INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
MEDISOL USA, INC.
AND
ELI AVIHOD

I. PREAMBLE

Medisol USA, Inc. (Medisol) and Eli Avihod (Avihod) hereby enter into this Integrity Agreement (Agreement) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, program requirements, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). This commitment to promote compliance applies to Medisol, Avihod, any entity that Medisol or Avihod owns, or acquires during the term of this Agreement, or in which Medisol or Avihod have a control interest during the term of this Agreement, as defined in 42 U.S.C. § 1320a-3(a)(3) (collectively referred to Medisol/Avihod), and Medisol/Avihod's Covered Persons as defined in Section II.C. Contemporaneously with this Agreement, Medisol and Avihod are entering into a Settlement Agreement with the United States, and this Agreement is incorporated by reference into the Settlement Agreement.

II. TERM OF THE AGREEMENT

A. The date on which the final signatory of this Agreement executes this Agreement shall be known as the Effective Date. The period of compliance obligations assumed by Medisol/Avihod under this Agreement shall be five years from the Effective Date of this Agreement. Each one-year period beginning with the one-year period following the Effective Date shall be referred to as a "Reporting Period.

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days from OIG's receipt of: (1) Medisol/Avihod's final Annual Report; or (2) any additional

materials submitted by Medisol/Avihod pursuant to OIG's request, whichever is later.

C. The scope of this Agreement shall be governed by the following definitions:

1. "Covered Persons" includes:

a. all owners, officers, directors, associates, and employees of Medisol/ Avihod; and

b. all contractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Medisol/Avihod.

2. "Relevant Covered Persons" includes Covered Persons involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program.

III. INTEGRITY OBLIGATIONS

Medisol/Avihod shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Contact

Within 30 days after the Effective Date, Medisol/Avihod shall designate a person to be responsible for compliance activities (Compliance Contact). Medisol/Avihod shall maintain a Compliance Contact for the term of this IA. The Compliance Contact shall be responsible for: (1) developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this Agreement and with Federal health care program requirements; (2) monitoring Medisol/Avihod's day-to-day compliance activities; and (3) meeting all reporting obligations created under this Agreement.

Medisol/Avihod shall report to OIG, in writing, any changes in the identity or job responsibilities of the Compliance Contact, or any actions or changes that would affect the Compliance Contact's ability to perform the duties necessary to meet

the obligations in this Agreement, within 15 days after such change. The name, address, phone number, and a description of any other job responsibilities performed by the Compliance Contact shall be included in the Implementation Report.

B. Posting of Notice

1. Within the 90 days after the Effective Date, Medisol/Avihod shall post in a prominent place accessible to all patients and Covered Persons a notice, in both English and Spanish, detailing their commitment to comply with all Federal health care program requirements in the conduct of their business.

2. Medisol/Avihod shall provide each person to whom Medisol or Avihod provide services, items, or devices with a copy of this notice.

3. This notice shall include the following information: (i) a means (e.g., telephone number or address) by which billing concerns and other issues may be reported anonymously; (ii) Medisol/Avihod's commitment to maintain the confidentiality of the report; and (iii) notification that reporting concerns and issues will not result in retribution or retaliation by Medisol or Avihod.

4. This notice shall also include the HHS OIG Fraud Hotline telephone number (1-800-HHS-TIPS) as a confidential means by which suspected fraud or abuse in the Federal health care programs may be reported.

A copy of this notice shall be included in the Implementation Report.

C. Written Policies and Procedures

Within 120 days after the Effective Date, Medisol/Avihod shall develop, implement, and distribute written Policies and Procedures to all Covered Persons. In addition, Medisol/Avihod shall make the promotion of, and adherence to, the written Policies and Procedures an element in evaluating the performance of all employees. The written Policies and Procedures shall, at a minimum, set forth:

1. Medisol/Avihod'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;

2. the expectation that all of Medisol/Avihod's Covered Persons shall be expected to comply with all Federal health care program requirements and with Medisol/Avihod's own written Policies and Procedures as implemented pursuant to this Section III.C (including the requirements of this Agreement);

3. the responsibility and requirement that all Covered Persons report suspected violations of any Federal health care program requirements or of Medisol's or Avihod's own Policies and Procedures to the Compliance Contact and Medisol/Avihod's commitment to maintain confidentiality and anonymity, as appropriate, and not to retaliate with respect to such disclosures;

4. the possible consequences to Medisol, Avihod, and Covered Persons of failure to comply with Federal health care program requirements or with Medisol/Avihod's written Policies and Procedures and the failure to report such noncompliance;

5. Medisol/Avihod's commitment to remain current with all Federal health care program requirements by obtaining and reviewing program memoranda, newsletters, and any other correspondence from the carrier related to Federal health care program requirements;

6. the proper procedures for the accurate preparation and submission of claims in accordance with Federal health care program requirements;

7. the proper documentation of services and billing information; and

8. the necessity to ensure that there are no duplicate claims for services, items, or devices to beneficiaries of Federal health care programs.

Within 120 days after the Effective Date, each Covered Person shall certify in writing that he or she has received, read, understood, and shall abide by Medisol/Avihod's written Policies and Procedures. New Covered Persons shall receive and review the written Policies and Procedures and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

At least annually (and more frequently if appropriate), Medisol/Avihod shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

Copies of the written Policies and Procedures shall be included in the Implementation Report. Copies of any written Policies and Procedures that are subsequently revised shall be included in the next Annual Report along with a summary of any change or amendment to each Policy and Procedure required by this Section and the reason for each change.

C. **Training and Certification**

1. General Training. Within 120 days after the Effective Date, Medisol/Avihod shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall cover the following topics:

a. the requirements of Medisol/Avihod's Agreement;

b. an overview of Medisol/Avihod's compliance program; and

c. the written Policies and Procedures developed pursuant to Section III.C, above.

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. After receiving the initial General Training, described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. Specific Training. Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least two training hours of Specific Training in addition to the General Training required above. The Specific Training shall be provided by an individual or entity other than Medisol/Avihod or another Covered Person, and may be received from a variety of sources (e.g., CME classes, hospitals, associations, Medicare contractors).

This specific training shall include a discussion of:

a. the accurate coding and submission of claims for services rendered and/or items provided 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 coding and claims submission process to ensure that such claims are accurate;

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

e. the legal sanctions for the submission of improper claims or violations of the Federal health care program requirements;

f. examples of proper and improper claim submission practices; and

g. the necessity to ensure that there are no duplicate claims for services, items, or devices provided to beneficiaries of Federal health care programs.

Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming a Relevant Covered Person, or within 120 days after the Effective Date, whichever is later. A Medisol/Avihod 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 the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes his or her Specific Training. After receiving the initial Specific Training, each Relevant Covered Person shall receive at least two hours of Specific Training in each subsequent Reporting Period. The Compliance Contact shall annually review the training, and where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during Claims Reviews and any other relevant information.

3. Certification. Each individual that is required to receive training shall certify in writing, or in electronic form if the training is computerized, 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 shall retain the certifications along with all training materials. The training materials shall be provided in the Implementation Report, and to the extent the training is revised, shall also be included in the Annual Reports. The certifications shall be made available to OIG, upon request.

4. Qualifications of Trainer(s). Persons providing the training shall be knowledgeable about the subject area of durable medical equipment providers.

5. Update of Training. Medisol/Avihod shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during the Claims Review or other Review, and any other relevant information.

6. Computer Based Training. Medisol/Avihod may provide the training required under this Agreement through appropriate computer-based training approaches. If Medisol/Avihod chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

E. Review Procedures

1. General Description.

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Medisol/Avihod shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist Medisol/Avihod in assessing and evaluating their billing and coding practices and certain other obligations pursuant to this Agreement and the Settlement Agreement.

Each IRO engaged by Medisol/Avihod shall have expertise in the billing,

coding, reporting, and other requirements of durable medical equipment suppliers and in the general requirements of the Federal health care program(s) from which Medisol/Avihod seeks reimbursement. Each IRO shall assess, along with Medisol/Avihod, whether it can perform the IRO review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement; taking into account any other business relationships or other engagements that may exist.

The IRO(s) review shall evaluate and analyze Medisol/Avihod's coding, billing, and claims submission to the Federal health care programs and the reimbursement received ("Claims Review"). If Medisol, Avihod, or an entity in which Medisol or Avihod has an ownership or control interest in (as defined in 42 U.S.C. §1320a-3(a)(3)) submits cost reports, Medisol/ Avihod shall engage an IRO to analyze whether Medisol or Avihod sought payment for certain unallowable costs ("Unallowable Cost Review"). The applicable requirements relating to the IRO are outlined in Appendix A to this Agreement, which is incorporated by reference.

b. Frequency of Claims Review. The Claims Review shall be performed annually and shall cover each of the Reporting Periods. The IRO(s) shall perform all components of each annual Claims Review.

c. *Frequency of Unallowable Cost Review.* If applicable, the IRO shall perform the Unallowable Cost Review for the first Reporting Period. If not applicable, Medisol/Avihod shall sign a certification, as required by Section III.E.4 below, stating that they do not currently and have not submitted a cost report since this Agreement was executed.

d. *Retention of Records.* The IRO and Medisol/Avihod shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Medisol/Avihod) related to the reviews.

2. Claims Review. The Claims Review shall include a Discovery Sample and, if necessary, a Full Sample. The applicable definitions, procedures, and reporting requirements are outlined in Appendix B to this Agreement, which is incorporated by reference.

a. *Discovery Sample.* The IRO shall randomly select and review a sample of 50 Medicare Paid Claims submitted by or on behalf of Medisol/ Avihod (Discovery Sample).

The Paid Claims shall be reviewed based on the supporting documentation available at Medisol/Avihod's office or under Medisol/Avihod's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed.

i. If the Error Rate (as defined in Appendix B) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, Medisol/Avihod should, as appropriate, further analyze any errors identified in the Discovery Sample. Medisol/Avihod recognize that OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample or any other segment of the universe.)

ii. If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall perform a Full Sample and a Systems Review, as described below.

b. *Full Sample.* If necessary, as determined by procedures set forth in Section III.E.2.a, the IRO shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Appendix B. The Full Sample shall be designed to: (i) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate; and (ii) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on supporting documentation available at Medisol/Avihod's office or under Medisol/Avihod's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and

reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, Medisol/Avihod may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 50 Items, as part of its Full Sample, if: (i) statistically appropriate and (ii) Medisol/Avihod selects the Full Sample Items using the seed number generated by the Discovery Sample.

OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from Medisol/Avihod to the appropriate Federal health care program payor, including the Medicare contractor (e.g., carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

c. *Systems Review.* If Medisol/Avihod's Discovery Sample identifies an Error Rate of 5% or greater, Medisol/Avihod's IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO shall perform a "walk through" of the system(s) and process(es) that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

d. *Repayment of Identified Overpayments.* In accordance with Section III.H.1, Medisol/Avihod shall repay within 30 days any Overpayment(s) identified in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. Medisol/Avihod shall make available to OIG any and all documentation and the associated documentation that reflects the refund of the Overpayment(s) to the payor.

3. Claims Review Report. The IRO shall prepare a report based upon the Claims Review performed (Claims Review Report). Information to be included in the Claims Review Report is described in Attachment 1 to Appendix B.

4. Unallowable Cost Review.

a. Unless Section III.E.4.b, below, applies, the IRO shall conduct a review of Medisol/Avihod's compliance with the unallowable cost provisions of the Settlement Agreement. The IRO shall determine whether Medisol/ Avihod have complied with their obligations not to charge to, or otherwise seek payment from, federal or state payors for unallowable costs (as defined in the Settlement Agreement) and their obligation to identify to applicable federal or state payors any unallowable costs included in payments previously sought from the United States, or any State Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Medisol, Avihod, or any affiliates. To the extent that such cost reports, cost statements, information reports, or payment requests, even if already settled, have been adjusted to account for the effect of the inclusion of the unallowable costs, the IRO shall determine if such adjustments were proper. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous years.

b. If Medisol/Avihod executes and submits to the OIG in the first Annual Report a certification that Medisol, Avihod, nor any entity in which Medisol/Avihod have any ownership or control interest has ever submitted any cost report or other submission to a Federal health care program seeking reimbursement based on costs, then no Unallowable Cost Review will be required under this Agreement.

c. If Medisol/Avihod acquires or obtains any ownership or control interest a new entity during the term of this Agreement, then, if applicable, Medisol/Avihod must certify in the next Annual Report whether such an entity has ever submitted a cost report or other submission to a Federal Health care program seeking reimbursement based on costs. In the event that the entity has not ever submitted a cost report or other submission to a Federal Health care program seeking reimbursement based on costs, no Unallowable Cost Review will be required under this Agreement. However, if the entity has submitted a cost report or other submission to a Federal Health care program seeking reimbursement based on costs, the Unallowable Cost Review required by III.E.4.a is applicable.

5. Unallowable Cost Review Report. If applicable, the IRO shall prepare a report based upon the Unallowable Cost Review performed. The Unallowable Cost Review Report shall include the IRO's findings and supporting rationale regarding the Unallowable Costs Review and whether Medisol/Avihod have complied with their obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and their obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from such payor.

6. Validation Review. In the event OIG has reason to believe that: (a) Medisol/Avihod's Claims Review or any other review required by Section III.F (Review) fails to conform to the requirements of this Agreement; or (b) the IRO's findings or Claims Review results or other results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review or other Review complied with the requirements of the Agreement and/or the findings or Claims Review results or other results are inaccurate ("Validation Review"). Medisol or Avihod shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents so long as it is initiated within one year after Medisol's or Avihod's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Medisol/Avihod of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Medisol/Avihod may request a meeting with OIG to: (a) discuss the results of any Claims Review or other Review submissions or findings; (b) present any additional or relevant information to clarify the results of the Claims Review or other Review to correct the inaccuracy of the Claims Review or other Review; and/or (c) propose alternatives to the proposed Validation Review. Medisol/Avihod agree to provide any additional information requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Claims Review or other Review issues with Medisol/Avihod 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.

7. Independence/Objectivity Certification. The IRO shall include in its report(s) to Medisol/Avihod a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity, as appropriate to the nature of the

engagement, with regard to the Claims Review or other Review and that it has concluded that it is, in fact, independent and/or objective.

F. Ineligible Persons

1. Definitions. For purposes of this Agreement:

   a. An "Ineligible Person" shall include an individual or entity who: (i) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or (ii) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

   b. "Exclusion Lists" include: (i) the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov); and (ii) the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov)

   c. "Screened Persons" include prospective and current owners, officers, directors, employees, contractors, and agents of Medisol/Avihod.

2. Screening Requirements. Medisol/Avihod shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements.

   a. Medisol/Avihod shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such persons to disclose whether they are an Ineligible Person.

   b. Medisol/Avihod shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

c. Medisol/Avihod shall implement a policy requiring all Screened Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Medisol/Avihod shall maintain documentation demonstrating that: (1) they have checked the Exclusion Lists (e.g., print screens from search results) and determined that such individuals or entities are not Ineligible Persons; and (2) has required individuals and entities to disclose if they are an Ineligible Person (e.g., employment applications).

Nothing in this Section affects the responsibility or liability of Medisol or Avihod to refrain from billing Federal health care programs for services of the Ineligible Person.

3. Removal Requirement. If Medisol or Avihod have notice that any individual or entity in one of the positions identified in Section III.F.1.c has become an Ineligible Person, Medisol or Avihod shall remove such individual or entity from responsibility for, or involvement with, Medisol's or Avihod's business operations related to the Federal health care programs and shall remove such individual or entity from any position for which the individual's or entity's compensation or the items or services rendered, ordered, or prescribed by the individual or entity 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 individual or entity is reinstated into participation in the Federal health care programs.

4. Pending Charges and Proposed Exclusions. If Medisol or Avihod have notice that an individual identified in Section III.F.1.c is charged with a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), or an individual or entity identified in Section III.F.1.c is proposed for exclusion during his, her or its employment, involvement or contract term, Medisol/Avihod shall take all appropriate actions to ensure that the responsibilities of that individual or entity has 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 after discovery, Medisol or Avihod shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Medisol or Avihod conducted or brought by a governmental entity or its agents involving an allegation that Medisol or Avihod 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. Medisol or Avihod shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

H. Reporting

1. Overpayments

a. *Definition of Overpayments*. For purposes of this Agreement, an "Overpayment" shall mean the amount of money Medisol or Avihod has received in excess of the amount due and payable under any Federal health care program requirements.

b. *Reporting of Overpayments*. If, at any time, Medisol or Avihod identifies or learns of any Overpayment, Medisol or Avihod shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, Medisol or Avihod shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified within 30 days after identification, Medisol or Avihod shall notify the payor at that time of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies, and for Medicare contractors shall include the information contained on the Overpayment Refund Form, provided as Appendix C to this Agreement. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to

policies and procedures established by the payor should be handled in accordance with such policies and procedures.

2. Reportable Events.

a. *Definition of Reportable Event.* For purposes of this Agreement, a "Reportable Event" means anything that involves:

i. a substantial Overpayment; or

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

A Reportable Event may be the result of an isolated event or a series of occurrences.

b. *Reporting of Reportable Event.* If Medisol/Avihod determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Medisol/Avihod shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

i. If the Reportable Event 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) by which the Overpayment was repaid/refunded;

ii. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

iii. a description of Medisol/Avihod's actions taken to correct the Reportable Event; and

iv. any further steps Medisol/Avihod plans to take to address the Reportable Event and prevent it from recurring.

I. Third Party Billing

1. Future Contract with Third Party Biller. If, at any time during the term of this Agreement, Medisol/Avihod contracts with a third party billing company to submit claims to the Federal health care programs, at least 30 days prior to executing the contract, Medisol/Avihod shall submit a certification indicating whether they have an ownership or control interest (as defined in 42 U.S.C. § 1320a – 3(a)(3)) in the third party billing company and whether either Medisol or Avihod are employed by or acts as a consultant to the third party billing company.

Within 30 days after Medisol/Avihod contracts with the third party billing company, Medisol/Avihod shall obtain a certification from the third party billing company that the company: (i) is presently in compliance with all Federal health care program requirements as they relate to the submission of claims to Federal health care programs; (ii) has a policy of not employing any person who is excluded, debarred, suspended or otherwise ineligible to participate in Medicare or other Federal health care programs to perform any duties related directly or indirectly to the preparation or submission of claims to Federal health care programs; and (iii) provides the required training in accordance with Section III.D of the Agreement for those employees involved in the preparation and submission of claims to Federal health care programs.

If Medisol/Avihod contracts with a new third party billing company during the term of this Agreement, Medisol/Avihod shall, within 30 days of entering into such contract, obtain and send to OIG the certification described in this Section III.I.2.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, Medisol/Avihod changes locations or sells, closes, purchases, or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Medisol/ Avihod shall notify OIG of this fact as soon as possible, but no later than 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare Provider number, provider identification number, and/or supplier number, and the corresponding contractor's name and address that issued each number. Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements in this Agreement.

Prior to Medisol/Avihod becoming an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Medisol/Avihod shall notify that party of this Agreement. This notification shall include a copy of the Agreement, a statement indicating the remaining term of the Agreement, and a summary of Medisol/Avihod's obligations under the Agreement. In addition, Medisol/Avihod shall notify OIG of such relationship in its next Annual Report.

V. REPORTS

A. Implementation Report

Within 150 days after the Effective Date, Medisol/Avihod shall submit a written report to OIG summarizing the status of its implementation of the requirements of this Agreement (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the Compliance Contact's name, address, and phone number, a description of any other job responsibilities performed by the Compliance Contact, and the date the Compliance Contact was appointed;

2. a copy of the notice Medisol/Avihod posted in their office and distributed to beneficiaries of Federal health care programs as required by Section III.B, a description of where the notice is posted, and the date the notice was posted;

3. a copy of the written Policies and Procedures required by Section III.C of this Agreement and the date these Policies and Procedures were implemented and distributed;

4. a copy of all training materials used for the training session(s) required by Section III.D, a description of the training, including a summary of the topics covered, the length of each session, and a schedule of when the training session(s) were held;

5. the name and qualifications of the IRO(s), a summary/description of all engagements between Medisol/Avihod, and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, and the proposed start and completion dates of the first annual Claims Review and if applicable, the Unallowable Cost Review.

6. a copy of the IRO's engagement letter, including the length of the engagement;

7. a certification from the IRO regarding its professional independence and/or objectivity with respect to Medisol/Avihod;

8. a description of Medisol/Avihod's process to screen Covered Persons to determine if they are ineligible;

9. a summary of personnel actions (other than hiring) taken pursuant to Section III.F, the name, title and responsibilities of any person who is determined to be an Ineligible Person under Section III.F, and the actions taken in response to the obligations set forth in Section III.F;

10. a list of all Medisol/Avihod's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare Provider number(s), provider identification number(s), and/or supplier number(s), and the name and address of each contractor to which Medisol/Avihod currently submits claims;

11. if Medisol/Avihod became an employee or contractor with another party

related to the furnishing of items or services that may be reimbursed by Federal health care programs, Medisol/Avihod shall inform OIG of the name, location, relationship, and its responsibilities with respect Medisol/Avihod's employment or contract;

12. a certification by the Compliance Contact that:

    a. the written Policies and Procedures required by Section III.C of this Agreement have been developed, are being implemented, and have been distributed to all Covered Persons; and that all Covered Persons have executed the written Policies and Procedures certification in accordance with the timeframe required by Section III.C of this Agreement;

    b. all Covered Persons have completed the applicable training required by Section III.D of this Agreement; and that all Covered Persons have executed the applicable training certification(s) in accordance with the timeframe required by Section III.D of this Agreement;

    c. all owners, officers, directors, associates, employees, contractors, and agents that were hired or engaged since the execution of the Agreement were screened against the Exclusion Lists and asked to disclose if they are excluded, debarred, suspended, or are otherwise considered an Ineligible Person, prior to entering into their relationship with Medisol/Avihod, as required by Section III.F of this Agreement; and

    d. all current owners, officers, directors, associates, employees, contractors, and agents of Medisol/Avihod were screened against the Exclusion Lists within 90 days after the Effective Date of this Agreement, as required by Section III.F of this Agreement and the date(s) of the screening.

13. a certification signed by Medisol/Avihod certifying (a) to the best of their knowledge, except as otherwise described in the Implementation Report, Medisol/Avihod is in compliance with all of the requirements of this Agreement and (b) Medisol/Avihod have reviewed the Implementation Report and has made a reasonable inquiry regarding its content and believes that the information is

accurate and truthful.

B. Annual Reports

Medisol/Avihod shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Medisol/Avihod's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall, at a minimum, include:

1. any change in the name, address, phone number, or job responsibilities of Medisol/Avihod's Compliance Contact(s);

2. any changes to the posted notice and the reason for such changes;

3. a copy of any new compliance-related Policies and Procedures;

4. a summary of any changes or amendments to the written Policies and Procedures required by Section III.C and the reason(s) for such changes (e.g., change in contractor policies);

5. a copy of all training materials used for the training session(s) required by Section III.D (to the extent they have not already been provided as part of the Implementation Report); a description of the training, including a summary of the topics covered; the length of each session; and a schedule of when the training session(s) was held;

6. a complete copy of all reports prepared pursuant to the IRO's Claims Review or other Review, required by Section III.E (and, if applicable for the first Annual Report, a copy of the certification described in section III.E.4.b);

7. if applicable, a certification by Medisol/Avihod stating that they do not currently and have not submitted any cost reports to any Federal health care programs since this Agreement was executed;

8. Medisol/Avihod's response and corrective action plan(s) related to any issues raised or recommendations made by the IRO, as a result of the Review(s) performed pursuant to Section III.E;

9. a summary/description of all engagements between Medisol/Avihod and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, if different from what was submitted as part of the Implementation Report;

10. a certification from the IRO regarding its professional independence and/or objectivity to Medisol/Avihod;

11. a description of Medisol/Avihod's process to screen Covered Persons to determine if they are ineligible (to the extent it has changed from the Implementation Report);

12. a summary of personnel actions/other than hiring taken pursuant to Section III.F; the name, titles and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; and Medisol/Avihod's actions taken in response to the obligations set forth in Section III.F;

13. 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;

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

15. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: Medicare, Medicaid, and other Federal health care programs;

16. a copy of the certification from the third party billing company required by Section III.I of the Agreement, if applicable;

17. a description of all changes to the most recently provided list of Medisol/Avihod's locations (including addresses) as required by Section IV. Include the corresponding phone numbers, fax numbers, each location's

Medicare Provider Number(s), provider identification number(s), and/or supplier number(s), and the name and address of the contractor that issued each number;

18. if Medisol/Avihod became an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Medisol/Avihod shall inform OIG of the name, location, relationship, and their responsibilities with respect Medisol/Avihod's employment or contract;

19. A certification, where appropriate, by the Compliance Contact that certifies that:

a. the written Policies and Procedures have been reviewed during the Reporting Period, as required by Section III.B of this Agreement, and that all Covered Persons have executed the written Policies and Procedures certification in accordance with the timeframe required by Section III.C of this Agreement;

b. all Covered Persons have completed the applicable training required by Section III.D of this Agreement and that all Covered Persons have executed the applicable training certification(s) in accordance with the timeframe required by Section III.D of this Agreement;

c. all owners, officers, directors, associates, employees, contractors, and agents that were hired, engaged or otherwise involved with Medisol/ Avihod during the Reporting Period have been screened against the Exclusion Lists and asked to disclose if they are excluded, debarred, suspended, or are otherwise considered an Ineligible Person, prior to entering into their relationship with Medisol/Avihod, as required by Section III.F of this Agreement;

d. all owners, officers, directors, associates, employees, contractors, and agents (employed, engaged or otherwise involved with Medisol/Avihod for the entire Reporting Period) were screened against the Exclusion Lists during the Reporting Period, in accordance with Section III.F of this Agreement and the date(s) they were screened;

e. Medisol/Avihod have complied with their 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.

20. a certification signed by Medisol/Avihod certifying that (a) to the best of their knowledge, except as otherwise described in the applicable Report, Medisol/Avihod are in compliance with all of the requirements of this Agreement and (b) Medisol/Avihod have reviewed the Annual Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful.

The first Annual Report shall be received by 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. Designation of Information

Medisol/Avihod shall clearly identify any portions of its submissions that they believe 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. Medisol/Avihod 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, all notifications and Reports required under this Agreement shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General

U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201
Telephone: (202) 619-2078
Facsimile: (202) 205-0604

Medisol and Avihod:

Leon Small, Esq.
16530 Ventura Boulevard
Suite 306
Encino, CA 91436
Telephone: (818) 906-2555
Facsimile: (818) 907-8471

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

Medisol/Avihod present.

VIII. DOCUMENT AND RECORD RETENTION

Medisol/Avihod shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this Agreement, for six years (or longer if otherwise required by law).

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Medisol/Avihod prior to any release by OIG of information submitted by Medisol/Avihod pursuant to its obligations under this Agreement and identified upon submission by Medisol/Avihod as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Medisol/Avihod shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Medisol/Avihod are expected to fully and timely comply with all of its Agreement obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Medisol, Avihod, and OIG hereby agree that failure to comply with certain obligations set forth in this Agreement (unless a timely written request for an extension has been requested and approved in accordance with Section B below) 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 $750 (which shall begin to accrue on the day after the date the obligation became due) for each day Medisol or Avihod fails to:

   a. have a Compliance Contact in accordance with the requirements of Section III.A;

b. establish and/or post a notice in accordance with the requirements of Section III.B;

c. establish, implement, maintain, distribute and/or update the written Policies and Procedures in accordance with the requirements of Section III.C;

d. establish and implement a training program in accordance with the requirements of Section III.D.

e. obtain a certification from the third party biller, send the third party biller certification to OIG in accordance with the requirements of Section III.I, or notify OIG within 30 days prior to Medisol or Avihod obtaining an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in, or becoming employed by, or becoming a consultant to, any third party billing company;

f. engage an IRO in accordance with the requirements of Section III.E.1.a and Appendix A;

g. submit the IRO's annual Claims Review Report and any other required Review in accordance with the requirements of Section III.E and Appendix B;

h. obtain and/or maintain the following documentation: Policies and Procedures certifications in accordance with the requirements of Section III.C, training certification(s) in accordance with the requirements of Section III.D, and/or documentation of screening and disclosure requirements in accordance with the requirements of Section III.F.2.

i. screen current or prospective owners, officers, directors, associates, employees, contractors or agents in accordance with the requirements of Section III.F; or require owners, officers, directors, associates, employees, contractors or agents to disclose if they are debarred, excluded, suspended or are otherwise considered an Ineligible Person in accordance with the requirements of Section III.F; or

j. notify OIG of a Government investigation or legal proceeding, in

accordance with the requirements of Section III.G.

2. A Stipulated Penalty of $1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Medisol/Avihod fails to submit the Implementation Report or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

3. A Stipulated Penalty of $750 for each day Medisol/Avihod fails to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Medisol/Avihod fails to grant access.)

4. A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of Medisol/Avihod as part of its Implementation Report, Annual Reports, additional documentation to a Report (as requested by OIG), or as otherwise required by this Agreement.

5. A Stipulated Penalty of $750 for each day Medisol orAvihod fails to comply fully and adequately with any obligation of this Agreement. OIG shall provide notice (Notice) to Medisol orAvihod stating the specific grounds for its determination that Medisol or Avihod has failed to comply fully and adequately with the Agreement obligation(s) at issue and steps Medisol or Avihod shall take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date Medisol or Avihod receives this Notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-4 of this Section.

B. <u>Timely Written Requests for Extensions</u>

Medisol or Avihod may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or Report required by this Agreement. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or Report, Stipulated Penalties for failure to perform the act or file the notification or Report shall not begin to accrue until one day after Medisol or Avihod 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 Medisol or Avihod 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 Medisol or Avihod 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 Medisol or Avihod of: (a) Medisol's or Avihod's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. Response to Demand Letter. Within 10 days of the receipt of the Demand Letter, Medisol or Avihod shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) send in writing to OIG a request for a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Medisol or Avihod elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Medisol or Avihod cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this Agreement and shall be grounds for exclusion under Section X.D.

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

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

D. Exclusion for Material Breach of this Agreement

1. Definition of Material Breach. A material breach of this Agreement means:

a. a failure by Medisol or Avihod to report a Reportable Event, 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 Agreement, including, but not limited to, the obligations addressed in Section X.A;

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

d. a failure to engage and use an IRO in accordance with Section III.E.

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

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

2. Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the

only issues in a proceeding for Stipulated Penalties under this Agreement shall be: (a) whether Medisol or Avihod was in full and timely compliance with the obligations of this Agreement for which OIG demands payment; and (b) the period of noncompliance. Medisol/Avihod shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this Agreement and orders Medisol or Avihod to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Medisol or Avihod requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

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

a. whether Medisol, Avihod, or both were in material breach of this Agreement;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30 day period, but that: i. Medisol or Avihod had begun to take action to cure the material breach within that period; ii. Medisol or Avihod has pursued and is pursuing such action with due diligence; and iii. Medisol or Avihod provided to OIG within that period a reasonable timetable for curing the material breach and Medisol or Avihod has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Medisol or Avihod, only after a DAB decision in favor of OIG. Medisol's and Avihod's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to

exclude Medisol, Avihod, or both 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 Medisol or Avihod 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. Medisol/Avihod shall waive their right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Medisol or Avihod, Medisol, or Avihod shall be reinstated effective on the date of the original exclusion.

4. Finality of Decision. The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this Agreement agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this Agreement.

XI. EFFECTIVE AND BINDING AGREEMENT

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

A. This Agreement shall be binding on the successors, assigns, and transferees of Medisol and Avihod;

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

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

D. OIG may agree to a suspension of Medisol's or Avihod's obligations under this Agreement in the event of Medisol's or Avihod's cessation of participation in Federal health care programs. If Medisol or Avihod withdraws from participation in Federal health care programs and is relieved of their Agreement obligations by OIG, Medisol/Avihod shall notify OIG 30 days in advance of Medisol's or Avihod's intent to reapply as a participating provider or supplier

with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the Agreement shall be reactivated or modified.

E. All requirements and remedies set forth in this Agreement are in addition to, and do not effect, (1) Medisol's or Avihod's responsibility to follow all applicable Federal health care program requirements or (2) the Government's right to impose appropriate remedies for failure to follow applicable program requirements.

F. The undersigned Medisol and Avihod signatories represent and warrant that they are authorized to execute this Agreement. The undersigned OIG signatory represents that he is signing this Agreement in his official capacity and that he is authorized to execute this Agreement.

IN WITNESS WHEREOF, the parties hereto affix their signatures:

MEDISOL USA, INC.

ELI AVIHOD
President and majority shareholder
Medisol USA, Inc.

Date 9/14/05

GALINA AVIHOD
Secretary, Medisol USA, Inc.

Date 9/14/05

LEON SMALL, ESQ.
Counsel for Medisol USA, Inc.

Date 9/28/05

ELI AVIHOD

ELI AVIHOD

9/11/05
Date

LEON SMALL, ESQ.
Counsel for Eli Avihod

9/21/05
Date

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

LEWIS MORRIS
Chief Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services

10/13/05
Date

APPENDIX A
INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.D of the CIA.

A. IRO Engagement.

Eli Avihod (Avihod) and/or Medisol USA, Inc. (Medisol) shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and/or objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Avihod/Medisol if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Avihod/Medisol may continue to engage the IRO.

If Avihod/Medisol engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Avihod/Medisol shall submit the information identified in Section V.A.8 to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Avihod/Medisol if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Avihod/Medisol may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Claims Review and Unallowable Cost Review, if applicable engagement who have expertise in the billing, coding, reporting, and other requirements of durable medical equipment and medical supplies and in the general requirements of the Federal health care program(s) from which Avihod/Medisol seeks reimbursement;

2. assign individuals to design and select the Claims Review sample who are knowledgeable about the appropriate statistical sampling techniques;

3. assign individuals to conduct the coding review portions of the Claims Review who have a nationally recognized coding certification (e.g., CCA, CCS, CCS-P, CPC, RRA, etc.) and who have maintained this certification (e.g., completed applicable continuing education requirements); and

4. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each Claim Review and other reviews as may be required by the CIA, such as cost report, compliance reviews, if applicable in accordance with the specific requirements of the CIA;

2. follow all applicable Medicare, Medicaid, or other Federal health care programs rules and reimbursement guidelines in making assessments in the Claims Review;

3. if in doubt of the application of a particular Medicare, Medicaid, or other Federal health care programs policy or regulation, request clarification from the appropriate authority (e.g., fiscal intermediary or carrier);

4. respond to all OIG inquires in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendix B.

D. IRO Independence/Objectivity.

The IRO must perform the Claims Review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Medisol.

E. IRO Removal/Termination.

1. *Provider.* If Avihod/Medisol terminates its IRO during the course of the engagement, Avihod/Medisol must submit a notice explaining its reasons to OIG no later than 30 days after termination. Avihod/Medisol must engage a new IRO in accordance with Paragraph A of this Appendix.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Medisol to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring Avihod/Medisol to engage a new IRO, OIG shall notify Avihod/Medisol of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Avihod/Medisol may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. Avihod/Medisol shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Avihod/Medisol prior to requiring Avihod/Medisol to terminate the IRO. However, the final determination as to whether or not to require Avihod/Medisol to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B
CLAIMS REVIEW

A. Claims Review.

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

a. Overpayment: The amount of money Eli Avihod (Avihod) and/or Medisol USA, Inc. (Medisol) has received in excess of the amount due and payable under any Federal health care program requirements.

b. Item: Any discrete unit that can be sampled (e.g., code, line item, beneficiary, patient encounter, etc.).

c. Paid Claim: A code or line item submitted by Avihod/Medisol and for which Avihod/Medisol has received reimbursement from the Medicare program.

d. Population: For the first Reporting Period, the Population shall be defined as all Items for which a code or line item has been submitted by or on behalf of Avihod/Medisol and for which Avihod/Medisol has received reimbursement from Medicare (i.e., Paid Claim) during the 12-month period covered by the first Claims Review.

For the remaining Reporting Periods, the Population shall be defined as all Items for which Avihod/Medisol has received reimbursement from Medicare (i.e., Paid Claim) during the 12-month period covered by the Claims Review.

To be included in the Population, an Item must have resulted in at least one Paid Claim.

e. Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample shall be included as part of the net Overpayment calculation.)

The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Items in the sample.

2. *Other Requirements.*

a. Paid Claims without Supporting Documentation. For the purpose of appraising Items included in the Claims Review, any Paid Claim for which Avihod/Medisol cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Avihod/Medisol for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

b. Replacement Sampling. Considering the Population shall consist only of Paid Claims and that Items with missing documentation cannot be replaced, there is no need to utilize alternate or replacement sampling units.

c. Use of First Samples Drawn. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, the Paid Claims associated with the Items selected in each first sample (or first sample for each strata, if applicable) shall be used (i.e., it is not permissible to generate more than one list of random samples and then select one for use with the Discovery Sample or Full Sample).

B. Claims Review Report. The following information shall be included in the Claims Review Report for each Discovery Sample and Full Sample (if applicable).

1. *Claims Review Methodology.*

a. Sampling Unit. A description of the Item as that term is utilized for the Claims Review.

b. Claims Review Population. A description of the Population subject to the Claims Review

c. Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.

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

e. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).

f. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.

2. *Statistical Sampling Documentation.*

a. The number of Items appraised in the Discovery Sample and, if applicable, in the Full Sample.

b. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.

c. A copy of the statistical software printout(s) estimating how many Items are to be included in the Full Sample, if applicable.

d. A description or identification of the statistical sampling software package used to select the sample and determine the Full Sample size, if applicable.

3. *Claims Review Findings.*

a. Narrative Results.

i. A description of Avihod/Medisol's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.

ii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any).

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by Avihod/Medisol (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 Avihod/Medisol.

iii. Total dollar amount of all Overpayments in the sample.

iv. Total dollar amount of paid Items included in the sample and the net Overpayment associated with the sample.

v. Error Rate in the sample.

vi. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)

4. *Systems Review.* Observations, findings, and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s).

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

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 Reimbursed (IRO determined)	Dollar Difference between Amt Reimbursed and Correct Allowed Amt

Attachment 1 for
Appendix B
Eli Avihod/Medisol USA, Inc.

APPENDIX C

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

Date:_____
Contractor Deposit Control #_____ Date of Deposit: _____
Contractor Contact Name:_____ Phone #_____
Contractor Address:_____
Contractor Fax:

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

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.

PROVIDER/PHYSICIAN/SUPPLIERNAME_____
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:

Billing/Clerical Error	MSP/Other Payer Involvement	Miscellaneous
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		

Eli Avihod/Medisol USA, Inc.