

**INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
WILLIAM HENDRICKSON**

**I. PREAMBLE**

William Hendrickson hereby enters into this Integrity Agreement (Agreement) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, program requirements, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). This commitment to promote compliance applies to William Hendrickson and any entity that Hendrickson owns or in which Hendrickson has a control interest (collectively “Hendrickson”), as defined in 42 U.S.C. § 1320a-3(a)(3), and Hendrickson’s and any such entity’s Covered Persons, as defined in Section II.C. Contemporaneously with this Agreement, Hendrickson is entering into a Settlement Agreement with the United States, and this Agreement is incorporated by reference into the Settlement Agreement.

**II. TERM OF THE AGREEMENT**

A. The date on which the final signatory of this Agreement executes this Agreement shall be known as the Effective Date. The period of compliance obligations assumed by Hendrickson under this Agreement shall be three years from the Effective Date. Each one-year period beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days from OIG’s receipt of: (1) Hendrickson’s final Annual Report; or (2) any additional materials submitted by Hendrickson pursuant to OIG’s request, whichever is later.

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

1. "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 Hendrickson or a health care provider or supplier with whom Hendrickson consults, is employed, or contracts (hereafter, Subject Health Care Entity), and any actual or potential source of health care business or referrals to a Subject Health Care Entity or any actual or potential recipient of health care business or referrals from Subject Health Care Entity. 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 Subject Health Care Entity and a physician (or a physician's immediate family member (as defined at 42 C.F.R. § 411.351)) who makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to Subject Health Care Entity for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).
2. "Covered Persons" includes:
  - a. William Hendrickson and all owners, officers, directors, associates, and employees of Hendrickson; and
  - b. all contractors, agents, and other persons who perform billing or coding functions on behalf of Hendrickson or who provide assistance, advice, or consulting services to individuals or entities on behalf of Hendrickson concerning: (1) the provision of health care under Medicare, Medicaid, or any other Federal health care program, as defined by 42 U.S.C. § 1320a-7b(f); or (2) the negotiation, implementation, or management of Arrangements.
3. "Covered Person Date" is the date on which Hendrickson first hires, contracts, or otherwise associates with a Covered Person, other than William Hendrickson himself.
4. "Consulting Activities" includes any and all services and activities provided by Hendrickson as a consultant, except for giving speeches to audiences of ten or more persons.

5. "Client" is an individual or entity with whom Hendrickson enters into a contract, arrangement, engagement, or other agreement to provide Consulting Activities.
6. "Employment Date" is the date that William Hendrickson accepts a position as an officer at any Health Care Entity during the term of the Agreement.

### III. INTEGRITY OBLIGATIONS

Hendrickson shall establish and maintain a Compliance Program that includes the following elements.

#### A. Compliance Contact

**Hendrickson warrants that on the Effective Date there are no Covered Persons other than himself.**

Within 30 days after the Covered Person Date, Hendrickson shall designate a person to be responsible for compliance activities (Compliance Contact). Hendrickson shall then 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 Hendrickson's day-to-day compliance activities; and (3) meeting all reporting obligations created under this Agreement.

Hendrickson shall report to OIG, in writing, the establishment of the Compliance Contact, 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 event. The name, address, phone number, and a description of any other job responsibilities performed by the Compliance Contact shall be included in the Annual Report following the Covered Person Date and all subsequent Annual Reports.

**B. Posting and Provision of Notice**

**Hendrickson warrants that on the Effective Date there are no Covered Persons other than himself.**

Within 30 days after the Covered Person Date Hendrickson shall post in a prominent place in his office accessible to all clients and Covered Persons a notice detailing his commitment to comply with all Federal health care program requirements in the conduct of his business. In the event that Hendrickson does not have an office, Hendrickson may satisfy this requirement by providing a copy of the notice to all Covered Persons. However, within 15 days of acquiring an office after the Covered Person Date, Hendrickson shall post the notice as required above.

This notice shall include the following information: (i) a means (*e.g.*, telephone number or address) by which Arrangements concerns and other issues may be reported anonymously; (ii) Hendrickson'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 Hendrickson.

This notice shall 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 first Annual Report after the Covered Person Date.

**C. Written Policies and Procedures**

**Hendrickson warrants that on the Effective Date there are no Covered Persons other than himself.**

Within 30 days after the Covered Person Date Hendrickson shall develop, implement, and distribute written Policies and Procedures to all Covered Persons. In addition, Hendrickson 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. Hendrickson's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;
2. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute) and 42 U.S.C. § 1395nn (Stark Law), and the regulations and other guidance documents related to these statutes, and business or financial arrangements or contracts that generate unlawful Federal health care program business in violation of the Anti-Kickback Statute or the Stark Law;
3. the expectation that all of Hendrickson's Covered Persons shall be expected to comply with all Federal health care program requirements, the Anti-Kickback Statute, the Stark Law, and with Hendrickson's own written Policies and Procedures as implemented pursuant to this Section III.C (including the requirements of this Agreement);
4. the responsibility and requirement that all Covered Persons report suspected violations of any Federal health care program requirements, the Anti-Kickback Statute, the Stark Law, or Hendrickson's own Policies and Procedures to the Compliance Contact and Hendrickson's commitment to maintain confidentiality and anonymity, as appropriate, and not to retaliate with respect to such disclosures;
5. the possible consequences to both Hendrickson and Covered Persons of failure to comply with Federal health care program requirements, the Anti-Kickback Statute, the Stark Law, or with Hendrickson's written Policies and Procedures and the failure to report such noncompliance; and
6. Hendrickson's commitment to remain current with all Federal health care program requirements.

Within 30 days after the Covered Person Date each Covered Person shall certify in writing that he or she has received, read, understood, and shall abide by Hendrickson'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.

At least annually (and more frequently if appropriate), Hendrickson 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**

**Hendrickson warrants that on the Effective Date there are no Covered Persons other than himself.**

1. General Training. Within 90 days after the Covered Person Date, each Covered Person shall receive at least one hour of General Training.

General Training, at a minimum, shall cover the following topics:

- a. the requirements of Hendrickson's Agreement;
- b. an overview of Hendrickson's compliance program; and
- c. the written Policies and Procedures developed pursuant to Section III.C, above.

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 90 days after the Covered Person Date, whichever is later. After receiving the initial General Training, described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period. The General Training shall be provided by an individual or entity knowledgeable in the subject area other than a Covered Person, and may be received from a variety of sources.

2. Specific Training. Within 90 days after the Effective Date, each Covered Person shall receive at least three hours of Specific Training in addition to the General Training required above. The Specific Training shall be provided by an individual or entity knowledgeable in the subject area other than a Covered

Person, and may be received from a variety of sources (e.g., CME classes, hospitals, associations, Medicare contractors).

This specific training shall include a discussion of:

- a. Arrangements that potentially implicate the Anti-Kickback Statute or the Stark Law, as well as the regulations and other guidance documents related to these statutes;
- b. Hendrickson's policies, procedures, and other requirements relating to Arrangements, as applicable;
- c. the personal obligation of each individual involved in the development, approval, management, or review of Arrangements to know the applicable legal requirements and Hendrickson's policies and procedures;
- d. the legal sanctions under the Anti-Kickback Statute and the Stark Law; and
- e. examples of violations of the Anti-Kickback Statute and the Stark Law.

Covered Persons shall receive this training within 30 days after the beginning of their employment. A Hendrickson employee who has completed the Specific Training shall review a new Covered Person's work, to the extent that the work relates to the delivery of patient care items or services and/or the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Covered Person completes his or her Specific Training

After receiving the initial Specific Training, each Covered Person shall receive at least two hours of Specific Training in each subsequent Reporting Period. The Compliance Contact or, prior to the Covered Person Date, Hendrickson shall annually review the training, and where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during Claims Reviews and any other relevant information.

3. Certification. Each individual that is required to receive training shall certify in writing, or in electronic form if the training is computerized, that he or she has received the required training. The certification shall specify the type of training

received and the date received. The Compliance Contact, or prior to the Covered Person Date, Hendrickson shall retain the certifications along with all training materials. The training materials shall be provided in the Implementation Report, and to the extent the training is revised, shall also be included in the Annual Reports. The certifications shall be made available to OIG, upon request.

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

5. Update of Training. Hendrickson 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 preparation of the Annual Report, and any other relevant information.

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

**E. Review Procedures**

1. Within 15 days after Hendrickson enters into a contract, arrangement, or other agreement with a Client, Hendrickson shall inform OIG and provide OIG with the name of a person at the Client who can provide information to OIG regarding the services Hendrickson is providing for the Client.

2. The terms of Appendix A shall immediately go into effect on the Employment Date.

**F. Ineligible Persons**

1. Definitions. For purposes of this Agreement:

- a. An "Ineligible Person" shall include an individual or entity who: (i) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal

procurement or nonprocurement programs; or (ii) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

- b. "Exclusion Lists" include: (i) the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://oig.hhs.gov>); and (ii) the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.gov>).
- c. "Screened Persons" include William Hendrickson and all prospective and current owners, officers, directors, employees, associates, contractors, and agents of Hendrickson.

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

- a. Hendrickson 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 Screened Persons to disclose whether they are an Ineligible Person.
- b. Hendrickson shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.
- c. Hendrickson 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.

Hendrickson shall maintain documentation demonstrating that: (1) he has checked the Exclusion Lists (*e.g.*, print screens from search results) and determined that the Screened Persons are not Ineligible Persons; and (2) has required the Screened Persons to disclose if they are Ineligible Persons (*e.g.*, on employment applications).

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

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

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

**G. Notification of Government Investigation or Legal Proceedings**

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

## **H. Reporting**

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

2. Reporting of Reportable Event. If Hendrickson determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Hendrickson 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:

- a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- b. a description of Hendrickson’s actions taken to correct the Reportable Event; and
- c. any further steps Hendrickson plans to take to address the Reportable Event and prevent it from recurring.

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

In the event that, after the Effective Date, Hendrickson 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, Hendrickson 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, and fax number. Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements in this Agreement.

## V. REPORTS

### A. Implementation Report

Within 120 days after the Effective Date, Hendrickson 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 name, location, and relationship of each Client, and a description of Hendrickson's responsibilities thereunder;
2. 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;
3. a list of all Hendrickson's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers;
4. if the Covered Person Date has occurred within 90 days after the Effective Date, the following information:
  - a. 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;
  - b. a copy of the notice Hendrickson posted in its office or provided to Covered Persons as required by Section III.B, and, as applicable, a description of where the notice is posted, and the date the notice was posted;
  - c. a copy of the written Policies and Procedures required by Section III.C and the date these Policies and Procedures were implemented and distributed;
  - d. a description of Hendrickson's process to screen Covered Persons to determine if they are ineligible; and

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

5. if the Covered Person Date has occurred within 90 days after the Effective Date, 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;

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 Covered Persons that were hired or engaged since the execution of the Agreement were screened against the Exclusion Lists and asked to disclose if they are excluded, debarred, suspended, or are otherwise considered an Ineligible Person, prior to entering into their relationship with Hendrickson, as required by Section III.F; and

d. all current Covered Persons of Hendrickson were screened against the Exclusion Lists within 90 days after the Effective Date of this Agreement, as required by Section III.F and the date(s) of the screening;

6. if the Employment Date has occurred within 90 days after the Effective Date, the following information:

a. the name and qualifications of the IRO, a summary/description of all engagements between Hendrickson and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, and the proposed start and completion dates of the first annual Work Review;

- b. a copy of the IRO's engagement letter, including the length of the engagement; and
  - c. a certification from the IRO regarding its professional independence and/or objectivity with respect to Hendrickson;
7. a certification signed by Hendrickson certifying that: (a) to the best of his knowledge, except as otherwise described in the Implementation Report, Hendrickson is in compliance with all of the requirements of this Agreement; and (b) Hendrickson has reviewed the Implementation Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful.

**B. Annual Reports**

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

Each Annual Report shall, at a minimum, include:

1. for Subject Health Care Entities reimbursed by Federal health care programs, Hendrickson shall inform OIG of the name, location, relationship, and Hendrickson's responsibilities with respect to Hendrickson's employment or contract;
2. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
3. a summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;
4. a description of all changes to the most recently provided list of Hendrickson's locations (including addresses) as required by Section IV, including the corresponding phone numbers and fax numbers;

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. if applicable, 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;
7. if the Covered Person Date has occurred at least 30 days prior to the Reporting Date or earlier, the following information:
  - a. any change in the name, address, phone number, or job responsibilities of Hendrickson's Compliance Contact;
  - b. any changes to the posted notice and the reason for such changes;
  - c. a copy of any new compliance-related Policies and Procedures; and
  - d. 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);
8. if the Covered Person Date has occurred at least 90 days prior to the Reporting Date or earlier, a certification from the Compliance Contact 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 of this Agreement and that all Covered Persons have executed the applicable training certification(s) in accordance with the timeframe required by Section III.D;

c. all owners, officers, directors, associates, employees, contractors, and agents that were hired, engaged or otherwise involved with Hendrickson 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 Hendrickson, as required by Section III.F; and

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

9. if the Employment Date has occurred at least 30 days prior to the end of the Reporting Period or earlier, the following information:

a. if applicable, a complete copy of the Work Review Report prepared pursuant to the terms of Appendix A;

b. if applicable, the response and corrective action plan(s) related to any issues raised or recommendations made by the IRO, as a result of the Work Review performed pursuant to Appendix A;

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

d. a certification from the IRO regarding its professional independence and/or objectivity to Hendrickson;

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

The first Annual Report shall be received by OIG no later than 60 days after the

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

**C. Designation of Information**

Hendrickson shall clearly identify any portions of its submissions 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. Hendrickson shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

**VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

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

OIG: Administrative and Civil Remedies Branch  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue, SW  
Washington, DC 20201  
Telephone: (202) 619-2078  
Facsimile: (202) 205-0604

Hendrickson: Michael Monico, Esq.  
Monico, Pavich & Spevack  
20 South Clark Street, Suite 700  
Chicago, IL 60603-1894  
Telephone: (312) 782-8500  
Facsimile: (312) 759-2000

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,

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

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

Hendrickson shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this Agreement, for four 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 Hendrickson prior to any release by OIG of information submitted by Hendrickson pursuant to its obligations under this Agreement and identified upon submission by Hendrickson as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Hendrickson shall have the rights set forth at 45 C.F.R. § 5.65(d).

**X. BREACH AND DEFAULT PROVISIONS**

Hendrickson is expected to fully and timely comply with all of its Agreement obligations.

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

As a contractual remedy, Hendrickson 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 Hendrickson 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; and
- d. establish and implement a training program in accordance with the requirements of Section III.D.
- e. engage an IRO in accordance with the requirements of Appendix A;
- f. submit reports in accordance with the requirements of Appendix A;
- 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.F.2.

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

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

2. A Stipulated Penalty of \$1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Hendrickson 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 Hendrickson fails to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Hendrickson fails to grant access.)

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

5. A Stipulated Penalty of \$750 for each day Hendrickson fails to comply fully and adequately with any obligation of this Agreement. OIG shall provide notice (Notice) to Hendrickson stating the specific grounds for its determination that Hendrickson has failed to comply fully and adequately with the Agreement obligation(s) at issue and steps Hendrickson shall take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date Hendrickson 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**

Hendrickson 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 Hendrickson 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 Hendrickson receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

**C. Payment of Stipulated Penalties.**

1. Demand Letter. Upon a finding that Hendrickson 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 Hendrickson of: (a) Hendrickson'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, Hendrickson 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 Hendrickson elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Hendrickson 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 Hendrickson 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 Hendrickson to report a Reportable Event, take corrective action and make the appropriate refunds, as required in Section III.H;
- b. a repeated or flagrant violation of the obligations under this Agreement, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to engage and use an IRO in accordance with Appendix A.

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

4. Exclusion Letter. If at the conclusion of the 30-day period, Hendrickson fails to satisfy the requirements of Section X.D.3, OIG may exclude Hendrickson from participation in the Federal health care programs. OIG shall notify Hendrickson in writing of its determination to exclude Hendrickson (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 Hendrickson'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, Hendrickson 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 Hendrickson 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, Hendrickson 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 Hendrickson was in full and timely compliance with the obligations of this Agreement for which OIG demands payment; and (b) the period of noncompliance. Hendrickson 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 Hendrickson to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Hendrickson 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 Hendrickson was 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) Hendrickson had begun to take action to cure the material breach within that period; (ii) Hendrickson has pursued and is pursuing such action with due diligence; and (iii) Hendrickson provided to OIG within that period a reasonable timetable for curing the material breach and Hendrickson has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Hendrickson, only after a DAB decision in favor of OIG. Hendrickson's election of his contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Hendrickson 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 Hendrickson 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. Hendrickson shall waive his 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 Hendrickson, Hendrickson shall be reinstated effective on the date of the original exclusion.

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

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

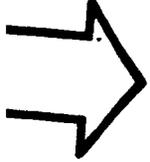
Consistent with the provisions in the Settlement Agreement pursuant to which this Agreement is entered, and into which this Agreement is incorporated, Hendrickson and OIG agree as follows:

- A. This Agreement shall be binding on the successors, assigns, and transferees of Hendrickson;
- B. This Agreement shall become final and binding on the date the final signature is obtained on the Agreement;
- C. Any modifications to this Agreement shall be made with the prior written consent of the parties to this Agreement;
- D. All requirements and remedies set forth in this Agreement are in addition to, and do not effect, (1) Hendrickson'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.

E. The undersigned Hendrickson 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.

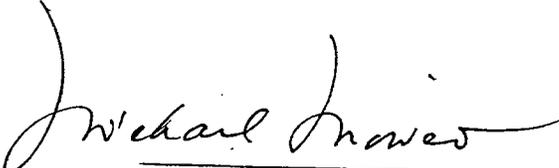
IN WITNESS WHEREOF, the parties hereto affix their signatures:

**WILLIAM HENDRICKSON**



  
William Hendrickson  
280 Banberg Drive  
Bluffton, S.C. 29910

6-9-05  
Date

  
Michael Monico, Esq.  
Monico, Pavich & Spevack  
Counsel for Hendrickson

6.8.05  
Date

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



\_\_\_\_\_  
Lewis Morris  
Chief Counsel to the Inspector General  
Office of Counsel to the Inspector General  
Office of Inspector General  
U. S. Department of Health and Human Services



\_\_\_\_\_  
Date

**HENDRICKSON INTEGRITY AGREEMENT  
APPENDIX A**

**I. IRO Review Procedures.**

**The provisions in this Appendix shall take effect on the Employment Date.**

**A. General Description.**

1. *Engagement of Independent Review Organization.* Within 30 days after the Employment Date, Hendrickson 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 Hendrickson in assessing his compliance with the Anti-Kickback Statute and Stark Law and certain other obligations pursuant to this Agreement (Arrangements Review). The IRO engaged by Hendrickson to perform the Arrangements Review shall have expertise in the Anti-Kickback Statute, Stark Law, and in the general requirements of the Federal health care programs from which the Subject Health Care Entity employing Hendrickson (Employer) seeks reimbursement.

The IRO shall assess, along with Hendrickson, whether it can perform the IRO review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist. The engagement of the IRO for the Arrangements Review shall not be deemed to create an attorney-client relationship between Hendrickson and the IRO. The other applicable requirements relating to the IRO(s) are outlined in Attachment 1 to this Appendix, which is incorporated by reference.

2. *Work Plan.* The IRO shall draw up a work plan annually prior to conducting its engagement, which shall be designed to address and review Hendrickson's work for the Employer for compliance with Federal health care program requirements, with a particular emphasis on compliance with the Stark Law and Anti-Kickback Statute (hereafter Work Review). The work plan shall be submitted to OIG for its approval no later than 60 days after the Employment Date and prior to the IRO beginning its engagement in subsequent Reporting Period(s). Within 30 days of receipt, OIG shall approve the work plan, requiring such revisions as necessary. However, any comments or recommendations made by the OIG in connection with a review of the submitted work plan(s) will not preclude the OIG from making further comments or recommendations for future workplan(s) after reviewing the applicable IRO report(s).

3. *Frequency of Work Review.* The Work Review shall be performed annually and shall cover each of the Reporting Periods (the first Reporting Period of the Work Review shall be considered to begin on the Employment Date and continue to the end of the current Reporting Period). The IRO shall perform all components of each annual Work Review.

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

4. *Responsibilities and Liabilities.* Nothing in this Appendix A affects Hendrickson'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.

B. Work Review Report. The IRO shall prepare a report based upon the Work Review performed (Work Review Report). The Work Review Report shall include the IRO's findings with respect to whether Hendrickson has complied with Federal health care program requirements, the Stark Law, and the Anti Kickback Statute. In addition, the Work Review Report shall include any observations, findings, and recommendations on possible improvements.

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

## II. VALIDATION REVIEW

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

Prior to initiating a Validation Review, OIG shall notify Hendrickson of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Hendrickson may request a meeting with OIG to: (a) discuss the results of any Work Review submissions or findings; (b) present any additional or relevant information to clarify the results of the Work Review or to correct the inaccuracy of the Work Review; and/or (c) propose alternatives to the proposed Validation Review. Hendrickson agrees to provide any additional information requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Claims Review issues with Hendrickson prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

## ATTACHMENT 1 TO APPENDIX A INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Appendix A of the Agreement. The provisions in this Appendix shall take effect on the Employment Date.

### A. IRO Engagement.

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

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

### B. IRO Qualifications.

The IRO shall:

1. assign individuals to develop the Work Plan and conduct the Work Review engagement who have expertise in Stark Law and Anti-Kickback Statute, and in the general requirements of the Federal health care program(s) from which Hendrickson's Employer seeks reimbursement;
2. have sufficient staff and resources to conduct the Work Review on a timely basis.

### C. IRO Responsibilities.

The IRO shall:

1. Conduct the Work Review in Accordance with the Work Plan after receiving approval of the Work Plan from the OIG;

2. follow all Federal health care rules and requirements regarding Arrangements and reimbursement, including rules and guidance published by the OIG concerning the Stark Law and the Anti-Kickback Statute;
3. if in doubt of the application of a particular Medicare policy or regulation, request clarification from the appropriate authority (e.g., fiscal intermediary, carrier, or program safeguard contractor);
4. respond to all OIG inquiries in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix A.

D. IRO Independence/Objectivity.

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

E. IRO Removal/Termination.

1. *Provider.* If Hendrickson terminates its IRO during the course of the engagement, Hendrickson must submit a notice explaining its reasons to OIG no later than 30 days after termination. Hendrickson shall engage a new IRO in accordance with Paragraph A of this Attachment.
2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Hendrickson to engage a new IRO in accordance with Paragraph A of this Attachment.

Prior to requiring Hendrickson to engage a new IRO, OIG shall notify Hendrickson of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Hendrickson may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence, or performance of its responsibilities and to present additional information regarding these matters. Hendrickson shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Hendrickson prior to requiring Hendrickson to terminate

the IRO. However, the final determination as to whether or not to require Hendrickson to engage a new IRO shall be made at the sole discretion of OIG.