

**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.

