

**CORPORATE INTEGRITY AGREEMENT**  
**BETWEEN THE**  
**OFFICE OF INSPECTOR GENERAL**  
**OF THE**  
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**AND**  
**SOLARIS HEALTHCARE, ANDREW P. MILLIGAN, AND NEIL F. LIVINGSTON**

**I. PREAMBLE**

Solaris Healthcare (Solaris), Andrew P. Milligan (Milligan), and Neil F. Livingston (Livingston) (collectively "Solaris" hereby enter into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). This CIA covers, and its terms apply to, Solaris Hospice, Inc., Livingston, Milligan, and all other entities owned, operated, or managed by Solaris, Livingston, and/or Milligan. Contemporaneously with this CIA, Solaris is entering into a Settlement Agreement with the United States.

**II. TERM AND SCOPE OF THE CIA**

A. The period of the compliance obligations assumed by Solaris under this CIA shall be five years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). 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, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Solaris' final Annual Report; or (2) any additional materials submitted by Solaris pursuant to OIG's request, whichever is later.

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

1. "Covered Persons" includes:

- a. all owners, officers, directors, employees, medical directors, and volunteers of Solaris; and
- b. all contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Solaris.

With the exception of medical directors, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

2. "Relevant Covered Persons" includes all Covered Persons who are engaged directly or in a supervisory role in the determination of whether Solaris patients meet applicable hospice benefit eligibility requirements or who are involved in the preparation or submission of claims for reimbursement to Federal health care programs.

### **III. CORPORATE INTEGRITY OBLIGATIONS**

Solaris shall establish and maintain a Compliance Program that includes the following elements:

#### **A. Compliance Officer and Committee.**

1. *Compliance Officer.* To the extent not already accomplished, within 90 days after the Effective Date, Solaris shall appoint an individual to serve as its Compliance Officer and it shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of Solaris, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Solaris, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the

day-to-day compliance activities engaged in by Solaris as well as for any reporting obligations created under this CIA.

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

2. *Compliance Committee.* To the extent not already accomplished, within 90 days after the Effective Date, Solaris shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

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

B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, Solaris developed, implemented, and distributed a written Code of Conduct (known as its "Standards of Conduct") to all Covered Persons. Solaris shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

- a. Solaris' commitment to full compliance with all Federal health care program requirements, including its commitment to ensure that patients meet eligibility requirements for hospice services, and to prepare and submit accurate claims consistent with Federal health care program requirements;

- b. Solaris' requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Solaris' own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);
- c. the requirement that all of Solaris' Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Solaris, suspected violations of any Federal health care program requirements or of Solaris' own Policies and Procedures;
- d. the possible consequences to both Solaris and Covered Persons of failure to comply with Federal health care program requirements and with Solaris' own Policies and Procedures and the failure to report such noncompliance; and
- e. the right of all individuals to use the Disclosure Program described in Section III.E, and Solaris' commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

To the extent not already accomplished, within 90 days after the Effective Date, each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by Solaris' Code of Conduct. New Covered Persons shall receive the Code of Conduct 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.

Solaris shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

*2. Policies and Procedures.* To the extent not already accomplished, ~~within 90 days after the Effective Date,~~ Solaris shall implement written Policies and

Procedures regarding the operation of Solaris' compliance program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. the OIG's Compliance Program Guidance for Hospice;
- c. Federal health care program requirements relating to the coverage of hospice services and the eligibility requirements for such coverage, including requirements relating to the initial admission of patients and eligibility of continued stay patients (*i.e.*, patients who have received more than six continuous months of hospice care); and
- d. Federal health care program requirements relating to the documentation of eligibility for hospice services and the services provided, and relating to the preparation and submission of accurate claims for such services.

To the extent not already accomplished, within 90 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Solaris 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 individuals whose job functions relate to those Policies and Procedures.

### C. Training and Education.

1. *General Training.* Within 90 days after the Effective Date, Solaris shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain Solaris':

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

New Covered Persons shall receive the General Training described above within 30 days 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 90 days after the Effective Date, each Relevant Covered Person shall receive at least four hours of Specific Training in addition to the General Training required above. This Specific Training shall include a discussion of:

- a. the Federal health care program requirements relating to the hospice benefit, including Federal health care program coverage for hospice services, eligibility and admission criteria, accurate documentation of eligibility, and accurate coding and submission of claims for hospice services;
- b. policies, procedures, and other requirements applicable to the documentation of medical records;
- c. the personal obligation of each individual involved in the hospice admission and certification processes to ensure that admissions are appropriate under Federal health care program requirements;
- d. the personal obligation of each individual involved in the claims submission process to ensure that claims are accurate;
- e. applicable reimbursement statutes, regulations, and program requirements and directives;
- f. the legal sanctions for violations of the Federal health care program requirements; and

g. examples of proper and improper hospice eligibility determination and admissions practices and claims submission practices.

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 90 days after the Effective Date, whichever is later. A Solaris 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 determination of eligibility, the admission of patients, 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 described in this Section, each Relevant Covered Person shall receive at least four hours of Specific Training in each subsequent Reporting Period.

3. *Certification.* Each individual who is required to attend training shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

4. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the hospice benefit and the Federal health care program requirements relating to the benefit.

5. *Update of Training.* Solaris shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or the Claims Review, Eligibility Review, or Unallowable Cost Review, and any other relevant information.

6. *Computer-based Training.* Solaris may provide the training required under this CIA through appropriate computer-based training approaches. If Solaris 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.

D. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Solaris 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 Solaris in assessing and evaluating its eligibility determination and admission practices, and certain other obligations pursuant to this CIA and the Settlement Agreement. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

Each IRO engaged by Solaris shall have expertise in the coverage and eligibility requirements relating to hospice services, in the billing, coding, documentation and other requirements relating to hospice services, and in the general requirements of the Federal health care program(s) from which Solaris seeks reimbursement. Each IRO shall assess, along with Solaris, whether it can perform the IRO review in a professionally independent and 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: (i) Solaris' Eligibility Criteria Review as described below in Section III.D.2 and in Appendix B to this CIA, which is incorporated by reference; and (ii) whether Solaris sought payment for certain unallowable costs (Unallowable Cost Review).

b. *IRO Verification Reviews.* On an annual basis, the IRO shall conduct a review of 30 of the sampling units reviewed by Solaris during the course of its Eligibility Criteria Reviews as described below in Section III.D.2 and in Appendix B. This IRO review shall be known as the "Verification Review". As part of Solaris' Annual Report, the IRO shall submit a report that verifies that the requirements outlined in this Section III.D and in Appendices A and B to this CIA have been satisfied. The IRO shall report the results,



sampling unit by sampling unit, of the Verification Review performed (Verification Review Report).

c. *Frequency of Unallowable Cost Review.* If applicable, the IRO shall perform the Unallowable Cost Review for the first Reporting Period.

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

2. *Internal Compliance Reviews.* Prior to the Effective Date, Solaris began to conduct quarterly Internal Compliance Reviews as described briefly below and as described more fully in Appendix B. Solaris shall continue to conduct the Internal Compliance Reviews on a quarterly basis. However, if in its discretion, the OIG determines that the Eligibility Criteria Review component of Solaris' Internal Compliance Reviews is not satisfactory for a given Reporting Period, the IRO shall conduct all aspects of the Eligibility Criteria Reviews for future Reporting Periods consistent with the Eligibility Criteria Review procedures outlined below in Section III.D.2 and in Appendix B. Such IRO reviews shall be referred to as "Comprehensive IRO Reviews".

As part of each quarterly Internal Compliance Review, Solaris shall review the files associated with a randomly selected sample of ten percent of the total number of Medicare beneficiaries who received hospice services during the quarter being reviewed and for whom Solaris submitted claims to Medicare and was reimbursed. For each set of sample files, Solaris shall review the issues and items further detailed in Section C of Appendix B.

Among the other elements of each Internal Compliance Review, Solaris shall conduct an "Eligibility Criteria Review." For purposes of the Eligibility Criteria Review, medical record documentation shall be reviewed for recommended eligibility criteria as defined by Medicare on all certification assessments in order to determine evidence supporting the terminal diagnosis. Reviews not supporting recommended criteria must evaluate evidence of progression of the terminal illness. Initial certifications and certifications for all subsequent benefit periods will be reviewed to determine whether the patient meets Local Coverage Determinations criteria and, if

not, whether the patient's medical record documentation establishes a decline in the patient's health condition.

3. *Repayment of Identified Overpayments.* In accordance with Section III.H.1 of this CIA, Solaris shall repay within 30 days any Overpayment(s) identified in any Internal Compliance Review and/or Comprehensive IRO Review, regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. Solaris shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

4. *Review Reports.* Solaris and/or the IRO shall prepare reports based upon each of the Reviews performed. More specifically, in connection with its Internal Compliance Reviews, Solaris shall prepare a report containing the information described in Appendix B. In connection with its Verification Review or Comprehensive IRO Review (as applicable), the IRO shall prepare a report containing the information described in Appendix C (and Appendix B, if applicable.)

5. *Unallowable Cost Review.* The IRO shall conduct a review of Solaris' compliance with the unallowable cost provisions of the Settlement Agreement. The IRO shall determine whether Solaris has complied with its obligations not to charge to, or otherwise seek payment from, federal or state payors for unallowable costs (as defined in the Settlement Agreement) and its 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 Solaris 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.

6. *Unallowable Cost Review Report.* 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 Solaris has complied with its obligation not to charge to, or otherwise seek payment from, federal or state payors for unallowable costs (as defined in

the Settlement Agreement) and its obligation to identify to applicable federal or state payors any unallowable costs included in payments previously sought from such payor.

7. *Validation Review.* In the event OIG has reason to believe that: (a) any of Solaris's and/or the IRO's Reviews (collectively "Reviews") fails to conform to the requirements of this CIA; or (b) Solaris's and/or the IRO's findings or Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Review complied with the requirements of the CIA and/or the findings or Review results are inaccurate (Validation Review). Solaris shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Solaris's final Annual Report must be initiated no later than one year after Solaris's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Solaris 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, Solaris may request a meeting with OIG to: (a) discuss the results of any Review submissions or findings; (b) present any additional information to clarify the results of the Review or to correct the inaccuracy of the Review at issue; and/or (c) propose alternatives to the proposed Validation Review. Solaris agrees to provide any additional information as may be requested by OIG under this Section III.D.7 in an expedited manner. OIG will attempt in good faith to resolve any Review issues with Solaris 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.

8. *Independence and Objectivity Certification.* The IRO shall include in its reports to Solaris a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the applicable Review(s), and that it has concluded that it is, in fact, independent and objective.

E. Disclosure Program.

Prior to the Effective Date, Solaris established a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Solaris' policies,

conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Solaris shall maintain this Disclosure Program throughout the term of this CIA. Solaris shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably:

- (1) permits a determination of the appropriateness of the alleged improper practice; and
- (2) provides an opportunity for taking corrective action, Solaris shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

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

#### F. Ineligible Persons.

##### 1. *Definitions.* For purposes of this CIA:

##### 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://www.oig.hhs.gov>); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).

c. "Screened Persons" include prospective and current owners, officers, directors, employees, medical directors, volunteers, contractors, and agents of Solaris.

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

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

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

c. Solaris 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.

Nothing in this Section affects the responsibility of (or liability for) Solaris to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. Solaris understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Solaris may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Solaris meets the requirements of Section III.F.

3. *Removal Requirement.* If Solaris has actual notice that a Screened Person has become an Ineligible Person, Solaris shall remove such Screened Person from responsibility for, or involvement with, Solaris' business operations related to the Federal health care programs and shall remove such Screened Person from any position for which the Screened Person's compensation or the items or services furnished, ordered, or prescribed by the Screened Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Screened Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Solaris has actual notice that a Screened Person is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Screened Person's employment or contract term, Solaris shall take all appropriate actions to ensure that the responsibilities of that Screened Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, Solaris shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Solaris conducted or brought by a governmental entity or its agents involving an allegation that Solaris 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. Solaris 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 investigation or proceedings, if any.

H. Reporting.

1. *Overpayments.*

a. *Definition of Overpayments.* For purposes of this CIA, an "Overpayment" shall mean the amount of money Solaris 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, Solaris identifies or learns of any Overpayment, Solaris 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, Solaris 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, Solaris shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the 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 CIA. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

## 2. *Reportable Events.*

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

- i. a substantial Overpayment;
- 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; or
- iii. the filing of a bankruptcy petition by Solaris.

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

b. *Reporting of Reportable Events.* If Solaris determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Solaris 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 Solaris' actions taken to correct the Reportable Event; and

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

v. If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the filing and a description of any Federal health care program authorities implicated.



#### **IV. NEW BUSINESS UNITS OR LOCATIONS**

In the event that, after the Effective Date, Solaris 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, Solaris shall notify OIG of this fact as soon as possible, but no later than within 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 has issued each Medicare number. Each new business unit or location shall be subject to all the requirements of this CIA.

#### **V. IMPLEMENTATION AND ANNUAL REPORTS**

A. Implementation Report. Within 120 days after the Effective Date, Solaris shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A;
3. a copy of Solaris' Code of Conduct required by Section III.B.1;
4. a copy of all Policies and Procedures required by Section III.B.2;
5. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
6. the following information regarding each type of training required by Section III.C:

- a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions;
- b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

7. a description of the Disclosure Program required by Section III.E;
8. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) a summary and description of any and all current and prior engagements and agreements between Solaris and the IRO; and (d) the proposed start and completion dates of the Verification Review and Unallowable Cost Review;
9. a certification from the IRO regarding its professional independence and objectivity with respect to Solaris;
10. a description of the process by which Solaris fulfills the requirements of Section III.F regarding Ineligible Persons;
11. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken in response to the screening and removal obligations set forth in Section III.F; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;
12. a list of all of Solaris' 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 Medicare contractor to which Solaris currently submits claims;
13. a description of Solaris' corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

14. the certifications required by Section V.C.

B. Annual Reports. Solaris shall submit to OIG annually a report with respect to the status of, and findings regarding, Solaris' compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in Section III.A;
2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy) and copies of any compliance-related Policies and Procedures;
3. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
4. the following information regarding each type of training required by Section III.C:
  - a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions;
  - b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

5. a complete copy of all Solaris and/or IRO reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter (if applicable);
6. Solaris' response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.D;

7. a summary and description of any and all current and prior engagements and agreements between Solaris and the IRO, if different from what was submitted as part of the Implementation Report;

8. a certification from the IRO regarding its professional independence and objectivity with respect to Solaris;

9. 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;

10. 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: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report;

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

12. any changes to the process by which Solaris fulfills the requirements of Section III.F regarding Ineligible Persons;

13. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken by Solaris in response to the screening and removal obligations set forth in Section III.F; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;

14. 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;

15. a description of all changes to the most recently provided list of Solaris' locations (including addresses) as required by Section V.A.11; 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 Medicare contractor to which Solaris currently submits claims; and

16. the certifications required by Section V.C.

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. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that:

1. to the best of his or her knowledge, except as otherwise described in the applicable report, Solaris is in compliance with all of the requirements of this CIA;

2. he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information in the Report is accurate and truthful; and

3. Solaris has complied with its obligations under the Settlement Agreement: (a) 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; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs;

D. Designation of Information. Solaris shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Solaris 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 CIA 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, S.W.  
Washington, DC 20201  
Telephone: 202.619.2078  
Facsimile: 202.205.0604

Solaris:

Leanne K. Peterson  
Chief Operations Officer  
2250 S FM 51  
Suite 400  
Decatur, TX 76234  
Telephone: 940.627.1011  
Facsimile: 940.627.6396

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

**VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS**

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Solaris' books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Solaris' locations for the purpose of verifying and evaluating: (a) Solaris' compliance with the terms of this CIA; and (b) Solaris' compliance with the requirements of the Federal health care programs in which it participates. The

documentation described above shall be made available by Solaris 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 Solaris' 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. Solaris shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Solaris' employees may elect to be interviewed with or without a representative of Solaris present.

### **VIII. DOCUMENT AND RECORD RETENTION**

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

### **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 Solaris prior to any release by OIG of information submitted by Solaris pursuant to its obligations under this CIA and identified upon submission by Solaris as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Solaris shall have the rights set forth at 45 C.F.R. § 5.65(d).

### **X. BREACH AND DEFAULT PROVISIONS**

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

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

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Solaris fails to establish and implement any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a written Code of Conduct;
- d. written Policies and Procedures;
- e. the training of Covered Persons;
- f. a Disclosure Program;
- g. Ineligible Persons screening and removal requirements; and
- h. notification of Government investigations or legal proceedings.

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

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Solaris 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.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Solaris fails to submit the annual Claims Review Report, Eligibility Review Report, or the Unallowable Cost Review Report in accordance with the requirements of Section III.D and Appendix B.

5. A Stipulated Penalty of \$1,500 for each day Solaris fails to comply with Section VII. (This Stipulated Penalty shall begin to accrue on the date Solaris fails to comply.)

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Solaris as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.



7. A Stipulated Penalty of \$1,000 for each day Solaris fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Solaris, stating the specific grounds for its determination that Solaris has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Solaris shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Solaris 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 1-6 of this Section.

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

satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

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

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

D. Exclusion for Material Breach of this CIA.

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

- a. a failure by Solaris 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 CIA, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to engage and use an IRO in accordance with Section III.D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Solaris constitutes an independent basis for Solaris' exclusion from participation in the Federal health care programs. Upon a determination by OIG that Solaris has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Solaris of: (a) Solaris' 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.* Solaris 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. Solaris is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Solaris has begun to take action to cure the material breach; (ii) Solaris is pursuing such action with due diligence; and (iii) Solaris has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Solaris fails to satisfy the requirements of Section X.D.3, OIG may exclude Solaris from participation in the Federal health care programs. OIG shall notify Solaris in writing of its determination to exclude Solaris (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 Solaris’ receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Solaris 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 Solaris of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Solaris shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG’s determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS

Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after 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 Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Solaris was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Solaris 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 CIA and orders Solaris to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Solaris 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 Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

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

decision in favor of OIG. Solaris' election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Solaris 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 Solaris 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. Solaris shall waive its 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 Solaris, Solaris 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 CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

#### **XI. EFFECTIVE AND BINDING AGREEMENT**

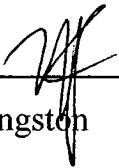
Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, Solaris and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of Solaris;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;
- D. OIG may agree to a suspension of Solaris' obligations under the CIA in the event of Solaris' cessation of participation in Federal health care programs. If Solaris withdraws from participation in Federal health care programs and is relieved of its CIA obligations by OIG, Solaris shall notify OIG at least 30 days in advance of Solaris' 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 CIA should be reactivated or modified.


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

F. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.


ON BEHALF OF SOLARIS HEALTHCARE

  
\_\_\_\_\_  
Neil F. Livingston

4/22/08  
\_\_\_\_\_  
DATE

  
\_\_\_\_\_  
Andrew P. Miligan

4/22/08  
\_\_\_\_\_  
DATE

  
\_\_\_\_\_  
Sarah Q. Wirskye  
Counsel for Solaris Healthcare

4/24/08  
\_\_\_\_\_  
DATE

ON BEHALF OF ANDREW P. MILLIGAN

Andrew P. Milligan  
Andrew P. Milligan

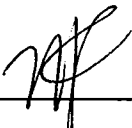
4/22/08  
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Sarah Q. Wirskye  
Sarah Q. Wirskye  
Counsel for Andrew P. Milligan

4/24/08  
DATE



ON BEHALF OF NEIL LIVINGSTON

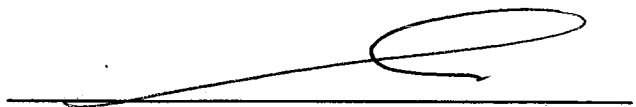
  
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Neil F. Livingston

4/22/08  
\_\_\_\_\_  
DATE

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Michael P. Heiskell  
Counsel for Neil F. Livingston~~

\_\_\_\_\_  
DATE

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



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GREGORY E. DEMSKE  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U. S. Department of Health and Human Services

4/29/08

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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.

Solaris 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 Reviews in a professionally independent and 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 Solaris if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Solaris may continue to engage the IRO.

If Solaris 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, Solaris 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 Solaris if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Solaris may continue to engage the IRO.

### B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Verification Review, the Comprehensive IRO Review (if applicable), and the Unallowable Cost Review (if applicable) who have expertise in the billing, coding, reporting, coverage, eligibility, and other requirements relating to hospice services and in the general requirements of the Federal health care program(s) from which Solaris seeks reimbursement;
2. assign individuals to design and select the Verification Review and/or Comprehensive IRO Review samples who are knowledgeable about the appropriate statistical sampling techniques;
3. assign individuals to conduct the coding review portions of the Verification and/or Comprehensive IRO Reviews 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 Verification Review, Comprehensive IRO Review, and Unallowable Cost Review in accordance with the specific requirements of the CIA;
2. follow all applicable Medicare rules and reimbursement guidelines in making assessments in the Verification Review, Comprehensive IRO Review, and Unallowable Cost Review;
3. if in doubt of the application of a particular Medicare policy or regulation, request clarification from the appropriate authority (e.g., fiscal intermediary or carrier);
4. respond to all OIG inquiries in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix C.

D. IRO Independence and Objectivity.

The IRO must perform each Verification Review, Comprehensive IRO Review, and Unallowable Cost Review in a professionally independent and 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 Solaris.

E. IRO Removal/Termination.

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

Prior to requiring Solaris to engage a new IRO, OIG shall notify Solaris 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, Solaris 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. Solaris 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 Solaris prior to requiring Solaris to terminate the IRO. However, the final determination as to whether or not to require Solaris to engage a new IRO shall be made at the sole discretion of OIG.

**APPENDIX B**  
**INTERNAL COMPLIANCE REVIEWS**

- A. *Population.*** The population from which Solaris' review sample is drawn shall include all Medicare hospice beneficiaries served during the quarter under audit and for whom claims were submitted and reimbursed by Medicare.
- B. *Internal Review Sample.*** Solaris shall randomly select and review, according to the criteria set forth below in Section C, a sample of the records relating to 10% of Medicare hospice beneficiaries from the population.
- C. *Scope of Review.*** Solaris shall review and analyze data and documentation to determine if Medicare hospice beneficiaries received appropriate hospice care in accordance with Medicare requirements and guidelines and whether Solaris complied with Medicare requirements and guidelines, including those relating to eligibility and coverage, admission practices, clinical assessments, and documentation and coding. More specifically, Solaris' review (Internal Compliance Review) shall include the following:
- a. Review of Informed Consents:  
Informed Consents shall be reviewed for accurate election dates and required signatures by the patient and/or the legal representative.
  - b. Review of Eligibility Criteria  
  
Medical record documentation shall be reviewed for recommended eligibility criteria as defined by Medicare on all certification assessments in order to determine evidence supporting the terminal diagnosis. Reviews not supporting recommended criteria must evaluate evidence of progression of the terminal illness. Initial certifications and certifications for all subsequent benefit periods will be reviewed to determine whether the patient meets Local Coverage Determinations ("LCD") criteria and, if not, whether the patient's medical record documentation establishes a decline in the patient's health condition.
  - c. Initial and Subsequent Certifications Review:  
  
Certifications shall be reviewed to determine whether they were timely obtained in accordance with Medicare requirements and guidelines, and whether the Medical Director and the patient's attending physician have signed an initial written certification that the patient's prognosis is 6 months or less if the terminal illness runs its normal course. Certifications for all subsequent benefit periods shall be reviewed to determine whether certifications were timely and obtained in accordance with Medicare requirements and guidelines, and whether the Medical Director has signed a written certification that a patient's prognosis is 6 months or less if the terminal illness runs its normal course.

d. Plan of Care Review:

The plan of care will be reviewed to determine if (1) the plan of care was established and approved by the Interdisciplinary Team ("IDT") prior to the start of care; (2) the plan of care identifies the level of care (routine home care, respite, continuous care or inpatient); (3) the plan of care includes required signatures from the core team, and the frequency of services provided; (4) the plan of care has been updated at least every 14 days; and (5) hospice visits were actually made consistent with the plan of care.

e. Review of physician Orders:

All physician orders/signatures will be reviewed to ensure that they contain sufficient information and were timely obtained in accordance with Medicare requirements and guidelines.

f. Review of Skilled Nursing Notes:

All skilled nursing notes shall be reviewed for recommended eligibility criteria as defined by Medicare on all nursing assessments in order to determine evidence supporting the terminal diagnosis.

g. Review of Level of Care Compliance:

Documentation will be reviewed to ensure that the appropriate level of care was billed to and reimbursed by Medicare.

The Continuous Care documentation will be reviewed to ensure that:

1. A comprehensive assessment was completed within an appropriate time period by a Registered Nurse prior to the initiation of Continuous Care;
2. The physician order was received;
3. Documentation reflected the need for the change in level of care, where applicable; and
4. During at least fifty percent (50%) of the time in a 24 hour period, care was provided by a licensed nurse.

General Inpatient Care documentation will be reviewed to ensure that:

1. A comprehensive assessment was completed within an appropriate time period by a Registered Nurse prior to the initiation of Hospice Inpatient Care;
2. Documentation reflected the need for the change in level of care, where applicable; and

3. The physician order was received.

Respite Care documentation will be reviewed to ensure that:

1. A comprehensive assessment was completed by a Registered Nurse prior to the initiation of Respite Care;
2. Documentation reflected the need for the change in level of care; and
3. The physician order was received.

**D. Repayment of Identified Overpayments.** In accordance with Section III.H.1 of the CIA, Solaris shall repay within 30 days any overpayment(s) identified in the Internal Compliance Reviews, regardless of the Error Rate, to the appropriate Federal health care program payor (Payor) in accordance with Payor refund policies. Solaris shall make available to the OIG any and all documentation that reflects the refunds, if any, of overpayment(s) to each Payor.

**E. Reporting:**

1. *Solaris's Internal Compliance Review Report.* Following each of its Internal Compliance Reviews, Solaris shall prepare a report that describes the review conducted and summarizes Solaris' findings for each element of the review outlined above in Section C (Internal Compliance Review Report). Reports of each Internal Compliance Review shall be presented to the Compliance Committee quarterly for review. Corrective action shall be implemented and documented by the Compliance Committee in all instances in which Solaris finds that its practices do not conform to Medicare requirements and guidelines and/or internal Solaris policies and procedures.
  - a. *Credentials.* The Internal Compliance Review Report shall list the names and credentials of the individuals who conducted the Internal Compliance Review and prepared the Internal Compliance Review Report. In conducting its Internal Compliance Reviews, Solaris shall utilize auditors who are knowledgeable about, and have experience with, the subject matter of their respective audits.
2. *Submission of Internal Compliance Review Report to OIG.* The Internal Compliance Review Reports for the applicable Reporting Period shall be included as part of Solaris' Annual Reports submitted to the OIG in accordance with Section V.B of the CIA.



**Appendix C**  
**Independent Review Organization Verification Review**

- A. *IRO Verification Review.* Except as otherwise set forth in Section III.D.2 of the CIA, the IRO shall annually conduct a review (Verification Review) of the records of 30 beneficiaries for which Solaris conducted a Review of Eligibility Criteria as set forth in Section C(b) of Appendix B as part of the Internal Compliance Reviews. The 30 records which will serve as the basis for the IRO's Verification Review shall be selected at random from the universe of beneficiary records for which Solaris conducted Eligibility Criteria Reviews during the four quarters of the applicable Reporting Period.
- B. *Verification Review Report.* The IRO shall prepare a report based upon each Verification Review performed (Verification Review Report). The following information shall be included in the IRO's Verification Review Report.
- a. Findings.  
For each beneficiary record reviewed by the IRO, the IRO shall make specific findings as to whether Solaris satisfied the applicable Medicare requirements and guidelines as described in Section C(b) of Appendix B (relating to the Eligibility Criteria). The IRO shall report its findings on sampling unit by sampling unit basis.
  - b. Observations.  
The IRO's observations, findings, and recommendations on possible improvements to Solaris' policies, procedures, and systems to ensure that Solaris complies with Medicare requirements and guidelines and with the requirements of its own internal policies and procedures as it relates to eligibility criteria.
  - c. Narrative.  
A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) based on the Verification Review conducted.
- C. *Credentials.* The names and credentials of the individuals who conducted the Verification Review and prepared the IRO Verification Review Reports.