

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
TUOMEY D/B/A TUOMEY HEALTHCARE SYSTEM**

I. PREAMBLE

Tuomey d/b/a Tuomey Healthcare System hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, Tuomey is entering into a Settlement Agreement with the United States.

For purposes of this CIA, “Tuomey” is defined to include Tuomey Healthcare System, the Tuomey Regional Medical Center, the Tuomey Healthcare System outpatient surgical center, and any ambulatory surgical center(s) that the Tuomey Healthcare System operates now or in the future. Prior to execution of this CIA, Tuomey voluntarily established a Compliance Program that applies to all Tuomey subsidiaries and facilities. Tuomey agrees that it shall maintain the Compliance Program during the term of the CIA in a manner that meets the CIA’s requirements. Tuomey may modify the Compliance Program as appropriate; however, any such modification of the Compliance Program must meet the requirements of the CIA.

II. TERM AND SCOPE OF THE CIA

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

C. The scope of this CIA 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 Tuomey and any actual or potential source of health care business or referrals to Tuomey or any actual or potential recipient of health care business or referrals from Tuomey. The term “source of health care business or referrals” shall mean any individual or entity that refers, recommends, arranges for, orders, leases, or purchases any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program and the term “recipient of health care business or referrals” shall mean any individual or entity: (1) to whom Tuomey refers an individual for the furnishing or arranging for the furnishing of any item or service; or (2) from whom Tuomey purchases, leases, or orders or arranges for or recommends the purchasing, leasing, or ordering 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 Tuomey 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 Tuomey for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).
2. “Focus Arrangements” means every Arrangement that:
 - a. is between Tuomey and any actual source of health care business or referrals to Tuomey and involves, directly or indirectly, the offer, payment, or provision of anything of value;
 - b. is between Tuomey and any 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 Tuomey for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)); or

- c. is between Tuomey and any physician (or a physician's immediate family member) or medical practice that involves, directly or indirectly, the offer, payment, or provision of anything of value in anticipation of that physician becoming an actual source of health care business or referrals (*e.g.*, for purposes of recruitment).

Notwithstanding the foregoing provisions of Section II.C.2, any Arrangement that satisfies the requirements of 42 C.F.R. § 411.356 (ownership or investment interests); 42 C.F.R. § 411.357(g) (remuneration unrelated to the provision of designated health services); 42 C.F.R. § 411.357(i) (payments by a physician for items and services); 42 C.F.R. § 411.357(k) (non-monetary compensation); 42 C.F.R. § 411.357(m) (medical staff incidental benefits); 42 C.F.R. § 411.357(o) (compliance training); 42 C.F.R. § 411.357(q) (referral services); 42 C.F.R. § 411.357(s) (professional courtesy); 42 C.F.R. § 357(u) (community-wide health information systems); or any exception to the prohibitions of 42 U.S.C. § 1395nn enacted following the Effective Date that does not require a written agreement shall not be considered a Focus Arrangement for purposes of this CIA.

- 3. "Covered Persons" includes:
 - a. all owners, officers, directors, and employees of Tuomey;
 - b. all contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Tuomey, excluding vendors whose sole connection with Tuomey is selling or otherwise providing medical supplies or equipment to Tuomey and who do not bill the Federal health care programs for such medical supplies or equipment; and
 - c. all physicians and other non-physician practitioners who are members of Tuomey's active medical staff.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours during a Reporting Period, except that any such

individuals shall become “Covered Persons” at the point when they work more than 160 hours during a Reporting Period.

4. “Arrangements Covered Persons” includes:
 - a. each Covered Person who is involved with the development, approval, management, or review of Tuomey’s Arrangements; and
 - b. each member of Tuomey’s Board of Directors.

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Responsibilities of Certain Tuomey Employees and the Board of Directors

1. *Compliance Officer.* Within 120 days after the Effective Date, Tuomey shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be an employee and a member of senior management of Tuomey, shall report directly to the Chief Executive Officer of Tuomey, and shall not be or be subordinate to the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Tuomey. The Compliance Officer shall be responsible for, without limitation:

- a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements;
- b. making periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Tuomey, and shall be authorized to independently report on such matters to the Board of Directors at any time. Written documentation of the Compliance Officer’s reports to the Board of Directors shall be made available to OIG upon request; and

- c. monitoring the day-to-day compliance activities engaged in by Tuomey as well as for any reporting obligations created under this CIA.

Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

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

2. *Compliance Committee.* Within 120 days after the Effective Date, Tuomey shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (*e.g.*, senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee, and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (*e.g.*, shall assist in the analysis of Tuomey's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

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

3. *Board of Directors Compliance Obligations.* The Board of Directors (or a committee of the Board) of Tuomey (Board) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA. The Board must include independent (*i.e.*, non-executive) members.

The Board shall, at a minimum, be responsible for the following:

- a. meeting at least quarterly to review and oversee Tuomey's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. submitting to the OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third-party resources, in its oversight of the Compliance Program and in support of making the resolution below during each Reporting Period;
- c. for the first, third, and fifth Reporting Periods, considering the results of the Compliance Program Reviews (as described in Section III.A.4.a.v of this CIA); and
- d. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board summarizing its review and oversight of Tuomey's compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

“The Board of Directors has made a reasonable inquiry into the operations of Tuomey's Compliance Program including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Tuomey has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA.”

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at Tuomey.

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

4. *Board Compliance Expert.* Within 120 days after the Effective Date, the Board shall retain an expert in corporate governance and compliance (Compliance Expert) to assist the Board in fulfilling the responsibilities described in Section III.A.3 of this CIA.

- a. Compliance Expert Obligations. At a minimum, the Compliance Expert shall:
 - i. attend each Board meeting at which the Compliance Officer is scheduled to present;
 - ii. be kept apprised of any direct reports that the Compliance Officer otherwise makes to the Board;
 - iii. assist the Board in reviewing and assessing Tuomey's Compliance Program;
 - iv. offer recommendations periodically, as appropriate, to improve the effectiveness of Tuomey's Compliance Program; and
 - v. for the first, third, and fifth Reporting Periods, conduct a comprehensive review of the effectiveness of Tuomey's Compliance Program and prepare a report describing the results of such review (Compliance Program Review Report). A copy of the Compliance Program Review Report shall be provided to OIG along with the Annual Report for the applicable Reporting Period.

- b. Engagement of Compliance Expert. Within 30 days of the Board engaging the Compliance Expert, Tuomey shall provide the following information to OIG:
 - i. the identity, address, and phone number of the Compliance Expert;
 - ii. a copy of the engagement letter between the Board and the Compliance Expert;

- iii. information demonstrating that the Compliance Expert has the background and qualifications necessary to assist the Board in fulfilling the responsibilities described in Section III.A.3 of this CIA; and
- iv. a certification from the Compliance Expert that neither he or she nor his or her firm:
 - 1. has previously represented or been employed or engaged by Tuomey; or
 - 2. has a relationship to Tuomey or its employees, officers, or directors that would cause a reasonable person to question the Compliance Expert's impartiality.

Within 30 days of receiving the above information, or any additional information submitted by Tuomey in response to a request by OIG, whichever is later, OIG will notify Tuomey if the Compliance Expert is unacceptable. Absent notification from OIG that the Compliance Expert is unacceptable, the Board may continue to engage the Compliance Expert.

If a new Compliance Expert is engaged, Tuomey shall submit the above information to OIG within 30 days of engagement of the Compliance Expert. Within 30 days after receiving this information or any additional information submitted by Tuomey at the request of OIG, whichever is later, OIG will notify Tuomey if the Compliance Expert is unacceptable. Absent notification from OIG that the Compliance Expert is unacceptable, the Board may continue to engage the Compliance Expert.

5. *Management Accountability and Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Tuomey officers or employees (Certifying Employees) are specifically expected to monitor and oversee activities within the hospital and shall certify annually that the areas under their authority are compliant with applicable Federal health care program requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: the Chief Executive Officer, the Chief Financial Officer, the Chief Operating Officer, the Chief Medical Officer, the Chief Nursing Officer, and any other employees of Tuomey with the title of Vice President or higher.

For each Reporting Period, each Certifying Employee shall sign a certification that states as follows:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [department or functional area], an area under my supervision. My job responsibilities include ensuring that the [department or functional area] remains compliant with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and Tuomey Policies and Procedures, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the [department or functional area] of Tuomey is in compliance with all applicable Federal health care program requirements and the obligations of the CIA. I understand that this certification is being provided to and relied upon by the United States.”

If any Certifying Employee is unable to provide such a conclusion in the certification, he or she shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above and the steps being taken to address the issues identified.

Within 120 days after the Effective Date, Tuomey shall develop and implement a written process for Certifying Employees to follow for the purpose of completing the certification required by this section (*e.g.*, reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc. prior to the Certifying Employee making the required certification).

B. Written Standards

1. *Code of Conduct.* Within 120 days after the Effective Date, Tuomey shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. Tuomey shall make the performance of job responsibilities in a manner consistent with the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

- a. Tuomey’s commitment to full compliance with all Federal health care program requirements;
- b. Tuomey’s requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Tuomey’s own Policies and Procedures;

- c. the requirement that all of Tuomey's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Tuomey, suspected violations of any Federal health care program requirements or of Tuomey's own Policies and Procedures; and
- d. the right of all individuals to use the Disclosure Program described in Section III.F, and Tuomey's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Tuomey certifies that the Code of Conduct shall apply to all subsidiaries and affiliates of Tuomey. Within 120 days after the Effective Date, each Covered Person shall certify, in writing or in electronic form, that he or she has received, read, understood, and shall abide by Tuomey's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. Tuomey shall distribute the Code of Conduct to all active medical staff members as described above and shall use its best efforts to encourage such active medical staff members to submit the required certification. The Compliance Officer shall maintain records indicating that the Code of Conduct was distributed to all active medical staff members and whether the certification was completed.

Tuomey shall review the Code of Conduct at least annually to determine if revisions are appropriate and shall make any necessary revisions based on such review. The Code of Conduct shall be distributed at least annually to all Covered Persons.

2. *Policies and Procedures.* Within 120 days after the Effective Date, Tuomey shall develop and implement written Policies and Procedures regarding the operation of its Compliance Program, including the compliance program requirements outlined in this CIA and Tuomey's compliance with Federal health care program requirements. At a minimum, the Policies and Procedures also shall address:

- a. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute) and 42 U.S.C. § 1395nn (Stark Law); 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; and

- b. the requirements set forth in Section III.D (Compliance with the Anti-Kickback Statute and Stark Law).

Within 120 days after the Effective Date, the Policies and Procedures shall be distributed to all Covered Persons whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures. Throughout the term of this CIA, Tuomey shall enforce and comply with its Policies and Procedures and shall make such compliance an element of evaluating the performance of all employees.

At least annually (and more frequently, if appropriate), Tuomey shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions or addition of new Policies and Procedures, a description of the revisions shall be communicated to all affected Covered Persons and any revised or new Policies and Procedures shall be made available to all Covered Persons.

C. Training and Education

1. *General Training.* Within 120 days after the Effective Date, Tuomey shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain Tuomey's:

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

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Arrangements Training.* Within 120 days after the Effective Date, each Arrangements Covered Person shall receive at least two hours of Arrangements Training, in addition to the General Training required above. The Arrangements 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. Tuomey's policies, procedures, and other requirements relating to Arrangements and Focus Arrangements, including but not limited to the Focus Arrangements Tracking System, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals required by Section III.D of the CIA;
- c. the personal obligation of each individual involved in the development, approval, management, or review of Tuomey's Arrangements to know the applicable legal requirements and Tuomey'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.

New Arrangements Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Arrangements Covered Persons, or within 120 days after the Effective Date, whichever is later. New Arrangements Covered Persons shall not develop, approve, manage, or review Tuomey's Arrangements until after they have completed the Arrangements Training.

After receiving the initial Arrangements Training described in this Section III.C.2, each Arrangements Covered Person shall receive at least two hours of Arrangements Training, in addition to the General Training, in each subsequent Reporting Period.

3. *Board Member Training.* Within 120 days after the Effective Date, Tuomey shall provide at least two hours of training to each member of the Board of Directors, in addition to the General Training and the Arrangements Training. This training shall address the corporate governance responsibilities of Board members, and the responsibilities of Board members with respect to review and oversight of the Compliance Program. Specifically, the training shall address the unique responsibilities of health care Board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be

conducted by the Compliance Expert and should include a discussion of the OIG's guidance on Board member responsibilities.

New members of the Board of Directors shall receive the Board Member Training described above within 30 days after becoming a member or within 120 days after the Effective Date, whichever is later.

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

5. *Qualifications of Trainer.* Persons preparing or providing the General Training shall be knowledgeable about the subject area. Persons preparing or providing the Arrangements Training shall have expertise in the Anti-Kickback Statute and Stark Law, as well as the regulations, directives, and guidance related to those laws.

6. *Update of Training.* Tuomey shall review its training annually, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits, the Arrangements Review, or the Compliance Program Review, and any other relevant information.

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

8. *Exception for Active Medical Staff Members.* Tuomey shall make the General Training described in this Section III.C available to all of Tuomey's active medical staff members and shall use its best efforts to encourage such active medical staff members to complete the training. The Compliance Officer shall maintain records of all active medical staff members who receive training, including the type of training and the date received. Notwithstanding this exception, any active medical staff member who is also a party to a Focus Arrangement must complete at least one hour of training regarding the Anti-Kickback Statute and the Stark Law and examples of arrangements that potentially implicate the Anti-Kickback Statute or the Stark Law.

D. Compliance with the Anti-Kickback Statute and Stark Law

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

- a. creating and maintaining a centralized tracking system for all existing and new or renewed Focus Arrangements (Focus Arrangements Tracking System);
- b. tracking remuneration to and from all parties to Focus Arrangements;
- c. tracking service and activity logs to ensure that parties to the Focus Arrangement are performing the services required under the applicable Focus 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 Focus Arrangement(s) (if applicable);
- e. establishing and implementing a written review and approval process for all Focus Arrangements, the purpose of which is to ensure that all new and existing or renewed Focus Arrangements do not violate the Anti-Kickback Statute and Stark Law, and that includes at least the following: (i) a legal review of all Focus Arrangements by counsel with expertise in the Anti-Kickback Statute and Stark Law, (ii) a process for specifying the business need or business rationale for all Focus Arrangements, and (iii) a process for determining and documenting the fair market value of the remuneration specified in the Focus Arrangement;
- f. requiring the Compliance Officer to review the Focus Arrangements Tracking System, internal review and approval process, and other Focus Arrangements Procedures on at least

an annual basis and to provide a report on the results of such review to the Compliance Committee; 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 Sections III.I and III.J when appropriate.

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

- a. ensure that each Focus Arrangement is set forth in writing and signed by Tuomey and the other parties to the Focus Arrangement;
- b. include in the written agreement a requirement that each party to a Focus Arrangement who meets the definition of a Covered Person shall complete the Arrangements Training required by Section III.C.2 of this CIA. Additionally, Tuomey shall provide each party to the Focus Arrangement with a copy of its Code of Conduct and Stark Law and Anti-Kickback Statute Policies and Procedures; and
- c. include in the written agreement a certification by the parties to the Focus Arrangement that the parties shall not violate the Anti-Kickback Statute and the Stark Law with respect to the performance of the Arrangement.

3. *Focus Arrangements Tracking System Verification and Certification.* For each Reporting Period, the Compliance Officer shall review the entries in Tuomey's Focus Arrangements Tracking System and certify in writing to OIG that, to the best of his or her knowledge, the Focus Arrangements Tracking System is complete and accurate, except for any discrepancies identified. The Compliance Officer shall provide an explanation for: (1) any Focus Arrangements found to have been missing from the Focus Arrangements Tracking System; and (2) any entries in the Focus Arrangements Tracking System found to have been incomplete or inaccurate.

4. *Records Retention and Access.* Tuomey shall retain and make available to OIG, upon request, the Focus Arrangements Tracking System and all supporting documentation of the Focus Arrangements subject to this Section III.D and, to the extent available, all non-privileged communications related to the Focus Arrangements and the actual performance of the duties under the Focus Arrangements.

E. Review Procedures

1. *General Description.*

- a. *Engagement of Legal Independent Review Organization.* Within 120 days after the Effective Date, Tuomey shall engage an entity (or entities) (hereinafter “Legal Independent Review Organization” or “Legal IRO”) to perform the reviews listed in this Section III.E. The applicable requirements relating to the Legal IRO are outlined in Appendix A to this CIA, which is incorporated by reference.
- b. *Retention of Records.* The Legal IRO and Tuomey shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the Legal IRO and Tuomey) related to the reviews.
- c. *Responsibilities and Liabilities.* Nothing in this Section III.E affects Tuomey’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 Legal IRO shall perform an Arrangements Review and prepare an Arrangements Review Report as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Validation Review.* In the event OIG has reason to believe that: (a) any Arrangements Review fails to conform to the requirements of this CIA; or (b) the Legal IRO’s findings or Arrangements Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Arrangements Review complied with the requirements of the CIA and/or the findings or Arrangements Review

results are inaccurate (Validation Review). Tuomey shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of an Arrangements Review submitted as part of Tuomey's final Annual Report shall be initiated no later than one year after Tuomey's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Tuomey in writing of its intent to do so and provide an explanation of the reasons OIG has determined a Validation Review is necessary. Tuomey shall have 30 days following the date of the OIG's written notice to submit a written response to OIG that includes any additional or relevant information to clarify the results of the Arrangements Review or to correct the inaccuracy of the Arrangements Review and/or propose alternatives to the proposed Validation Review. The final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

4. *Certification Regarding Legal IRO's Relationship to Tuomey.* The Legal IRO shall include in its report(s) to Tuomey a certification that the Legal IRO: (1) has not previously represented or been employed or engaged by Tuomey; and (2) does not have a relationship to Tuomey or its employees, officers, or directors that would cause a reasonable person to question the Legal IRO's impartiality.

F. Disclosure Program

Within 120 days after the Effective Date, Tuomey shall establish a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Tuomey's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Tuomey shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

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

should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Tuomey shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log and shall record each disclosure in the disclosure log within two business days of receipt of the disclosure. The disclosure log shall include a summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews.

G. Ineligible Persons

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

- a. an “Ineligible Person” shall include an individual or entity who:
 - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
 - ii. has been convicted of a criminal offense that falls within the scope 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 (LEIE) (available through the Internet at <http://www.oig.hhs.gov>); and
 - ii. the General Services Administration’s System for Award Management (SAM) (available through the Internet at <http://www.sam.gov>).

2. *Screening Requirements.* Tuomey shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. Tuomey shall screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.
- b. Tuomey shall screen all Covered Persons against the Exclusion Lists within 120 days after the Effective Date and thereafter shall screen against the LEIE on a monthly basis and screen against SAM on an annual basis.
- c. Tuomey shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

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

3. *Removal Requirement.* If Tuomey has actual notice that a Covered Person has become an Ineligible Person, Tuomey shall remove such Covered Person from responsibility for, or involvement with, Tuomey's business operations related to the Federal health care programs and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered 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 Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Tuomey has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)–(3), or is proposed for exclusion during the

Covered Person's employment or contract term or during the term of a physician's or other practitioner's medical staff privileges, Tuomey shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary 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, Tuomey shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Tuomey conducted or brought by a governmental entity or its agents involving an allegation that Tuomey 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. Tuomey shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

I. Repayment of Overpayments

1. *Definition of Overpayments.* For purposes of this CIA, an "Overpayment" shall mean the amount of money Tuomey has received in excess of the amount due and payable under any Federal health care program requirements.

2. *Overpayment Policies and Procedures.* Within 120 days after the Effective Date, Tuomey shall develop and implement written policies and procedures regarding the identification, quantification, and repayment of Overpayments received from any Federal health care program.

3. *Repayment of Overpayments.*

- a. If, at any time, Tuomey identifies any Overpayment, Tuomey shall repay the Overpayment to the appropriate payor (*e.g.*, Medicare contractor) within 60 days after identification of the Overpayment and take remedial steps within 90 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. If not yet quantified, within 60 days after identification, Tuomey shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such

work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies.

- b. 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.

J. Reportable Events

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

- a. a substantial Overpayment;
- b. 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;
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or
- d. the filing of a bankruptcy petition by Tuomey.

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

2. *Reporting of Reportable Events.* If Tuomey determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Tuomey shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. To the extent the Reportable Event involves a probable violation of the Anti-Kickback Statute or the Stark Law, Tuomey also shall notify the Legal IRO, in writing, concurrently with the notification to OIG.

3. *Reportable Events under Section III.J.1.a.* For Reportable Events under Section III.J.1.a, the report to OIG shall be made within 30 days after making the determination that a substantial Overpayment exists and shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions, or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;
- b. the Federal health care programs affected by the Reportable Event;
- c. a description of the steps taken by Tuomey to identify and quantify the Overpayment; and
- d. a description of Tuomey's actions taken to correct the Reportable Event and prevent it from recurring.

Within 60 days of identification of the Overpayment, Tuomey shall provide OIG with a copy of the notification and repayment (if quantified) to the payor required in Section III.I.3.

4. *Reportable Events under Section III.J.1.b.* For Reportable Events under Section III.J.1.b, the report to OIG shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions, or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;
- b. a statement of the Federal criminal, civil, or administrative laws that are probably violated by the Reportable Event;
- c. the Federal health care programs affected by the Reportable Event;

- d. a description of Tuomey's actions taken to correct the Reportable Event and prevent it from recurring; and
- e. if the Reportable Event has resulted in an Overpayment, a description of the steps taken by Tuomey to identify and quantify the Overpayment.

5. *Reportable Events under Section III.J.1.c.* For Reportable Events under Section III.J.1.c, the report to OIG shall include:

- a. the identity of the Ineligible Person and the job duties performed by that individual;
- b. the dates of the Ineligible Person's employment or contractual relationship;
- c. a description of the Exclusion Lists screening that Tuomey completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the Ineligible Persons screening process that led to the hiring or contracting with the Ineligible Person;
- d. a description of how the Reportable Event was discovered; and
- e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

6. *Reportable Events under Section III.J.1.d.* For Reportable Events under Section III.J.1.d, the report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

7. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves only a probable violation of section 1877 of the Social Security Act, 42 U.S.C. § 1395nn (the Stark Law) should be submitted by Tuomey to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. The requirements of Section III.I.3 that require repayment to the payor of any identified Overpayment within 60 days shall not apply to any Overpayment that may result from a probable violation of only the Stark Law that is disclosed to CMS pursuant

to the SRDP. If Tuomey identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then Tuomey is not required by this Section III.J to submit the Reportable Event to CMS through the SRDP.

IV. SUCCESSOR LIABILITY; CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Sale of Business, Business Unit, or Location

In the event that, after the Effective Date, Tuomey proposes to sell any or all of its business, business units, or locations (whether through a sale of assets, sale of stock, or other type of transaction) that are subject to this CIA, Tuomey shall notify OIG of the proposed sale at least 30 days prior to the sale of its business, business unit, or location. This notification shall include a description of the business, business unit, or location to be sold; a brief description of the terms of the sale; and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of the business, business unit, or location, unless otherwise determined and agreed to in writing by the OIG.

B. Change or Closure of Business, Business Unit, or Location

In the event that, after the Effective Date, Tuomey changes locations or closes a business, business unit, or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Tuomey shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the business, business unit, or location.

C. Purchase or Establishment of New Business, Business Unit, or Location

In the event that, after the Effective Date, Tuomey purchases or establishes a new business, business unit, or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Tuomey shall notify OIG at least 30 days prior to such purchase or the operation of the new business, business unit, or location. This notification shall include the address of the new business, business unit, or location; the location's phone number and fax number; the location's Medicare and state Medicaid program provider number and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which Tuomey currently submits claims. Each new business, business unit, or location and all Covered Persons at each new business, business unit, or location shall be subject to the applicable requirements of this CIA, unless otherwise agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

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

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
3. the names of the Board members who are responsible for satisfying the Board of Directors compliance obligations described in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.5;
5. a copy of Tuomey's Code of Conduct required by Section III.B.1;
6. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be made available to OIG upon request);
7. a summary of all Policies and Procedures required by Section III.B (copies of the Policies and Procedures shall be made available to OIG upon request);
8. the following information regarding each type of training required by Section III.C:
 - a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;

- b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions; and
- c. with respect to active medical staff members, the number and percentage who completed the training, the type of training and the date received, and a description of Tuomey's efforts to encourage medical staff members to complete the training.

9. a description of: (a) the Focus Arrangements Tracking System required by Section III.D.1.a; (b) the internal review and approval process required by Section III.D.1.e; and (c) the tracking and monitoring procedures and other Focus Arrangements Procedures required by Section III.D.1;

10. the following information regarding the Legal IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the Legal IRO has the qualifications outlined in Appendix A to this CIA; and (d) a certification from the Legal IRO that it does not have a prohibited relationship to Tuomey as set forth in Section III.E.4;

11. a description of the Disclosure Program required by Section III.F;

12. a certification that Tuomey has implemented the screening requirements described in Section III.G regarding Ineligible Persons, or a description of why Tuomey cannot provide such a certification;

13. a copy of Tuomey's policies and procedures regarding the identification, quantification, and repayment of Overpayments required by Section III.I;

14. a list of all of Tuomey's locations (including physical 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 and state Medicaid program provider number(s) and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which Tuomey currently submits claims;

15. a description of Tuomey's corporate structure, including identification of any owners, parent and sister companies, subsidiaries, and their respective lines of business; and

16. the certifications required by Section V.C.

B. Annual Reports

Tuomey shall submit to OIG annually a report with respect to the status of, and findings regarding, Tuomey's compliance activities for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; any change in the membership of the Compliance Committee described in Section III.A.2; any change in the Board members who are responsible for satisfying the Board of Directors compliance obligations described in Section III.A.3; and any change in the group of Certifying Employees described in Section III.A.5;
2. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available to OIG upon request);
3. the Board resolution required by Section III.A.3 and a description of the documents and other materials reviewed by the Board, as well as any additional steps taken, in its oversight of the Compliance Program and in support of making the resolution;
4. a copy of the Compliance Program Review Report required by Section III.A.4.a.v for the first, third, and fifth Reporting Periods;
5. the information pertaining to the Board Compliance Expert set forth in Section III.A.4.b;
6. a summary of any changes or amendments to Tuomey's Code of Conduct or the Policies and Procedures required by Section III.B and the reasons for such changes (*e.g.*, change in contractor policy);
7. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be made available to OIG upon request);

8. the following information regarding each type of training required by Section III.C:

- a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;
- b. the number of individuals required to complete the initial and annual training, the percentage of individuals who actually completed the initial and annual training, and an explanation of any exceptions; and
- c. with respect to active medical staff members, the number and percentage who completed the training, the type of training and the date received, and a description of Tuomey's efforts to encourage medical staff members to complete the training.

9. a description of: (a) any changes to the Focus Arrangements Tracking System required by Section III.D.1.a; (b) any changes to the internal review and approval process required by Section III.D.1.e; and (c) any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1;

10. the certification regarding the completeness and accuracy of the Focus Arrangements Tracking System required by Section III.D.3, as well as an explanation of: (1) any Focus Arrangements found to have been missing from the Focus Arrangements Tracking System; and (2) any entries in the Focus Arrangements Tracking System found to have been incomplete or inaccurate;

11. a complete copy of all reports prepared pursuant to Section III.E, along with a copy of the Legal IRO's engagement letter and Tuomey's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;

12. a certification from the Legal IRO that it does not have a prohibited relationship to Tuomey as set forth in Section III.E.4;

13. a summary of the disclosures in the disclosure log required by Section III.F that: (a) relate to Federal health care programs; or (b) involve allegations of conduct that may involve illegal remunerations or inappropriate referrals in violation of the Anti-Kickback Statute or Stark Law (the complete disclosure log shall be made available to OIG upon request);

14. a certification that Tuomey has completed the screening required by Section III.G regarding Ineligible Persons;

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 description of any changes to the Overpayment policies and procedures required by Section III.I, including the reasons for such changes;

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

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

19. a description of all changes to the most recently provided list of Tuomey's locations (including addresses) as required by Section V.A.14; and

20. the certifications required by Section V.C.

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

C. Certifications

1. *Certifying Employees.* In each Annual Report, Tuomey shall include the certifications of Certifying Employees as required by Section III.A.5, along with a copy of the written process that Certifying Employees followed for the purpose of completing their certifications.

2. *Compliance Officer and Chief Executive Officer.* The Implementation Report and each Annual Report shall include a certification by the Compliance Officer and Chief Executive Officer that:

- a. to the best of his or her knowledge, except as otherwise described in the report, Tuomey is in compliance with all of the requirements of this CIA;
- b. to the best of his or her knowledge, Tuomey has implemented procedures reasonably designed to ensure that all Focus Arrangements do not violate the Anti-Kickback Statute and Stark Law, including the Focus Arrangements Procedures required in Section III.D of the CIA;
- c. to the best of his or her knowledge, Tuomey has fulfilled the requirements for New and Renewed Focus Arrangements under Section III.D.2 of this CIA; and
- d. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful.

3. *Chief Financial Officer.* The first Annual Report shall include a certification by the Chief Financial Officer that, to the best of his or her knowledge, Tuomey has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs.

D. Designation of Information

Tuomey shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Tuomey shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

OIG: Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

Tuomey: Alice V. Harris
Vice President, Corporate Integrity
Tuomey Healthcare System
129 N. Washington Street
Sumter, SC 29150
Telephone: 803.774.1775
Facsimile: 803.774.9524

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, Tuomey may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), in addition to a paper copy.

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 Tuomey's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Tuomey's locations for the purpose of verifying and evaluating: (a) Tuomey's compliance with the terms of this CIA; and (b) Tuomey's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Tuomey to OIG or its duly authorized representative(s) at all

reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Tuomey's Covered Persons 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. Tuomey shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Tuomey's Covered Persons may elect to be interviewed with or without a representative of Tuomey present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

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

X. BREACH AND DEFAULT PROVISIONS

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

A. Stipulated Penalties for Failure to Comply with Certain Obligations

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

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

a. a Compliance Officer;

- b. a Compliance Committee;
- c. the Board of Directors compliance obligations;
- d. engagement and retention of the Board Compliance Expert required by Section III.A.4;
- e. completion of the Compliance Program Review and accompanying Compliance Program Review Report, as required by Section III.A.4.a.v for the first, third, and fifth Reporting Periods;
- f. the management certification obligations;
- g. a written Code of Conduct;
- h. written Policies and Procedures;
- i. the training of Covered Persons, Arrangements Covered Persons, and Board Members;
- j. the Focus Arrangements Procedures and/or Focus Arrangements Requirements described in Sections III.D.1 and III.D.2;
- k. a Disclosure Program;
- l. Ineligible Persons screening and removal requirements;
- m. notification of Government investigations or legal proceedings;
- n. policies and procedures regarding the repayment of Overpayments;
- o. the repayment of Overpayments as required by Section III.I;
- p. reporting of Reportable Events; and

q. disclosure of changes to business units or locations.

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

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Tuomey fails to submit the Implementation Report or any Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Tuomey fails to submit any Arrangements Review Report in accordance with the requirements of Section III.E and Appendix B.

5. A Stipulated Penalty of \$1,500 for each day Tuomey fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Tuomey fails to grant access.)

6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of Tuomey as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of \$1,000 for each day Tuomey fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Tuomey stating the specific grounds for its determination that Tuomey has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Tuomey shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date Tuomey receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1–6 of this Section.

B. Timely Written Requests for Extensions

Tuomey may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for

failure to perform the act or file the notification or report shall not begin to accrue until one day after Tuomey 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 days after Tuomey 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 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 Tuomey 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 Tuomey of: (a) Tuomey's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

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

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

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 Tuomey has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA

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

- a. a failure by Tuomey to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.J;
- b. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to engage and use a Legal IRO in accordance with Section III.E, Appendix A, and Appendix B.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Tuomey constitutes an independent basis for Tuomey's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that Tuomey has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Tuomey of: (a) Tuomey's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Opportunity to Cure.* Tuomey shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate that:

- a. the alleged material breach has been cured; or
- b. the alleged material breach cannot be cured within the 30-day period, but that: (i) Tuomey has begun to take action to cure the material breach; (ii) Tuomey is pursuing such action with due diligence; and (iii) Tuomey has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Tuomey fails to satisfy the requirements of Section X.D.3, OIG may exclude Tuomey from participation in the Federal health care programs. OIG shall notify Tuomey in writing of its determination to exclude Tuomey. (This letter shall be referred to 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 Tuomey’s receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Tuomey 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 Tuomey of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Tuomey shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG’s determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2–1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter. The procedures relating to the filing of a request for a hearing can be found at <http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html>.

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

decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be whether Tuomey was in material breach of this CIA and, if so, whether:

- a. Tuomey cured such breach within 30 days of its receipt of the Notice of Material Breach; or
- b. the alleged material breach could not have been cured within the 30-day period, but that, during the 30-day period following Tuomey's receipt of the Notice of Material Breach:
 - (i) Tuomey had begun to take action to cure the material breach;
 - (ii) Tuomey pursued such action with due diligence;
 - and (iii) Tuomey provided to OIG a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Tuomey, only after a DAB decision in favor of OIG. Tuomey's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Tuomey 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 Tuomey 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. Tuomey shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Tuomey, Tuomey shall be reinstated effective on the date of the original exclusion.

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

XI. EFFECTIVE AND BINDING AGREEMENT

Tuomey and OIG agree as follows:

A. This CIA shall become final and binding on the date the final signature is obtained on the CIA.

B. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

C. OIG may agree to a suspension of Tuomey's obligations under this CIA based on a certification by Tuomey that it is no longer providing health care items or services that will be billed to any Federal health care program and that it does not have any ownership or control interest, as defined in 42 U.S.C. § 1320a-3, in any entity that bills any Federal health care program. If Tuomey is relieved of its CIA obligations, Tuomey will be required to notify OIG in writing at least 30 days in advance if Tuomey plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.

D. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) Tuomey'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 Federal health care program requirements.

E. The undersigned Tuomey signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacities and that they are authorized to execute this CIA.

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

ON BEHALF OF TUOMEY D/B/A TUOMEY HEALTHCARE SYSTEM

/L. Michelle Owens/

10/16/15

MICHELLE LOGAN-OWENS
President & Chief Executive Officer
Tuomey d/b/a Tuomey Healthcare System

DATE

/Thomas F. Moran/

10/14/15

THOMAS F. MORAN
Nelson Mullins Riley & Scarborough LLP
Counsel for Tuomey d/b/a Tuomey Healthcare System

DATE

/Laurence J. Freedman/

Oct. 16, 2015

LAURENCE J. FREEDMAN
Mintz, Levin, Cohn, Ferris, Glovsky
and Popeo, P.C.
Counsel for Tuomey d/b/a Tuomey Healthcare System

DATE

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

/Robert K. DeConti/

10/16/15

ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

DATE

/Kevin R. Barry/

10/16/15

KEVIN R. BARRY
Deputy Branch Chief
Office of Counsel to the Inspector General
U.S. Department of Health and Human Services

DATE

/Kaitlyn L. Dunn/

10/16/15

KAITLYN L. DUNN
Associate Counsel
Office of Counsel to the Inspector General
U.S. Department of Health and Human Services

DATE

APPENDIX A

LEGAL INDEPENDENT REVIEW ORGANIZATION

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

A. Legal IRO Engagement

1. Tuomey shall engage a Legal IRO that possesses the qualifications set forth in Section B, below, to perform the responsibilities in Section C, below. The Legal IRO shall not have a prohibited relationship to Tuomey, as set forth in Section D, below. Within 30 days after OIG receives the information identified in Section V.A.10 of the CIA or any additional information submitted by Tuomey in response to a request by OIG, whichever is later, OIG will notify Tuomey if the Legal IRO is unacceptable. Absent notification from OIG that the Legal IRO is unacceptable, Tuomey may continue to engage the Legal IRO.

2. If Tuomey engages a new Legal IRO during the term of the CIA, this Legal IRO shall also meet the requirements of this Appendix. If a new Legal IRO is engaged, Tuomey shall submit the information identified in Section V.A.10 of the CIA to OIG within 30 days of engagement of the Legal IRO. Within 30 days after OIG receives this information or any additional information submitted by Tuomey at the request of OIG, whichever is later, OIG will notify Tuomey if the Legal IRO is unacceptable. Absent notification from OIG that the Legal IRO is unacceptable, Tuomey may continue to engage the Legal IRO.

B. Legal IRO Qualifications

The Legal IRO shall:

1. be a law firm or individual with a legal degree;
2. assign individuals to conduct the Arrangements Review who are knowledgeable in the requirements of the Anti-Kickback Statute and the Stark Law and the regulations, directives, and other guidance documents related to these statutes;
3. possess expertise in fair market valuation issues or have the ability to associate a valuation firm to assist in conducting the transactions review component of the Arrangements Review; and

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

C. Legal IRO Responsibilities

The Legal IRO shall:

1. perform each Arrangements Review in accordance with the specific requirements of the CIA;
2. respond to all OIG inquires in a prompt, objective, and factual manner; and
3. prepare timely, clear, well-written reports that include all the information required by Section III.E of the CIA and Appendix B to the CIA.

D. Legal IRO's Relationship to Tuomey

The entity that Tuomey selects to serve as the Legal IRO shall not:

1. have previously represented or been employed or engaged by Tuomey; or
2. have a relationship to Tuomey or its employees, officers, or directors that would cause a reasonable person to question the Legal IRO's impartiality.

E. Assertions of Privilege

Tuomey shall not assert claims of attorney-client privilege in order to avoid disclosing to OIG information related to or resulting from the Legal IRO's engagement. Tuomey's engagement letter with the Legal IRO shall include a provision stating that the Legal IRO agrees not to assert claims of work product privilege in order to avoid disclosing to OIG information related to or resulting from its engagement.

F. Legal IRO Removal/Termination

1. *Tuomey and Legal IRO.* If Tuomey terminates its Legal IRO or if the Legal IRO withdraws from the engagement during the term of the CIA, Tuomey must

submit a notice explaining (a) its reasons for termination of the Legal IRO or (b) the IRO's reasons for its withdrawal to OIG, no later than 30 days after termination or withdrawal. Tuomey must engage a new Legal IRO in accordance with Section A of this Appendix and within 60 days of termination or withdrawal of the Legal IRO.

2. *OIG Removal of Legal IRO.* In the event OIG has reason to believe that the Legal IRO does not possess the qualifications described in Section B, has a relationship to Tuomey prohibited under Section D, or has failed to carry out its responsibilities as described in Section C, OIG shall notify Tuomey in writing regarding OIG's basis for determining that the Legal IRO has not met the requirements of this Appendix. Tuomey shall have 30 days from the date of OIG's written notice to provide information regarding the Legal IRO's qualifications, independence, or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by Tuomey regarding the Legal IRO, OIG determines that the Legal IRO has not met the requirements of this Appendix, OIG shall notify Tuomey in writing that Tuomey shall be required to engage a new Legal IRO in accordance with Section A of this Appendix. Tuomey must engage a new Legal IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require Tuomey to engage a new Legal IRO shall be made at the sole discretion of OIG.

APPENDIX B

ARRANGEMENTS REVIEW

The Arrangements Review shall consist of two components: a systems review and a transactions review. The Legal IRO shall perform all components of each Arrangements Review. If there are no material changes to Tuomey's systems, processes, policies, and procedures relating to Arrangements, the Arrangements Systems Review shall be performed for the first and fourth Reporting Periods. If Tuomey materially changes the Arrangements systems, processes, policies, and procedures, the Legal IRO shall perform an Arrangements Systems Review for the Reporting Period in which such changes were made in addition to conducting the systems review for the first and fourth Reporting Periods. The Arrangements Transactions Review shall be performed annually and shall cover each of the five Reporting Periods.

A. Arrangements Systems Review. The Arrangements Systems Review shall be a review of Tuomey's systems, policies, processes, and procedures relating to the initiation, review, approval, and tracking of Arrangements. Specifically, the Legal IRO shall review the following:

1. Tuomey's systems, policies, processes, and procedures with respect to creating and maintaining a centralized tracking system for all existing and new and renewed Focus Arrangements (Focus Arrangements Tracking System), including a detailed description of the information captured in the Focus Arrangements Tracking System;
2. Tuomey's systems, policies, processes, and procedures for tracking remuneration to and from all parties to Focus Arrangements;
3. Tuomey's systems, policies, processes, and procedures for tracking service and activity logs to ensure that parties to the Focus Arrangement(s) are performing the services required under the applicable Focus Arrangement(s) (if applicable);
4. Tuomey's systems, policies, processes, and procedures for 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 Focus Arrangement(s) (if applicable);
5. Tuomey's systems, policies, processes, and procedures for initiating Arrangements, including those policies that identify the individuals with authority to

initiate an Arrangement and that specify the business need or business rationale required to initiate an Arrangement;

6. Tuomey's systems, policies, processes, and procedures for the internal review and approval of all Arrangements, including those policies that identify the individuals required to approve each type or category of Arrangement entered into by Tuomey, the internal controls designed to ensure that all required approvals are obtained, and the processes for ensuring that all Focus Arrangements are subject to a legal review by counsel with expertise in the Anti-Kickback Statute and Stark Law;

7. the Compliance Officer's annual review of and reporting to the Compliance Committee and Board of Directors on the Focus Arrangements Tracking System; Tuomey's internal review and approval process; and other Arrangements systems, policies, processes, and procedures;

8. Tuomey's systems, policies, processes, and procedures for 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 when appropriate; and

9. Tuomey's systems, policies, processes, and procedures for ensuring that all new and renewed Focus Arrangements comply with the Focus Arrangements Requirements set forth in Section III.D.2 of the CIA.

B. Arrangements Systems Review Report. The Legal IRO shall prepare a report based upon each Arrangements Systems Review performed. The Arrangements Systems Review Report shall include the following information:

1. a description of the documentation (including policies) reviewed and personnel interviewed;

2. a detailed description of Tuomey's systems, policies, processes, and procedures relating to the items identified in Section A.1–9, above;

3. findings and supporting rationale regarding weaknesses in Tuomey's systems, policies, processes, and procedures relating to Arrangements described in Section A.1–9, above; and

4. recommendations to improve Tuomey's systems, policies, processes, or procedures relating to Arrangements described in Section A.1–9, above.

C. Arrangements Transactions Review. The Arrangements Transactions Review shall consist of a review by the IRO of 50 Focus Arrangements (or 10%, whichever is less) that were entered into or renewed by Tuomey during the Reporting Period. The Legal IRO shall select its sample of Focus Arrangements for review in consultation with OIG. The Legal IRO shall assess whether Tuomey has complied with the Focus Arrangements Procedures and the Focus Arrangements Requirements described in Sections III.D.1 and III.D.2 of the CIA with respect to the selected Focus Arrangements.

The Legal IRO's assessment with respect to each Focus Arrangement that is subject to review shall include:

1. verifying that the Focus Arrangement is maintained in Tuomey's centralized tracking system in a manner that permits the Legal IRO to identify the parties to the Focus Arrangement and the relevant terms of the Focus Arrangement (*i.e.*, the items/services/equipment/space to be provided, the amount of compensation, the effective date, the expiration date, etc.);
2. verifying that the Focus 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;
3. verifying that the remuneration related to the Focus Arrangement is properly documented and supported by a sound fair market valuation methodology;
4. verifying that the Focus Arrangement is supported by a valid and properly documented business need or business rationale;
5. verifying that the service and activity logs are properly completed and reviewed by Tuomey, and that the parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangement (if applicable);
6. verifying that the use of leased space, medical supplies, medical devices, equipment, and other patient care items is properly monitored by Tuomey, and that such use is consistent with the terms of the applicable Focus Arrangement (if applicable); and
7. verifying that the Focus Arrangement satisfies the Focus Arrangements Requirements of Section III.D.2 of the CIA.

D. Arrangements Transactions Review Report. The Legal IRO shall prepare a report based on each Arrangements Transactions Review performed. The Arrangements Transactions Review Report shall include the following information:

1. *Review Methodology*

- a. Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for the sample reviewed.
- b. Sources of Data: A full description of the documentation and other information, if applicable, relied upon by the Legal IRO in performing the Arrangements Transactions Review.
- c. Supplemental Materials. The Legal IRO shall request all documentation and materials required for its review of the Focus Arrangements selected as part of the Arrangements Transactions Review and Tuomey shall furnish such documentation and materials to the Legal IRO, prior to the Legal IRO initiating its review of the Focus Arrangements. If the Legal IRO accepts any supplemental documentation or materials from Tuomey after the Legal IRO has completed its initial review of the Focus Arrangements (Supplemental Materials), the Legal IRO shall identify in the Arrangements Transactions Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the Legal IRO gave to the Supplemental Materials in its review. In addition, the Legal IRO shall include a narrative in the Arrangements Transactions Review Report describing the process by which the Supplemental Materials were accepted and the Legal IRO's reasons for accepting the Supplemental Materials.

2. *Review Findings*. The Arrangements Transactions Review Report shall include the Legal IRO's findings with respect to each of the items set forth in Section C.1–7, above. In addition, the Legal IRO shall identify in the Arrangements Transactions Review Report any Focus Arrangement(s) reviewed that a reasonable person would consider a probable violation of the Anti-Kickback Statute or Stark Law, along with the Legal IRO's basis for reaching that conclusion.

The Arrangements Transactions Review Report also shall include observations, findings, and recommendations on possible improvements to Tuomey's systems, policies, processes, and procedures in place to ensure that all Focus Arrangements comply with the Focus Arrangements Procedures and Focus Arrangements Requirements.