CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
UNION CITY MEDICAL SUPPLY, INC.

I. PREAMBLE

Union City Medical Supply, Inc. ("Union City") 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 Union City's officers, directors, employees, independent contractors and billing agents 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, Union City is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

For the purposes of this CIA, the term "Covered Persons" means (i) all Union City officers, directors and employees, and (ii) all independent contractors involved in the sales or marketing of items or services provided by Union City.

For the purposes of this CIA, the term "Billing Agent" means any entity or organization that has entered into an agreement with Union City for the purposes of preparation of claims, reports, or other requests for reimbursement of items or services reimbursable by Federal health care programs on behalf of Union City.

II. TERM OF THE CIA

The period of the compliance obligations assumed by Union City under this CIA shall be three (3) years from the effective date of this CIA (unless otherwise specified). The effective date of this CIA shall be the date on which the final signatory of this CIA executes this CIA.

Sections VII, VIII, IX, X and XII shall remain in effect until OIG has completed

its review of the final annual report and any additional materials submitted by Union City pursuant to OIG's request. However, Section VII, VIII, IX, X and XII shall expire no later than 120 days from OIG's receipt of (1) Union City's final annual report or (2) any additional materials submitted by Union City pursuant to OIG's request, whichever is later.

III. CORPORATE INTEGRITY OBLIGATIONS

Union City hereby agrees to establish (or maintain as appropriate) a Compliance Program that includes the following elements:

A. Compliance Contact

Within 30 days of execution of this CIA, Union City 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 OIG regarding compliance with the CIA 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, Union City shall notify OIG, in writing, within 15 days of such a change.

B. Written Standards.

1. *Code of Conduct.* To the extent Union City has not already done so, within 90 days of the effective date of this CIA, Union City shall establish a Code of Conduct. The Code of Conduct shall be distributed to all Covered Persons who have not previously received it within 90 days of the effective date of this CIA. Union City shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

a. Union City'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. Union City's requirement that all of its Covered Persons shall be

expected to comply with all Federal health care program requirements and with Union City's own Policies and Procedures as implemented pursuant to section III.B (including the requirements of this CIA);

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

d. the possible consequences to both Union City and Covered Persons of failure to comply with all Federal health care program requirements and with Union City'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 Union City's commitment to maintain confidentiality, as appropriate, and non-retaliation with respect to disclosures.

Within 90 days of the effective date of the CIA, each Covered Person shall certify, in writing, that he or she has received, read, understood, and will abide by Union City's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within two weeks after becoming a Covered Person or within 90 days of the effective date of the CIA, whichever is later.

Union City shall annually review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Code of Conduct 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 Conduct within 30 days of the distribution of such revisions.

2. *Policies and Procedures*. To the extent Union City has not already done so, within 90 days of the effective date of this CIA, Union City shall implement written Policies and Procedures regarding the operation of its compliance program and its

compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

a. the subjects relating to the Code of Conduct identified in section III.B.1;

b. business arrangements or contracts that induce the unlawful referral of Federal health care program beneficiaries, in violation of 42 U.S.C. § 1320a-7b(b) (the "anti-kickback" statute) and 42 U.S.C. § 1395nn (the "Stark" statute); and

c. procedures requiring legal review of all contracts and agreements that are entered into with individuals or entities who are either directly or indirectly in a position to make referrals to Union City.

To the extent Union City has not already done so, within 90 days of the effective date of the CIA, the relevant portions of the Policies and Procedures shall be distributed to all Covered Persons 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), Union City 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 Covered Persons whose job functions are related to those Policies and Procedures.

C. Training and Education.

1. *General Training.* Within 90 days of the effective date of this CIA, Union City shall provide at least two (2) hours of general training to each Covered Person. This training, at a minimum, shall explain Union City's:

a. CIA requirements; and

b. Compliance Program (including the Code of Conduct 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 90 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. *Sales Training.* Within 90 days of the effective date of this CIA, each Covered Person who is involved directly or indirectly in the sales or marketing of items and services provided by Union City ("Sales Person" or "Sales Personnel") shall receive at least four (4) hours of specific training in addition to the general training required above (the "sales training"). The sales training shall include a discussion of:

a. the anti-kickback and Stark statutes, and the regulations and other guidance related to these statutes;

b. the personal obligation of each individual to make appropriate and accurate representations regarding coverage and billing for items and services provided by Union City;

c. applicable legal requirements;

d. applicable reimbursement statutes, regulations, and program requirements and directives;

e. the legal sanctions for improper sales or marketing strategies or arrangements; and

f. examples of proper and improper marketing strategies and arrangements.

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

Sales Personnel shall receive this training within 30 days of the beginning of their employment or becoming a Sales Person or within 90 days of the effective date of this CIA, whichever is later. An existing Union City Sales Person who has completed the sales training shall review a new Sales Person's work, to the extent that the work relates to the sales or marketing of items or services provided by Union City, until such time as the new Sales Person completes applicable training.

After receiving the initial training described in this section and section III.C.1, every Sales Person shall receive at least two (2) hours of sales 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 Contact (or his or her designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

D. Review Procedures.

For the term of this CIA, Union City shall retain an entity or entities, such as an accounting, auditing or law firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist Union City in assessing the adequacy of its contracting and compliance practices pursuant to this CIA. This shall be an annual requirement and shall cover a twelve (12) month period. The Independent Review Organization must have expertise in the requirements of the Federal health care programs that prohibit certain investment, compensation, and referral arrangements, such as the anti-kickback and "Stark" statutes. The IRO(s) must be retained to conduct the audits of the first year within ninety (90) days of the effective date of this CIA.

These IRO reviews will involve two separate engagements. One will be an analysis of Union City's contracting practices to assist Union City and OIG in determining compliance with all applicable statutes, regulations, and directives/guidance ("contracting engagement"). The second engagement will determine whether Union City is in compliance with this CIA ("compliance engagement").

1. *Contracting Engagement.* The contracting engagement shall consist of a review of all contracts and agreements between Union City and third parties that are potential referral sources including, but not limited to, those appended hereto in Appendix A. Union City represents that Appendix A provides a list of all contracts and agreements between Union City and third parties that are potential referral sources as of the effective date of this CIA. Once a contract or agreement has been reviewed, subsequent review will only be required if there are any amendments thereto. Any new contracts or agreements shall be reviewed by the IRO. Each review shall include an analysis of whether the contract or agreement is in compliance with the anti-kickback and Stark statutes, regulations and/or directives/guidance related to these statutes. The IRO

shall also conduct an analysis of the steps Union City is taking to bring its operations into compliance or to correct problems previously identified by the IRO.

2. *Compliance Engagement.* An IRO shall also conduct a compliance engagement, that shall provide an analysis of whether Union City's Compliance Program, policies, procedures and operations comply with the terms of this CIA. This engagement shall include a section by section analysis of the requirements of this CIA.

A complete copy of the IRO's contracting and compliance engagements shall be included in each of Union City's Annual Reports to OIG.

3. *Validation Review.* In the event OIG has reason to believe that: (a) Union City's contracting or compliance engagement fails to conform to the requirements of this CIA OIG may, at its sole discretion, conduct its own review to determine whether the contracting and/or compliance engagement comply with the requirements of this CIA. Union City 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 the final submission (as described in section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Union City of its intent to do so and provide a written explanation for believing why such a review is necessary. In order to resolve any concerns raised by OIG, Union City may request a meeting with OIG to discuss the results of any engagement submissions; present any additional or relevant information to clarify the results of the engagements; and/or propose alternatives to the proposed Validation Review. Union City 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 contracting or compliance engagement issues with Union City 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.

4. *Independence Certification.* Within 120 days from the effective date of this CIA, the IRO shall provide to Union City a certification or sworn affidavit that it has evaluated its professional independence with regard to the contracting and compliance engagements and that it has concluded that it is, in fact, independent. Such certification shall be included in Union City's Implementation Report submission.

E. Disclosure Program.

To the extent Union City has not already done so, within 90 days after the effective date of this CIA, Union City shall establish a Disclosure Program, that must include a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose to the Compliance Contact any identified issues or questions associated with Union City'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. Union City shall 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 Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communications. Upon receipt of a disclosure, the Compliance Contact (or designee) shall gather to the extent possible all relevant information from the disclosing individual. The Compliance Contact (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, Union City shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Contact (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. During the term of this CIA, 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 or 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*. Union City shall not knowingly hire as employees or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Union City 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 90 days of the effective date of this CIA, Union City shall review its list of current employees and contractors against the Exclusion Lists. Thereafter, Union City shall review its list of current employees and contractors against the Exclusion Lists annually. In addition, Union City shall require employees and contractors to disclose immediately any debarment, exclusion or other event that makes the employee an Ineligible Person.

If Union City has notice that an employee or contractor has become an Ineligible Person, Union City shall remove such person from responsibility for, or involvement with, Union City'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*. To the extent permitted by State law, if Union City 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, Union City 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, Union City 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 Union City has committed a crime or has engaged in fraudulent activities. This notification (to the extent known by Union City) shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Union City 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 Union City has received in excess of the amount due and payable under any Federal health care program requirements. Union City may not subtract any underpayments for purposes of determining the amount of relevant "overpayments" for CIA reports.

b. Reporting of Overpayments. If, at any time, Union City identifies or learns of any overpayments, Union City shall notify the Federal health care program payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of identification of the overpayment and take remedial steps within 60 days of identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Also, within 30 days of identification of the overpayment, Union City 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, Union City 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 Federal health care program 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 Union City determines through any means that there is a Material Deficiency, Union City shall notify OIG, in writing, within 30 days of making the determination that the Material Deficiency exists. The report to the OIG shall include the following information:

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

(iv) any further steps Union City 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, Union City (i) changes locations or (ii) purchases or establishes new business units related to the furnishing of items or services that may be reimbursed by Federal health care programs, Union City 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 Union City 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).

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the effective date of this CIA, Union City shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:

1. the name, address, phone number, position description, and summary of other non-compliance job responsibilities of the Compliance Contact required by section III.A;

2. a copy of Union City's Code of Conduct required by section III.B.1;

3. a copy of all compliance-related Policies and Procedures required by section III.B.2 and a summary of all other Policies and Procedures required by section III.B.2;

4. a copy of all training materials used for the initial training required by section III.C, a description of such training, 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 certification by the Compliance Contact that:

a. the Policies and Procedures required by section III.B have been developed, are being implemented, and have been distributed to all appropriate Covered Persons;

b. all Covered Persons have completed the Code of Conduct certification required by section III.B.1; and

c. all Covered Persons have completed the applicable initial training and executed the certification(s) required by section III.C.;

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

6. a description of the Disclosure Program required by section III.E;

7. the identity of the IRO(s), a summary/description of all engagements between Union City and the IRO, and the proposed start and completion dates of the first annual review;

8. a certification from the IRO regarding its professional independence from Union City;

9. a summary of personnel actions (other than hiring) taken pursuant to section III.F.;

10. a list of all of Union City'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 Union City identification number(s) and the contractor's name and address that issued each Union City identification number;

11. to the extent not already furnished to OIG, or if modified, a description of Union City's corporate structure, including identification of any parent and sister companies, subsidiaries and their respective lines of business; and

12. the Compliance Contact certification required by section V.C that: (i) except as otherwise described in the applicable report, Union City is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (ii) the Compliance Contact has reviewed the Implementation Report and has made reasonable inquiry regarding its content and believes that the information is accurate and truthful.

B. Annual Reports. Union City shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Union City'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 Contact described in section III.A;

2. a certification by the Compliance Contact that:

a. all Covered Persons have completed any Code of Conduct 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;

c. Union City 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;

4. a copy of all training materials used for the training required by section III.C (to the extent it has not already been provided as part of the Implementation Report), 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 contracting and compliance engagements, including a copy of the methodology used, along with a copy of the IRO's engagement letter;

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

7. a revised summary/description of all engagements between Union City and the IRO, if different from what was submitted as part of the Implementation Report;

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, 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;

11. a description of any personnel actions (other than hiring) taken by Union City 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 description of all changes to the most recently provided list (as updated) of Union City's locations (including locations and mailing addresses) as required by section V.A.10, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program Union City identification number(s), and the contractor name and address that issued each Union City identification number; and

14. the Compliance Contact certification required by section V.C that: (i) except as otherwise described in the applicable report, Union City is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance Contact has reviewed the Annual

Report and has made reasonable inquiry regarding its content and believes that the information is accurate and truthful.

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.

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Contact that: (1) except as otherwise described in the applicable report, Union City is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance Contact 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: Union City 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. Union City 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

Union City:

Union City Medical Supply, Inc., d/b/a Bio-Dynamic Technologies
1 Madison Street
Building A
East Rutherford, NJ 07073
Attn: Bob Zaita
Phone 1-800-879-2276
Fax 973-472-7551

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

VIII. DOCUMENT AND RECORD RETENTION

Union City 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 (4) years from the effective date of this CIA (or longer if otherwise required by law).

IX. PRIVILEGES AND DISCLOSURES

Nothing contained in this CIA shall constitute or be construed as a waiver by Union City of its attorney-client, attorney work product, or other applicable privileges. Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Union City prior to any release by OIG of information submitted by Union City pursuant to its obligations under this CIA and identified upon submission by Union City as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Union City shall have the rights set forth at 45 C.F.R. § 5.65(d). Union City 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

Union City 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, Union City and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Union City fails to have in place any of the obligations described in section III:

a. a Compliance Contact;

b. a written Code of Conduct;

c. written Policies and Procedures;

d. a requirement that Covered Persons be trained; and

e. a Disclosure Program.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Union City fails to retain the IROs, as required in section III.D.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Union City fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

4. A Stipulated Penalty of $2,000 (which shall begin to accrue on the date the failure to comply began) for each day Union City employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Union City'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 Union City 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 Union City 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 Union City fails to grant access.)

6. A Stipulated Penalty of $1,000 for each day Union City fails to comply fully and adequately with any obligation of this CIA. In its notice to Union City, OIG shall state the specific grounds for its determination that Union City has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Union City must take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to Union City 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 1-5 of this section.

B. Timely Written Requests for Extensions. Union City 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 Union City 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 Union City 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 Union City 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 Union City of: (a) Union City's failure to comply; and (b) the 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, Union City 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 Union City elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Union City 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 Union City 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 Union City 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 Union City constitutes an independent basis for Union City's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Union City has materially breached this CIA and that exclusion should be imposed, OIG shall notify Union City of: (a) Union City'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.* Union City 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. Union City is in compliance with the obligations of the CIA cited by 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) Union City has begun to take action to cure the material breach; (ii) Union City is pursuing such action with due diligence; and (iii) Union City has provided to OIG a reasonable timetable for curing the material breach.

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

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

(iii) Union City provided to OIG within that period a reasonable timetable for curing the material breach and Union City 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 Union City, only after a DAB decision in favor of OIG. Union City's election of its contractual right to appeal to the DAB shall

not abrogate the OIG's authority to exclude Union City 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 Union City 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. Union City agrees that its receipt of a DAB decision in favor of OIG constitutes notice of Union City's exclusion.

XI. APPLICATION OF CIA TO BILLING AGENTS

Union City shall take the following steps with respect to a Billing Agent: (1) require in its contract or other agreement with the Billing Agent that the Billing Agent acknowledge Union City's Compliance Plan and Code of Conduct and (2) ensure that the Code of Conduct, relevant policies and procedures described in section III.B.2, and a description of the Disclosure Program are provided to the Billing Agent. Union City shall require future contracts with Billing Agents to include the above-described provisions. Union City shall make all reasonable efforts to secure the cooperation of all existing Billing Agents.

XII. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Stipulation and Order of Settlement and Dismissal pursuant to which this CIA is entered, and into which this CIA is incorporated, Union City and OIG agree as follows:

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

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

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 Union City's obligations under the CIA in the event of Union City's cessation of participation in Federal health care programs. If Union City withdraws from participation in Federal health care programs and is relieved from its CIA obligations by the OIG, Union City agrees to notify OIG 30 days in advance

of its intent to reapply as a participating Union City or supplier with the Federal health care programs. Upon receipt of such notification, OIG will evaluate whether the CIA should be reactivated or modified; and

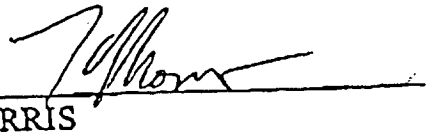
E. The undersigned Union City signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF UNION CITY MEDICAL SUPPLY, INC.

FELIX GARCIA
President and Chief Executive Officer

6/22/01
DATE

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



6/25/07
DATE

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

APPENDIX A

1. Rental and Maintenance of Continuous Passive Motion Units Between The Hospital for Special Surgery and Union City Medical Supply, Inc. d/b/a Bio-Dynamic Technologies

2. Durable Medical Equipment Storage Agreement Between The Hospital for Special Surgery and Union City Medical Supply, Inc.