Epstein Becker & Green, P.C.
Counsel to OrthoLogic Corp.

June 8, 2001
DATE



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



LEWIS MORRIS
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

6/2/01
DATE



CONFIDENTIAL- DO NOT RELEASE

Appendix A

Claim Review Results

Federal Health Care Program Billed	Bene HIC #	Date of Service	Procedure Code Submitted	Procedure Code Reimbursed	Allowed Amount Reimbursed	Correct Procedure Code (IRO determined)	Correct Allowed Amt (IRO determined)	Dollar Difference between Amt Reimbursed and Correct Allowed Amt

288

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR	
Date: _____	Date of Deposit: _____
Contractor Deposit Control # _____	Contractor Contact Name: _____ Phone # _____
Contractor Address: _____	
Contractor Fax: _____	

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER	
<i>Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.</i>	
PROVIDER/PHYSICIAN/SUPPLIER NAME _____	
ADDRESS _____	
PROVIDER/PHYSICIAN/SUPPLIER # _____	CHECK NUMBER# _____
CONTACT PERSON: _____	PHONE # _____
AMOUNT OF CHECK \$ _____	CHECK DATE _____

REFUND INFORMATION

For each Claim, provide the following:

Patient Name _____	HIC # _____
Medicare Claim Number _____	Claim Amount Refunded \$ _____
Reason Code for Claim Adjustment: _____ (Select reason code from list below. Use one reason per claim)	

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

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

For Institutional Facilities Only:

Cost Report Year(s) _____

(If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)

For OIG Reporting Requirements:

Do you have a Corporate Integrity Agreement with OIG? Yes No

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

LBB