

**INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
HERCULES S. COLLIS, M.D. (A/K/A RICKY COLLIS, M.D.),  
INTERVENTIONAL REHABILITATION OF KENTUCKY, P.S.C.,  
KENTUCKY REHABILITATION INSTITUTE, P.L.C., AND  
NOVAMED PAIN MANAGEMENT**

**I. PREAMBLE**

Hercules S. Collis, M.D. (a/k/a Ricky Collis, M.D.), Interventional Rehabilitation of Kentucky, P.S.C. and the Kentucky Rehabilitation Institute, NovaMed Pain Management (collectively Collis) 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 exclusively to any entity that Collis owns or in which Collis has a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), and any such entity's Covered Persons as defined in Section II.C. Contemporaneously with this Agreement, Dr. Ricky Collis, in his individual capacity, is entering into an individual Settlement Agreements with the OIG.

Dr. Ricky Collis owns and has a control interest in the practice group Interventional Rehabilitation of Kentucky, P.S.C., Kentucky Rehabilitation Institute, P.S.C. and NovaMed Pain Management, LLC (the Practices). Thus, the obligations set forth in this Agreement expressly apply to the Practices. For so long as Dr. Ricky Collis owns and has a control interest in the Practices and Dr. Ricky Collis does not own or have any control interest in any other entity that furnishes items or services that may be reimbursable in whole or in part, by a Federal health care program, the integrity obligations set forth in Sections III through VII may be satisfied by the Practices on behalf of Dr. Ricky Collis. In the event that Dr. Ricky Collis obtains an ownership or a control interest in any other entity that furnishes items or services that may be reimbursable in whole or in part, by a Federal health care program, the integrity obligations of this agreement shall apply to such entity and such entity's Covered Persons.

## **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 Collis under this Agreement shall be 5 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) Collis's final Annual Report; or (2) any additional materials submitted by Collis pursuant to OIG's request, whichever is later.

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

"Covered Persons" includes:

- a. all owners, officers, directors, associates, and employees of Collis; 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 Collis.

"Arrangements" shall mean every arrangement or transaction that:

- a. involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between Collis and any actual or potential source of health care business or referrals to Collis or any actual or potential recipient of health care business or referrals from Collis. The term "source" shall mean any physician, contractor, vendor, or agent and the term "health care business or referrals" shall be read to include referring, recommending, arranging for, ordering, leasing, or purchasing of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program; or
- b. is between Collis (or an immediate family member of Collis (as defined at 42 C.F.R. § 411.351)) and a physician who makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to Collis for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

### **III. INTEGRITY OBLIGATIONS**

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

#### **A. Compliance Contact**

Within 60 days after the Effective Date, Collis shall designate a person to be responsible for compliance activities (Compliance Contact). Collis shall maintain a Compliance Contact for the term of this Agreement. 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 Collis's day-to-day compliance activities; and (3) meeting all reporting obligations created under this Agreement.

Collis 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**

Within 90 days after the Effective Date, Collis shall post in a prominent place accessible to all patients and Covered Persons a notice detailing their commitment to comply with all Federal health care program requirements in the conduct of their business. 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) Collis'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 Collis.

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, Collis shall develop, implement, and distribute written Policies and Procedures to all Covered Persons. In addition, Collis 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. Collis's commitment to full compliance with all Federal health care program requirements, including their commitment to prepare and submit accurate claims consistent with such requirements;
2. the expectation that all of Collis's Covered Persons shall be expected to comply with all Federal health care program requirements and with Collis'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 Collis's own Policies and Procedures to the Compliance Contact or Collis. Any Covered Person who makes an inquiry regarding compliance with Federal health care program requirements shall be able to do so without risk of retaliation or other adverse effect;
4. the possible consequences to Collis and Covered Persons of failure to comply with Federal health care program requirements or with Collis's written Policies and Procedures and the failure to report such noncompliance;
5. Collis'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 the retention of such information in a readily retrievable form;

8. the commitment to comply with 42 U.S.C. § 1320a-7b (the “Anti-Kickback Statute”) and 42 U.S.C. § 1395nn (the “Stark Law”), and all applicable regulations and to be aware of and to review other guidance documents related to these statutes; and

9. the commitment to avoid business or financial arrangements or contracts that, directly or indirectly, induce the unlawful referral of Federal health care program beneficiaries, in violation of the Anti-Kickback Statute and/or the Stark Law.

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 Collis’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 120 days after the Effective Date, whichever is later.

At least annually (and more frequently if appropriate), Collis 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.

#### **D. Training and Certification**

Within 120 days after the Effective Date and at least once each year thereafter, Collis and Covered Persons shall receive at least two hours of training from an individual or entity, other than Collis or another Covered Person. Persons providing the training shall be knowledgeable about the subject area and may be received from a variety of sources (e.g., CME classes, hospitals, associations, carriers).

New Covered Persons shall receive the training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is

later. The training for new Covered Persons may either be provided internally by a Covered Person who has completed the required annual training or externally by a qualified individual or entity. A new Covered Person shall work under the direct supervision of a Covered Person who has received such training, 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 Covered Person completes the training.

At a minimum, the annual and new employee training sessions shall cover the following topics:

1. the requirements of Collis's Agreement;
2. an overview of Collis compliance program;
3. the written Policies and Procedures developed pursuant to Section III.C, above;
4. the legal sanctions for improper contracting or entering into unlawful financial arrangements;
5. examples of violations of the Anti-Kickback Statute and the Stark Law; and
6. a review of Collis's contracting Policies and Procedures related to "Arrangements," as defined in Section II.C above, as developed pursuant to Section III.E below, and the personal obligations of each individual involved in the development or maintenance of Arrangements to know applicable legal requirements and Collis's Policies and Procedures.

Each Covered Person shall annually 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. Collis 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 Arrangements Review (See Section III.F.2 below), and any other relevant information.

Collis may provide the training required under this Agreement through appropriate computer-based training approaches or videos. If Collis choose to provide computer-based training, they shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

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.

**E. Compliance with the Anti-Kickback Statute and the Stark Law**

1. Arrangements Procedures. Within 120 days after the Effective Date, Collis shall create procedures reasonably designed to ensure that each existing and new or renewed Arrangement does not violate the Anti-Kickback Statute and/or the Stark Law or the regulations, directives, and guidance related to these statutes (Arrangements Procedures). These procedures shall include the following:

- a. creating and maintaining a database of all existing and new or renewed Arrangements that shall contain the information specified in Appendix A (Arrangements Database);
- b. tracking remuneration to and from all parties to Arrangements;
- c. tracking service and activity logs to ensure that parties to the Arrangement are performing the services required under the applicable Arrangement(s) (if applicable);
- d. monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Arrangement(s) (if applicable);
- e. establishing and implementing a written review and approval process for all Arrangements, including but not limited to a legal review by counsel with expertise in the Anti-Kickback Statute and Stark Law and appropriate documentation of all internal controls, the purpose of which is to ensure that all new and existing or renewed

Arrangements do not violate the Anti-Kickback Statute and Stark Law;

f. requiring the Compliance Contact to review the Arrangements Database, internal review and approval process, and other Arrangements Procedures on at least a quarterly basis; and

g. implementing effective responses when suspected violations of the Anti-Kickback Statute and Stark Law are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments pursuant to Section III.I (Reporting) when appropriate.

2. New or Renewed Arrangements. Prior to entering into new Arrangements or renewing existing Arrangements, in addition to complying with the Arrangements Procedures set forth above, Collis shall comply with the following requirements (Arrangements Requirements):

a. Ensure that each Arrangement is set forth in writing and signed by Collis and the other parties to the Arrangement;

b. Include in the written agreement a requirement that all individuals who meet the definition of Covered Persons shall comply with Collis's Compliance Program, including the training related to the Anti-Kickback Statute and the Stark Law. Additionally, Collis shall provide each party to the Arrangement with a copy of their written Policies and Procedures, including the Stark Law and Anti-Kickback Statute Policies and Procedures; and

c. Include in the written agreement a certification by the parties to the Arrangement that the parties shall not violate the Anti-Kickback Statute and the Stark Law with respect to the performance of the Arrangement.

3. Records Retention and Access. Collis shall retain and make available to OIG, upon request, the Arrangements Database and all supporting documentation of the Arrangements subject to this Section and, to the extent available, all non-privileged communications related to the Arrangements and the actual performance of the duties under the Arrangements.



**F. Review Procedures**

1. General Description.

a. Engagement of Independent Review Organization. Within 120 days after the Effective Date, Collis shall engage an individual or entity (or entities), such as an accounting, auditing, law or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform a review to assist Collis in assessing its compliance with the obligations pursuant to Section III.E of this Agreement (Arrangements Review).

Each IRO shall assess, along with Collis, whether it can perform the Arrangements 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 engagement of the IRO for the Arrangements Review shall not be deemed to create an attorney-client relationship between Collis and the IRO.

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

c. Retention of Records. The IRO and Collis shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Collis) related to the Arrangements Review.

d. Responsibilities and Liabilities. Nothing in this Section III.F affects Collis’s responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute and/or the Stark Law.

2. Arrangements Review. The IRO shall perform a review to assess whether Collis are complying with the Arrangements Procedures and Arrangements Requirements required by Sections III.E.1 and III.E.2 of this Agreement. For each physician, Collis, the IRO shall review all Arrangements that were entered into or

renewed during the Reporting Period. The IRO shall assess whether Collis has implemented the Arrangements Procedures and, for each selected Arrangement, the IRO shall assess whether Collis has complied with the Arrangements Procedures and Arrangements Requirements specifically with respect to that Arrangement. The IRO's assessment shall include, but is not limited to (a) verifying that the Arrangement is listed in the Arrangements Database; (b) verifying that the Arrangement was subject to the internal review and approval process (including both a legal and business review) and obtained the necessary approvals and that such review and approval is appropriately documented; (c) verifying that the remuneration related to the Arrangement is properly tracked; (d) verifying that the service and activity logs are properly completed and reviewed (if applicable); (e) verifying that leased space, medical supplies, medical devices, and equipment, and other patient care items are properly monitored (if applicable); (f) verifying that the Compliance Contact is reviewing the Arrangements Database, internal review and approval process, and other Arrangements Procedures on a quarterly basis and reporting the results of such review to Collis; (g) verifying that effective responses are being implemented when violations of the Anti-Kickback Statute and Stark Law are discovered; and (h) verifying that Collis has met the requirements of Section III.E.2.

3. Arrangements Review Report. The IRO shall prepare a report based upon the Arrangements Review performed (Arrangements Review Report). The Arrangements Review Report shall include the IRO's findings with respect to (a) whether Collis has generally implemented the Arrangements Procedures described in Section III.E.1; and (b) specific findings as to whether Collis has complied with the Arrangements Procedures and Arrangements Requirements with respect to each of their Arrangements. In addition, the Arrangements Review Report shall include any observations, findings and recommendations on possible improvements to Collis's policies, procedures, and systems in place to ensure that all Arrangements do not violate the Anti-Kickback Statute and Stark Law.

## **G. Ineligible Persons**

1. Definitions. For purposes of this Agreement:

- a. An "Ineligible Person" shall include an individual or entity who:
  - (i) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
  - (ii) has been convicted of a criminal offense that falls within the ambit of 42

U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

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

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

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

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

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

c. Collis 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.

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

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

3. Removal Requirement. If Collis has notice that any individual or entity in one of the positions identified in Section III.G.1.c has become an Ineligible Person, Collis shall remove such individual or entity from responsibility for, or involvement with, Collis's business operations related to the Federal health care programs and shall remove

such individual or entity from any position for which the individual's or entity's compensation or the items or services rendered, ordered, or prescribed by the individual or entity are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds, at least until such time as the individual or entity is reinstated into participation in the Federal health care programs.

4. Pending Charges and Proposed Exclusions. If Collis has notice that an individual identified in Section III.G.1.c is charged with a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), or an individual or entity identified in Section III.G.1.c is proposed for exclusion during his, her, or its employment, involvement or contract term, Collis shall take all appropriate actions to ensure that the responsibilities of that individual or entity 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.

#### **H. Notification of Government Investigation or Legal Proceedings**

Within 30 days after discovery, Collis shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Collis conducted or brought by a governmental entity or its agents involving an allegation that Collis 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. Collis shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

#### **I. Reporting**

##### **1. Overpayments**

a. Definition of Overpayments. For purposes of this Agreement, an "Overpayment" shall mean the amount of money Collis 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, Collis identifies or learns of any Overpayment, Collis 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, Collis 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, Collis shall notify the payor at that time of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies, and for Medicare contractors shall include the information contained on the Overpayment Refund Form, provided as Appendix B to this Agreement. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

2. Reportable Events

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

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

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

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

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

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

In the event that, after the Effective Date, Collis 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, Collis shall notify OIG of this fact as soon as possible, but no later than 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare Provider number, provider identification number, and/or supplier number, and the corresponding contractor's name and address that issued each number. If the Medicare Provider number, provider identification number, and/or supplier number have not been issued on or before 30 days after the date of change of location, sale, closure, purchaser or establishment, Collis shall notify OIG of the number(s) no later than 15 days after the number(s) is issued. Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements in this Agreement.

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

## **V. REPORTS**

### **A. Implementation Report**

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

1. the Compliance Contact's name, address, and phone number, a description of any other job responsibilities performed by the Compliance Contact, and the date the Compliance Contact was appointed;
2. a copy of the notice Collis posted in his office as required by Section III.B, a description of where the notice is posted, and the date the notice was posted;
3. a copy of the written Policies and Procedures required by Section III.C of this Agreement and the date these Policies and Procedures were implemented and distributed;
4. a copy of all training materials used for the training session(s) required by Section III.D, a description of the training, including a summary of the topics covered, the length of each session, and a schedule of when the training session(s) were held;
5. a description of the Arrangements Database required by Section III.E.1.a;
6. a description of the internal review and approval process required by Section III.E.1.e;

7. a description of the tracking and monitoring procedures and other Arrangements Procedures required by Section III.E.1;
8. the following information regarding the IRO: (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 Collis and the IRO; and (d) the proposed start and completion dates of the Arrangements Review;
9. a certification from the IRO regarding its professional independence and/or objectivity with respect to Collis;
10. a description of Collis's process to screen Covered Persons to determine if they are ineligible;
11. a summary of personnel actions (other than hiring) taken pursuant to Section III.G, the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G, and the actions taken in response to the obligations set forth in Section III.G;
12. a list of all Collis's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare Provider number(s), provider identification number(s), and/or supplier number(s), and the name and address of each contractor to which Collis currently submits claims;
13. if Collis became an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Collis shall inform OIG of the name, location, relationship, and his responsibilities with respect to Collis's employment or contract;
14. a certification by the Compliance Contact that:
  - a. the written Policies and Procedures required by Section III.C have been developed, are being implemented, and have been distributed to all Covered Persons; and that all Covered Persons have executed the written Policies and Procedures certification in accordance with the timeframe required by Section III.C of this Agreement;



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

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

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

15. a certification signed by Collis certifying (a) to the best of their knowledge, except as otherwise described in the Implementation Report, Collis is in compliance with all of the requirements of this Agreement; and (b) Collis has reviewed the Implementation Report and has made a reasonable inquiry regarding its content and believe that the information is accurate and truthful.

**B. Annual Reports**

Collis shall submit to OIG Annual Reports with respect to the status of, and findings regarding, their compliance activities for each of the three Reporting Periods (Annual Report).

Each Annual Report shall, at a minimum, include:

1. any change in the name, address, phone number, or job responsibilities of Collis's Compliance Contact;
2. any changes to the posted notice and the reason for such changes;
3. a copy of any new compliance-related Policies and Procedures;

4. a summary of any changes or amendments to the written Policies and Procedures required by Section III.C and the reason(s) for such changes (e.g., change in contractor policies);
5. a copy of all training materials used for the training session(s) required by Section III.D (to the extent they have not already been provided as part of the Implementation Report); a description of the training, including a summary of the topics covered; the length of each session; and a schedule of when the training session(s) was held;
6. a description of any changes to the Arrangements Database required by Section III.E.1.a;
7. a description of any changes to the internal review and approval process required by Section III.E.1.e;
8. a description of any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.E.1;
9. a complete copy of all reports prepared pursuant to Section III.F, along with a copy of the IRO's engagement letter (if applicable);
10. Collis's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.F;
11. a summary and description of any and all current and prior engagements and agreements between Collis and the IRO, if different from what was submitted as part of the Implementation Report;
12. a certification from the IRO regarding its professional independence and/or objectivity with respect to Collis;
13. a description of Collis's process to screen Covered Persons to determine if they are ineligible (to the extent it has changed from the Implementation Report);
14. a summary of personnel actions involving Ineligible Persons, other than hiring, taken pursuant to Section III.G; the name, titles, and responsibilities of any person who is determined to be an Ineligible Person

under Section III.G; and Collis's actions taken in response to the obligations set forth in Section III.G;

15. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. 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;

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

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

18. a description of all changes to the most recently provided list of Collis's locations (including addresses) as required by Section IV. Include the corresponding phone numbers, fax numbers, each location's Medicare Provider Number(s), provider identification number(s), and/or supplier number(s), and the name and address of the contractor that issued each number;

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

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

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

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

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

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

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

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

**C. Designation of Information**

Collis shall clearly identify any portions of his submission that he 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. Collis shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

**VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

Unless otherwise stated in writing after the Effective Date, all notifications and Reports required under this Agreement shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue, SW  
Washington, D.C. 20201

Telephone: (202) 619-2078  
Facsimile: (202) 205-0604

COLLIS:

Kelly Shattuck  
Office Manager  
315 East Broadway  
Suite 250  
Louisville, KY 40202

Phone: (502) 589-4765  
Fax: (502) 589-4799

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

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

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Collis's

books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Collis's locations for the purpose of verifying and evaluating: (a) Collis's compliance with the terms of this Agreement; and (b) Collis's compliance with the requirements of the Federal health care programs in which they participate. The documentation described above shall be made available by Collis 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 Collis's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Collis shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Collis's employees may elect to be interviewed with or without a representative of Collis present.

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

Collis shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this Agreement, for 4 years (or longer if otherwise required by law).

#### **IX. DISCLOSURES**

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

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

Collis is expected to fully and timely comply with all of their Agreement obligations.

##### **A. Stipulated Penalties for Failure to Comply with Certain Obligations**

As a contractual remedy, Collis and OIG hereby agree that failure to comply with certain obligations set forth in this Agreement (unless a timely written request for an extension has been requested and approved in accordance with Section B below) may

lead to the imposition of the following monetary penalties (hereinafter referred to as “Stipulated Penalties”) in accordance with the following provisions.

1. A Stipulated Penalty of \$750 (which shall begin to accrue on the day after the date the obligation became due) for each day Collis fails to:

- a. have a Compliance Contact in accordance with the requirements of Section III.A;
- b. establish and/or post a notice in accordance with the requirements of Section III.B;
- c. establish, implement, maintain, distribute and/or update the written Policies and Procedures in accordance with the requirements of Section III.C;
- d. engage an IRO in accordance with the requirements of Section III.F;
- e. submit the IRO’s annual Arrangements Review Report in accordance with the requirements of Section III.F;
- f. establish and implement the Arrangements Procedures and/or Arrangements Requirements described in Sections III.E.1 and III.E.2;
- g. obtain and/or maintain the following documentation: Policies and Procedures certifications in accordance with the requirements of Section III.C, training certification(s) in accordance with the requirements of Section III.D, and/or documentation of screening and disclosure requirements in accordance with the requirements of Section III.G.2;
- h. screen current or prospective owners, officers, directors, associates, employees, contractors or agents in accordance with the requirements of Section III.G; or require owners, officers, directors, associates, employees, contractors or agents to disclose if they are debarred, excluded, suspended or are otherwise considered an Ineligible Person in accordance with the requirements of Section III.G; or

i. notify OIG of a Government investigation or legal proceeding, in accordance with the requirements of Section III.H.

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

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

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

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

**B. Timely Written Requests for Extensions**

Collis may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or Report required by this Agreement. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or Report, Stipulated Penalties for failure to perform the act or file the notification or Report shall not begin to accrue until one day after Collis 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 Collis 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. A written request may be submitted in either hard copy or electronic format.

**C. Payment of Stipulated Penalties**

1. Demand Letter. Upon a finding that Collis 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 Collis of: (a) Collis's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

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

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

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

**D. Exclusion for Material Breach of this Agreement**

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

- a. a failure by Collis to report a Reportable Event, take corrective action and make the appropriate refunds, as required in Section III.I;

- b. a repeated or flagrant violation of the obligations under this Agreement, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to conduct an Arrangements Review in accordance with Section III.F.

2. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this Agreement by Collis constitutes an independent basis for Collis's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Collis has materially breached this Agreement and that exclusion is the appropriate remedy, OIG shall notify Collis of: (a) Collis's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. Opportunity to Cure. Collis 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. Collis is in compliance with the obligations of the Agreement cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Collis has begun to take action to cure the material breach; (ii) Collis is pursuing such action with due diligence; and (iii) Collis has provided to OIG a reasonable timetable for curing the material breach.

4. Exclusion Letter. If at the conclusion of the 30-day period, Collis fails to satisfy the requirements of Section X.D.3, OIG may exclude Collis from participation in the Federal health care programs. OIG shall notify Collis in writing of its determination to exclude Collis (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 Collis's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Collis 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 Collis of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this Agreement, Collis shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this Agreement. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this Agreement shall be: (a) whether Collis is in full and timely compliance with the obligations of this Agreement for which OIG demands payment; and (b) the period of noncompliance. Collis shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this Agreement and orders Collis to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Collis requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

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

- a. whether Collis were in material breach of this Agreement;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30 day period, but that: (i) Collis had begun to take action to cure the material breach within that period; (ii) Collis has pursued and are pursuing such action with due diligence; and (iii) Collis provided to OIG within that period a reasonable timetable for curing the material breach and Collis have 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 Collis, only after a DAB decision in favor of OIG. Collis's election of their contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Collis 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 Collis 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. Collis shall waive their right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Collis, Collis shall be reinstated effective on the date of the original exclusion.

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

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

Consistent with the provisions in the Settlement Agreement pursuant to which this Agreement is entered. Collis and OIG agree as follows:

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

B. The obligations set forth in this Agreement are binding on Collis in his individual capacity and will continue in full force and effect, notwithstanding if he leaves the Practice.

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

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

E. OIG may agree to a suspension of Collis's obligations under this Agreement in the event of Collis's cessation of participation in Federal health care programs. If Collis withdraws from participation in Federal health care programs and is relieved of their Agreement obligations by OIG, Collis shall notify OIG 30 days in advance of Collis's intent to reapply as a participating provider or supplier with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the Agreement shall be reactivated or modified.

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

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

IN WITNESS WHEREOF, the parties hereto affix their signatures:

ON BEHALF OF HERCULES S. COLLIS, M.D.

*Hercules S. Collis*

HERCULES S. COLLIS, M.D.

*5-18-07*

Date

*Robert W. Liles*

ROBERT W. LILES  
Liles Parker  
440 MacArthur Blvd., N.W.  
Suite 203  
Washington, D.C. 20007

*5/22/07*

Date

ON BEHALF OF KENTUCKY REHABILITATION INSTITUTE,  
INTERVENTION REHABILITATION KENTUCKY, P.S.C., AND  
NOVAMED PAIN MANAGEMENT

*Hercules S. Collis*

HERCULES S. COLLIS, M.D.

*5-18-07*

Date

*Robert W. Liles*

ROBERT W. LILES  
Liles Parker  
440 MacArthur Blvd., N.W., Suite 203  
Washington, D.C. 20007

*5/22/07*

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

5/14/07

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Date

## APPENDIX A

### ARRANGEMENTS DATABASE

Collis shall create and maintain an Arrangements Database to track all new and existing Arrangements in order to ensure that each Arrangement does not violate the Anti-Kickback Statute and Stark Law. The Arrangements Database shall contain certain information to assist Collis in evaluating whether each Arrangement violates the Anti-Kickback Statute and Stark Law, including but not limited to the following:

1. Each party involved in the Arrangement;
2. The type of Arrangement (e.g., physician employment contract, medical directorship, lease agreement);
3. The term of the Arrangement, including the effective and expiration dates and any automatic renewal provisions;
4. The amount of compensation to be paid pursuant to the Arrangement and the means by which compensation is paid;
5. The methodology for determining the compensation under the Arrangements, including the methodology used to determine the fair market value of such compensation;
6. Whether the amount of compensation to be paid pursuant to the Arrangement is determined based on the volume or value of referrals between the parties;
7. Whether each party has fulfilled the requirements of Section III.E.2; and
8. Whether the Arrangement satisfies the requirements of an Anti-Kickback Statute safe harbor and/or a Stark Law exception or safe harbor, as applicable.



## APPENDIX B

# OVERPAYMENT REFUND

### TO BE COMPLETED BY MEDICARE CONTRACTOR

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

### TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

*Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.*

PROVIDER/PHYSICIAN/SUPPLIER NAME \_\_\_\_\_  
 ADDRESS \_\_\_\_\_  
 PROVIDER/PHYSICIAN/SUPPLIER # \_\_\_\_\_ CHECK NUMBER# \_\_\_\_\_  
 CONTACT PERSON: \_\_\_\_\_ PHONE # \_\_\_\_\_  
 AMOUNT OF CHECK \$ \_\_\_\_\_ CHECK DATE \_\_\_\_\_

### REFUND INFORMATION

**For each Claim, provide the following:**

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

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

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

**For Institutional Facilities Only:**

Cost Report Year(s) \_\_\_\_\_  
 (If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)

**For OIG Reporting Requirements:**

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

**Reason Codes:**

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

**FIRST AMENDMENT TO THE  
INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
HERCULES S. COLLIS, M.D. (A/K/A RICKY COLLIS, M.D.),  
INTERVENTIONAL REHABILITATION OF KENTUCKY, P.S.C., AND  
KENTUCKY REHABILITATION INSTITUTE, P.L.C.**

**I. PREAMBLE**

Hercules S. Collis, M.D. (a/k/a Ricky Collis, M.D.), Interventional Rehabilitation of Kentucky, P.S.C. and the Kentucky Rehabilitation Institute (collectively Collis) hereby enter into this First Amendment to the Integrity Agreement (Agreement) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS), which supersedes the Integrity Agreement entered into between the OIG and Collis on May 22, 2007, 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 exclusively to any entity that Collis owns or in which Collis has a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), and any such entity's Covered Persons as defined in Section II.C. Previously, Dr. Ricky Collis, in his individual capacity, entered into an individual Settlement Agreement with the OIG, which was effective May 14, 2007.

Dr. Ricky Collis owns and has a control interest in the practice group Interventional Rehabilitation of Kentucky, P.S.C., Kentucky Rehabilitation Institute, P.S.C. and NovaMed Pain Management of New Albany, LLC (the Practices). Thus, the obligations set forth in this Agreement expressly apply to Dr. Collis's activities at the Practices. In the event that Dr. Ricky Collis obtains an ownership or a control interest in any other entity that furnishes items or services that may be reimbursable in whole or in part, by a Federal health care program, Dr. Collis's integrity obligations shall apply to Collis's activities at such entity and such entity's Covered Persons.

**II. TERM OF THE AGREEMENT**

A. The Effective Date of this Agreement shall be the Effective Date of the original Integrity Agreement between the OIG and Collis, or May 22, 2007. The period of compliance obligations assumed by Collis under this Agreement shall be 5 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) Collis's final Annual Report; or (2) any additional materials submitted by Collis pursuant to OIG's request, whichever is later.

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

"Covered Persons" includes:

- a. all owners, officers, directors, associates, and employees of Collis; and
- b. all contractors, agents, and other persons, including but not limited to all such persons at the Practices, who provide patient care items or services or who perform billing or coding functions on behalf of Collis.

"Arrangements" shall mean every arrangement or transaction that:

- a. involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between Collis and any actual or potential source of health care business or referrals to Collis or any actual or potential recipient of health care business or referrals from Collis. The term "source" shall mean any physician, contractor, vendor, or agent and the term "health care business or referrals" shall be read to include referring, recommending, arranging for, ordering, leasing, or purchasing of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program; or
- b. is between Collis (or an immediate family member of Collis (as defined at 42 C.F.R. § 411.351)) and a physician who makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to Collis for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

### **III. INTEGRITY OBLIGATIONS**

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

**A. Compliance Contact**

Within 60 days after the Effective Date, Collis shall designate a person to be responsible for compliance activities (Compliance Contact). Collis shall maintain a Compliance Contact for the term of this Agreement. 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 Collis's day-to-day compliance activities; and (3) meeting all reporting obligations created under this Agreement.

Collis 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**

Within 90 days after the Effective Date, Collis shall post in a prominent place accessible to all patients and Covered Persons a notice detailing their commitment to comply with all Federal health care program requirements in the conduct of their business. 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) Collis'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 Collis.

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, Collis shall develop, implement, and distribute written Policies and Procedures to all Covered Persons. In addition, Collis 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. Collis's commitment to full compliance with all Federal health care program requirements, including their commitment to prepare and submit accurate claims consistent with such requirements;
2. the expectation that all of Collis's Covered Persons shall be expected to comply with all Federal health care program requirements and with Collis'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 Collis's own Policies and Procedures to the Compliance Contact or Collis. Any Covered Person who makes an inquiry regarding compliance with Federal health care program requirements shall be able to do so without risk of retaliation or other adverse effect;
4. the possible consequences to Collis and Covered Persons of failure to comply with Federal health care program requirements or with Collis's written Policies and Procedures and the failure to report such noncompliance;
5. Collis'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 the retention of such information in a readily retrievable form;
8. the commitment to comply with 42 U.S.C. § 1320a-7b (the "Anti-Kickback Statute") and 42 U.S.C. § 1395nn (the "Stark Law"), and all applicable regulations and to be aware of and to review other guidance documents related to these statutes; and
9. the commitment to avoid business or financial arrangements or contracts that, directly or indirectly, induce the unlawful referral of Federal health

care program beneficiaries, in violation of the Anti-Kickback Statute and/or the Stark Law.

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 Collis'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 120 days after the Effective Date, whichever is later.

At least annually (and more frequently if appropriate), Collis 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.

**D. Training and Certification**

Within 120 days after the Effective Date and at least once each year thereafter, Collis and Covered Persons shall receive at least two hours of training from an individual or entity, other than Collis or another Covered Person. Persons providing the training shall be knowledgeable about the subject area and may be received from a variety of sources (e.g., CME classes, hospitals, associations, carriers).

New Covered Persons shall receive the training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. The training for new Covered Persons may either be provided internally by a Covered Person who has completed the required annual training or externally by a qualified individual or entity. A new Covered Person shall work under the direct supervision of a Covered Person who has received such training, 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 Covered Person completes the training.

At a minimum, the annual and new employee training sessions shall cover the following topics:

1. the requirements of Collis's Agreement;
2. an overview of Collis compliance program;
3. the written Policies and Procedures developed pursuant to Section III.C, above;
4. the legal sanctions for improper contracting or entering into unlawful financial arrangements;
5. examples of violations of the Anti-Kickback Statute and the Stark Law; and
6. a review of Collis's contracting Policies and Procedures related to "Arrangements," as defined in Section II.C above, as developed pursuant to Section III.E below, and the personal obligations of each individual involved in the development or maintenance of Arrangements to know applicable legal requirements and Collis's Policies and Procedures.

Each Covered Person shall annually 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. Collis 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 Arrangements Review (See Section III.F.2 below), and any other relevant information.

Collis may provide the training required under this Agreement through appropriate computer-based training approaches or videos. If Collis choose to provide computer-based training, they shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

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.

**E. Compliance with the Anti-Kickback Statute and the Stark Law**

1. Arrangements Procedures. Within 120 days after the Effective Date, Collis shall create procedures reasonably designed to ensure that each existing and new or renewed Arrangement does not violate the Anti-Kickback Statute and/or the Stark Law or the regulations, directives, and guidance related to these statutes (Arrangements Procedures). These procedures shall include the following:

- a. creating and maintaining a database of all existing and new or renewed Arrangements that shall contain the information specified in Appendix A (Arrangements Database);
- b. tracking remuneration to and from all parties to Arrangements;
- c. tracking service and activity logs to ensure that parties to the Arrangement are performing the services required under the applicable Arrangement(s) (if applicable);
- d. monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Arrangement(s) (if applicable);
- e. establishing and implementing a written review and approval process for all Arrangements, including but not limited to a legal review by counsel with expertise in the Anti-Kickback Statute and Stark Law and appropriate documentation of all internal controls, the purpose of which is to ensure that all new and existing or renewed Arrangements do not violate the Anti-Kickback Statute and Stark Law;
- f. requiring the Compliance Contact to review the Arrangements Database, internal review and approval process, and other Arrangements Procedures on at least a quarterly basis; and
- g. implementing effective responses when suspected violations of the Anti-Kickback Statute and Stark Law are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments pursuant to Section III.I (Reporting) when appropriate.



2. New or Renewed Arrangements. Prior to entering into new Arrangements or renewing existing Arrangements, in addition to complying with the Arrangements Procedures set forth above, Collis shall comply with the following requirements (Arrangements Requirements):

- a. Ensure that each Arrangement is set forth in writing and signed by Collis and the other parties to the Arrangement;
- b. Include in the written agreement a requirement that all individuals who meet the definition of Covered Persons shall comply with Collis's Compliance Program, including the training related to the Anti-Kickback Statute and the Stark Law. Additionally, Collis shall provide each party to the Arrangement with a copy of their written Policies and Procedures, including the Stark Law and Anti-Kickback Statute Policies and Procedures; and
- c. Include in the written agreement a certification by the parties to the Arrangement that the parties shall not violate the Anti-Kickback Statute and the Stark Law with respect to the performance of the Arrangement.

3. Records Retention and Access. Collis shall retain and make available to OIG, upon request, the Arrangements Database and all supporting documentation of the Arrangements subject to this Section and, to the extent available, all non-privileged communications related to the Arrangements and the actual performance of the duties under the Arrangements.

**F. Review Procedures**

1. General Description.

- a. Engagement of Independent Review Organization. Within 120 days after the Effective Date, Collis shall engage an individual or entity (or entities), such as an accounting, auditing, law or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform a review to assist Collis in assessing its compliance with the obligations pursuant to Section III.E of this Agreement (Arrangements Review).

Each IRO shall assess, along with Collis, whether it can perform the Arrangements 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 engagement of the IRO for the Arrangements Review shall not be deemed to create an attorney-client relationship between Collis and the IRO.

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

c. Retention of Records. The IRO and Collis shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Collis) related to the Arrangements Review.

d. Responsibilities and Liabilities. Nothing in this Section III.F affects Collis's responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute and/or the Stark Law.

2. Arrangements Review. The IRO shall perform a review to assess whether Collis are complying with the Arrangements Procedures and Arrangements Requirements required by Sections III.E.1 and III.E.2 of this Agreement. For each physician, Collis, the IRO shall review all Arrangements that were entered into or renewed during the Reporting Period. The IRO shall assess whether Collis has implemented the Arrangements Procedures and, for each selected Arrangement, the IRO shall assess whether Collis has complied with the Arrangements Procedures and Arrangements Requirements specifically with respect to that Arrangement. The IRO's assessment shall include, but is not limited to (a) verifying that the Arrangement is listed in the Arrangements Database; (b) verifying that the Arrangement was subject to the internal review and approval process (including both a legal and business review) and obtained the necessary approvals and that such review and approval is appropriately documented; (c) verifying that the remuneration related to the Arrangement is properly tracked; (d) verifying that the service and activity logs are properly completed and reviewed (if applicable); (e) verifying that leased space, medical supplies, medical devices, and equipment, and other patient care items are properly monitored (if

applicable); (f) verifying that the Compliance Contact is reviewing the Arrangements Database, internal review and approval process, and other Arrangements Procedures on a quarterly basis and reporting the results of such review to Collis; (g) verifying that effective responses are being implemented when violations of the Anti-Kickback Statute and Stark Law are discovered; and (h) verifying that Collis has met the requirements of Section III.E.2.

3. Arrangements Review Report. The IRO shall prepare a report based upon the Arrangements Review performed (Arrangements Review Report). The Arrangements Review Report shall include the IRO's findings with respect to (a) whether Collis has generally implemented the Arrangements Procedures described in Section III.E.1; and (b) specific findings as to whether Collis has complied with the Arrangements Procedures and Arrangements Requirements with respect to each of their Arrangements. In addition, the Arrangements Review Report shall include any observations, findings and recommendations on possible improvements to Collis's policies, procedures, and systems in place to ensure that all Arrangements do not violate the Anti-Kickback Statute and Stark Law.

#### **G. Ineligible Persons**

1. Definitions. For purposes of this Agreement:

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

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

c. "Screened Persons" include prospective and current owners, officers, directors, employees, contractors, and agents of Collis, including all Covered Persons at the Practices.

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

- a. Collis shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such persons to disclose whether they are an Ineligible Person.
- b. Collis shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.
- c. Collis 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.

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

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

3. Removal Requirement. If Collis has notice that any individual or entity in one of the positions identified in Section III.G.1.c has become an Ineligible Person, Collis shall remove such individual or entity from responsibility for, or involvement with, Collis's business operations related to the Federal health care programs and shall remove such individual or entity from any position for which the individual's or entity's compensation or the items or services rendered, ordered, or prescribed by the individual or entity are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds, at least until such time as the individual or entity is reinstated into participation in the Federal health care programs.

4. Pending Charges and Proposed Exclusions. If Collis has notice that an individual identified in Section III.G.1.c is charged with a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), or an individual or entity identified in Section III.G.1.c is proposed for exclusion during his, her, or its employment, involvement or contract term, Collis shall take all appropriate actions to ensure that the responsibilities of that individual or entity 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.

#### **H. Notification of Government Investigation or Legal Proceedings**

Within 30 days after discovery, Collis shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Collis conducted or brought by a governmental entity or its agents involving an allegation that Collis 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. Collis shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

#### **I. Reporting**

##### **1. Overpayments**

a. Definition of Overpayments. For purposes of this Agreement, an “Overpayment” shall mean the amount of money Collis 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, Collis identifies or learns of any Overpayment, Collis 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, Collis 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, Collis shall notify the payor at that time of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor’s policies, and for Medicare contractors shall include the information contained on the Overpayment Refund Form, provided as Appendix B to this Agreement. Notwithstanding the

above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

2. Reportable Events

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

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

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

b. Reporting of Reportable Event. If Collis determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Collis 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.I.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 Collis's actions taken to correct the Reportable Event; and
- iv. any further steps Collis plans to take to address the Reportable Event and prevent it from recurring.

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

In the event that, after the Effective Date, Collis 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, Collis shall notify OIG of this fact as soon as possible, but no later than 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare Provider number, provider identification number, and/or supplier number, and the corresponding contractor's name and address that issued each number. If the Medicare Provider number, provider identification number, and/or supplier number have not been issued on or before 30 days after the date of change of location, sale, closure, purchaser or establishment, Collis shall notify OIG of the number(s) no later than 15 days after the number(s) is issued. Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements in this Agreement.

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

**V. REPORTS**

**A. Implementation Report**

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

1. the Compliance Contact's name, address, and phone number, a description of any other job responsibilities performed by the Compliance Contact, and the date the Compliance Contact was appointed;
2. a copy of the notice Collis posted in his office as required by Section III.B, a description of where the notice is posted, and the date the notice was posted;
3. a copy of the written Policies and Procedures required by Section III.C of this Agreement and the date these Policies and Procedures were implemented and distributed;
4. a copy of all training materials used for the training session(s) required by Section III.D, a description of the training, including a summary of the topics covered, the length of each session, and a schedule of when the training session(s) were held;
5. a description of the Arrangements Database required by Section III.E.1.a;
6. a description of the internal review and approval process required by Section III.E.1.e;
7. a description of the tracking and monitoring procedures and other Arrangements Procedures required by Section III.E.1;
8. the following information regarding the IRO: (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 Collis and the IRO; and (d) the proposed start and completion dates of the Arrangements Review;



9. a certification from the IRO regarding its professional independence and/or objectivity with respect to Collis;
10. a description of Collis's process to screen Covered Persons to determine if they are ineligible;
11. a summary of personnel actions (other than hiring) taken pursuant to Section III.G, the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G, and the actions taken in response to the obligations set forth in Section III.G;
12. a list of all Collis's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare Provider number(s), provider identification number(s), and/or supplier number(s), and the name and address of each contractor to which Collis currently submits claims;
13. if Collis became an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Collis shall inform OIG of the name, location, relationship, and his responsibilities with respect to Collis's employment or contract;
14. a certification by the Compliance Contact that:
  - a. the written Policies and Procedures required by Section III.C have been developed, are being implemented, and have been distributed to all Covered Persons; and that all Covered Persons have executed the written Policies and Procedures certification in accordance with the timeframe required by Section III.C of this Agreement;
  - b. all Covered Persons have completed the applicable training required by Section III.D; and that all Covered Persons have executed the applicable training certification(s) in accordance with the timeframe required by Section III.D;
  - c. all owners, officers, directors, associates, employees, contractors, and agents of Collis, including all Covered Persons at the Practices, that were hired or engaged since the execution of the Agreement

were screened against the Exclusion Lists and asked to disclose if they are excluded, debarred, suspended, or are otherwise considered an Ineligible Person, before entering into their relationship with Collis, as required by Section III.G; and

d. all current owners, officers, directors, associates, employees, contractors, and agents of Collis, including all Covered Persons at the Practices, were screened against the Exclusion Lists within 90 days after the Effective Date, as required by Section III.G and the date(s) of the screening.

15. a certification signed by Collis certifying (a) to the best of their knowledge, except as otherwise described in the Implementation Report, Collis is in compliance with all of the requirements of this Agreement; and (b) Collis has reviewed the Implementation Report and has made a reasonable inquiry regarding its content and believe that the information is accurate and truthful.

**B. Annual Reports**

Collis shall submit to OIG Annual Reports with respect to the status of, and findings regarding, their compliance activities for each of the three Reporting Periods (Annual Report).

Each Annual Report shall, at a minimum, include:

1. any change in the name, address, phone number, or job responsibilities of Collis's Compliance Contact;
2. any changes to the posted notice and the reason for such changes;
3. a copy of any new compliance-related Policies and Procedures;
4. a summary of any changes or amendments to the written Policies and Procedures required by Section III.C and the reason(s) for such changes (e.g., change in contractor policies);
5. a copy of all training materials used for the training session(s) required by Section III.D (to the extent they have not already been provided as part of the Implementation Report); a description of the training, including a

summary of the topics covered; the length of each session; and a schedule of when the training session(s) was held;

6. a description of any changes to the Arrangements Database required by Section III.E.1.a;
7. a description of any changes to the internal review and approval process required by Section III.E.1.e;
8. a description of any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.E.1;
9. a complete copy of all reports prepared pursuant to Section III.F, along with a copy of the IRO's engagement letter (if applicable);
10. Collis's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.F;
11. a summary and description of any and all current and prior engagements and agreements between Collis and the IRO, if different from what was submitted as part of the Implementation Report;
12. a certification from the IRO regarding its professional independence and/or objectivity with respect to Collis;
13. a description of Collis's process to screen Covered Persons to determine if they are ineligible (to the extent it has changed from the Implementation Report);
14. a summary of personnel actions involving Ineligible Persons, other than hiring, taken pursuant to Section III.G; the name, titles, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; and Collis's actions taken in response to the obligations set forth in Section III.G;
15. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. 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;

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

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

18. a description of all changes to the most recently provided list of Collis's locations (including addresses) as required by Section IV. Include the corresponding phone numbers, fax numbers, each location's Medicare Provider Number(s), provider identification number(s), and/or supplier number(s), and the name and address of the contractor that issued each number;

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

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

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

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

c. all owners, officers, directors, associates, employees, contractors, and agents that were hired, engaged or contracted with Collis during the Reporting Period, including all Covered Persons at the Practices,

have been screened against the Exclusion Lists and asked to disclose if they are excluded, debarred, suspended, or are otherwise considered an Ineligible Person, prior to entering into their relationship with Collis, as required by Section III.G; and

d. all owners, officers, directors, associates, employees, contractors, and agents (employed, engaged or contracted with Collis for the entire Reporting Period) , including all Covered Persons at the Practices, were screened against the Exclusion Lists during the Reporting Period, in accordance with Section III.G and the date(s) they were screened;

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

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

**C. Designation of Information**

Collis shall clearly identify any portions of his submission that he 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. Collis shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

**VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

Unless otherwise stated in writing after the Effective Date, all notifications and Reports required under this Agreement shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue, SW  
Washington, D.C. 20201

Telephone: (202) 619-2078  
Facsimile: (202) 205-0604

COLLIS:

Kelly Shattuck  
Office Manager  
315 East Broadway  
Suite 250  
Louisville, KY 40202

Phone: (502) 589-4765  
Fax: (502) 589-4799

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

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

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Collis's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Collis's locations for the purpose of verifying and evaluating: (a) Collis's compliance with the terms of this Agreement; and (b) Collis's compliance with the requirements of the Federal health care programs in which they participate. The documentation described above shall be made available by Collis 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 Collis's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Collis shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Collis's employees may elect to be interviewed with or without a representative of Collis present.

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

Collis shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this Agreement, for 4 years (or longer if otherwise required by law).

#### **IX. DISCLOSURES**

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

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

Collis is expected to fully and timely comply with all of their Agreement obligations.

##### **A. Stipulated Penalties for Failure to Comply with Certain Obligations**

As a contractual remedy, Collis and OIG hereby agree that failure to comply with certain obligations set forth in this Agreement (unless a timely written request for an extension has been requested and approved in accordance with Section B below) may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$750 (which shall begin to accrue on the day after the date the obligation became due) for each day Collis fails to:

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

- b. establish and/or post a notice in accordance with the requirements of Section III.B;
- c. establish, implement, maintain, distribute and/or update the written Policies and Procedures in accordance with the requirements of Section III.C;
- d. engage an IRO in accordance with the requirements of Section III.F;
- e. submit the IRO's annual Arrangements Review Report in accordance with the requirements of Section III.F;
- f. establish and implement the Arrangements Procedures and/or Arrangements Requirements described in Sections III.E.1 and III.E.2;
- g. obtain and/or maintain the following documentation: Policies and Procedures certifications in accordance with the requirements of Section III.C, training certification(s) in accordance with the requirements of Section III.D, and/or documentation of screening and disclosure requirements in accordance with the requirements of Section III.G.2;
- h. screen current or prospective owners, officers, directors, associates, employees, contractors or agents in accordance with the requirements of Section III.G; or require owners, officers, directors, associates, employees, contractors or agents to disclose if they are debarred, excluded, suspended or are otherwise considered an Ineligible Person in accordance with the requirements of Section III.G; or
- i. notify OIG of a Government investigation or legal proceeding, in accordance with the requirements of Section III.H.

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



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

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

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

**B. Timely Written Requests for Extensions**

Collis may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or Report required by this Agreement. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or Report, Stipulated Penalties for failure to perform the act or file the notification or Report shall not begin to accrue until one day after Collis 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 Collis 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. A written request may be submitted in either hard copy or electronic format.

**C. Payment of Stipulated Penalties**

1. Demand Letter. Upon a finding that Collis 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 Collis of: (a) Collis's failure to comply; and

(b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

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

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

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

**D. Exclusion for Material Breach of this Agreement**

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

- a. a failure by Collis to report a Reportable Event, take corrective action and make the appropriate refunds, as required in Section III.I;
- b. a repeated or flagrant violation of the obligations under this Agreement, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or

d. a failure to conduct an Arrangements Review in accordance with Section III.F.

2. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this Agreement by Collis constitutes an independent basis for Collis's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Collis has materially breached this Agreement and that exclusion is the appropriate remedy, OIG shall notify Collis of: (a) Collis's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. Opportunity to Cure. Collis 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. Collis is in compliance with the obligations of the Agreement cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Collis has begun to take action to cure the material breach; (ii) Collis is pursuing such action with due diligence; and (iii) Collis has provided to OIG a reasonable timetable for curing the material breach.

4. Exclusion Letter. If at the conclusion of the 30-day period, Collis fails to satisfy the requirements of Section X.D.3, OIG may exclude Collis from participation in the Federal health care programs. OIG shall notify Collis in writing of its determination to exclude Collis (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 Collis's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Collis 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 Collis of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this Agreement, Collis shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this Agreement. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this Agreement shall be: (a) whether Collis is in full and timely compliance with the obligations of this Agreement for which OIG demands payment; and (b) the period of noncompliance. Collis shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this Agreement and orders Collis to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Collis requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

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

- a. whether Collis were in material breach of this Agreement;
- b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30 day period, but that: (i) Collis had begun to take action to cure the material breach within that period; (ii) Collis has pursued and are pursuing such action with due diligence; and (iii) Collis provided to OIG within that period a reasonable timetable for curing the material breach and Collis have 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 Collis, only after a DAB decision in favor of OIG. Collis's election of their contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Collis 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 Collis 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. Collis shall waive their right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Collis, Collis shall be reinstated effective on the date of the original exclusion.

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

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

Consistent with the provisions in the Settlement Agreement pursuant to which this Agreement is entered. Collis and OIG agree as follows:

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

B. The obligations set forth in this Agreement are binding on Collis in his individual capacity and will continue in full force and effect, notwithstanding if he leaves one or all of the Practices.

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

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

E. OIG may agree to a suspension of Collis's obligations under this Agreement in the event of Collis's cessation of participation in Federal health care programs. If Collis withdraws from participation in Federal health care programs and is relieved of their Agreement obligations by OIG, Collis shall notify OIG 30 days in advance of Collis's intent to reapply as a participating provider or supplier with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the Agreement shall be reactivated or modified.

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

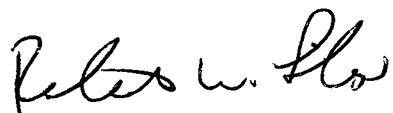
G. The undersigned Collis signatories represent and warrant that they are authorized to execute this Agreement. The undersigned OIG signatory represents that he is signing this Agreement in his official capacity and that he is authorized to execute this Agreement.

IN WITNESS WHEREOF, the parties hereto affix their signatures:

**ON BEHALF OF HERCULES S. COLLIS, M.D.**

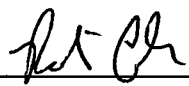
  
\_\_\_\_\_  
HERCULES S. COLLIS, M.D.

12-1-7  
Date

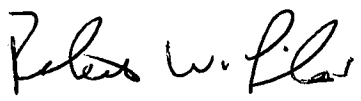
  
\_\_\_\_\_  
ROBERT W. LILES  
Liles Parker  
440 MacArthur Blvd., N.W.  
Suite 203  
Washington, D.C. 20007

12/1/07  
Date

**ON BEHALF OF KENTUCKY REHABILITATION INSTITUTE AND  
INTERVENTION REHABILITATION KENTUCKY, P.S.C.**

  
\_\_\_\_\_  
HERCULES S. COLLIS, M.D.

12-17  
Date

  
\_\_\_\_\_  
ROBERT W. LILES  
Liles Parker  
440 MacArthur Blvd., N.W., Suite 203  
Washington, D.C. 20007

12/1/07  
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 Counsel to the Inspector General  
Office of Inspector General  
U. S. Department of Health and Human Services

12/19/07  
Date



## **APPENDIX A**

### **ARRANGEMENTS DATABASE**

Collis shall create and maintain an Arrangements Database to track all new and existing Arrangements in order to ensure that each Arrangement does not violate the Anti-Kickback Statute and Stark Law. The Arrangements Database shall contain certain information to assist Collis in evaluating whether each Arrangement violates the Anti-Kickback Statute and Stark Law, including but not limited to the following:

1. Each party involved in the Arrangement;
2. The type of Arrangement (e.g., physician employment contract, medical directorship, lease agreement);
3. The term of the Arrangement, including the effective and expiration dates and any automatic renewal provisions;
4. The amount of compensation to be paid pursuant to the Arrangement and the means by which compensation is paid;
5. The methodology for determining the compensation under the Arrangements, including the methodology used to determine the fair market value of such compensation;
6. Whether the amount of compensation to be paid pursuant to the Arrangement is determined based on the volume or value of referrals between the parties;
7. Whether each party has fulfilled the requirements of Section III.E.2; and
8. Whether the Arrangement satisfies the requirements of an Anti-Kickback Statute safe harbor and/or a Stark Law exception or safe harbor, as applicable.

## APPENDIX B

### OVERPAYMENT REFUND

<b><u>TO BE COMPLETED BY MEDICARE CONTRACTOR</u></b>	
Date: _____	Date of Deposit: _____
Contractor Deposit Control # _____	Phone # _____
Contractor Contact Name: _____	
Contractor Address: _____	
Contractor Fax: _____	

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

#### **REFUND INFORMATION**

**For each Claim, provide the following:**

Patient Name \_\_\_\_\_ HIC # \_\_\_\_\_

Medicare Claim Number \_\_\_\_\_ Claim Amount Refunded \$ \_\_\_\_\_

Reason Code for Claim Adjustment: \_\_\_\_\_ (Select reason code from list below. Use one reason per claim)

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

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

**For Institutional Facilities Only:**

Cost Report Year(s) \_\_\_\_\_

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

**For OIG Reporting Requirements:**

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

**Reason Codes:**

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