

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
MILLENNIUM HEALTH, LLC**

I. PREAMBLE

Millennium Health LLC (Millennium) 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, Millennium is entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Millennium 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) Millennium’s final annual report; or (2) any additional materials submitted by Millennium 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 Millennium and any actual or potential source of health care business or referrals to Millennium or any actual or potential

recipient of health care business or referrals from Millennium. 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 Millennium refers an individual for the furnishing or arranging for the furnishing of any item or service, or (2) from whom Millennium 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 Millennium 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 Millennium for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

2. “Arrangements Covered Persons” includes each Covered Person who is involved with the development, approval, management, or review of Millennium’s Arrangements.

3. “Covered Persons” includes:

- a. all owners who are natural persons (other than those who have an ownership interest of less than 5% and are not involved in the business operations of Millennium)¹, officers, directors, and employees of Millennium; and
- b. all contractors, subcontractors, agents, and other persons who (1) provide items or services relating to the provision of Government Reimbursed Services, (2) perform research or

¹ Whether natural person or entity, and regardless of the percentage owned, any owner involved in the business operations of Millennium will be included in the definition of Covered Persons.

data analytics related to Government Reimbursed Services, (3) furnish patient care items or services, (4) perform billing or coding functions on behalf of Millennium, or (5) are engaged in sales or marketing activities relating to Government Reimbursed Services , but excluding vendors whose sole connection with Millennium is selling or otherwise providing medical supplies or equipment to Millennium.

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. “Focus Arrangements” means every Arrangement that:
 - a. is between Millennium and any actual source of health care business or referrals to Millennium and involves, directly or indirectly, the offer, payment, or provision of anything of value; or
 - b. is between Millennium 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 Millennium for designated health services (as defined at 42 U.S.C. §1395nn(h))(6)).

Notwithstanding the foregoing provisions of Section II.C.4, 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.

5. “Government Reimbursed Services” refers to all items or services furnished by Millennium that are reimbursed, in whole or in part, by any Federal health care program.

6. “Sales and Marketing Covered Persons” includes all Covered Persons who are involved in the sales or marketing of Government Reimbursed Services, or who supervise Covered Persons involved in such sales or marketing activities.

7. “Sales and Marketing Materials” refers to any materials utilized in any way in selling, marketing, advertising, or promoting, any Government Reimbursed Services.

8. “Reimbursement Covered Persons” includes Covered Persons involved in testing (including, but not limited to, conducting urine drug testing and/or pharmacogenetic testing), the delivery of any Government Reimbursed Services, and/or in the preparation or submission of claims for reimbursement from any Federal health care program.

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Officer, Compliance Committee, and Chief Clinical Officer

1. *Compliance Officer.* Within 90 days after the Effective Date, Millennium shall appoint an employee to serve as its Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be a member of senior management of Millennium, shall report directly to the Chief Executive Officer of Millennium, 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 Millennium. 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 Millennium, and shall be authorized to 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 Millennium 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.

Millennium 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 90 days after the Effective Date, Millennium 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, sales/marketing, 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 Millennium'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.

Millennium 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. *Chief Clinical Officer.* Within 90 days after the Effective Date, Millennium shall appoint an employee to serve as its Chief Clinical Officer and shall maintain a Chief Clinical Officer for the term of the CIA. The Chief Clinical Officer shall be a member of senior management of Millennium, shall report directly to the Chief Executive Officer of Millennium, and shall not be subordinate to the General Counsel or Chief Financial Officer. The Chief Clinical Officer shall be responsible for, without limitation:

- a. reviewing and approving policies, procedures, and practices related to any clinical decision-making, including, but not limited to, reviewing standard requisition forms, reviewing and approving any clinical content included in any Sales and Marketing Materials, and implementing and monitoring risk assessment and internal audit programs that review referral patterns and practices to identify and address situations where referral sources may be ordering medically unnecessary tests; and
- b. making periodic (at least quarterly) reports regarding clinical matters directly to the Chief Executive Officer and Board of Directors of Millennium, and shall be authorized to report on such matters to the Chief Executive Officer and Board of Directors at any time. Written documentation of the Chief Clinical Officer's reports to the Chief Executive Officer and Board of Directors shall be made available to OIG upon request.

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

4. *Board of Directors Compliance Obligations.* The Board of Directors (or a committee of the Board) of Millennium (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 maintain a majority of independent (*i.e.*, non-executive and non-family) members.

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

- a. meeting at least quarterly to review and oversee Millennium's compliance program, including but not limited to the performance of the Compliance Officer, Compliance Committee, and Chief Clinical Officer;
- 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 each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board summarizing its review and oversight of Millennium's compliance with Federal health care program requirements and the obligations of this CIA; and
- d. for each Reporting Period of the CIA, the Board shall retain an individual or entity with expertise in compliance with Federal health care program requirements (Compliance Expert) to perform a review of the effectiveness of Millennium's Compliance Program (Compliance Program Review). The Compliance Expert shall create a work plan for the Compliance Program Review and prepare a written report about the Compliance Program Review. The written report (Compliance Program Review Report) shall include a description of the Compliance Program Review and any recommendations with respect to Millennium's compliance program. The Board shall review the Compliance Program Review Report as part of its review and oversight of Millennium's compliance program. A copy of the Compliance Program Review report shall be provided to OIG in each Annual Report submitted by Millennium. In addition, copies of any materials provided to the Board by the Compliance Expert, along with minutes of any meetings between the Compliance Expert and the Board, shall be made available to the OIG upon request.

At minimum, the resolution referenced in subsection c of this Paragraph shall include the following language:

“The Board of Directors has made a reasonable inquiry into the operations of Millennium’s Compliance Program including the performance of the Compliance Officer, the Compliance Committee, and the Chief Clinical Officer. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Millennium 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 Millennium.

Millennium 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 15 days after such a change.

5. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Millennium employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Millennium department is in compliance with applicable Federal health care program requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Founder, Chief Executive Officer, President, Chief Operating Officer, Executive Vice President of Strategy and Corporate Development, Chief Financial Officer, Chief Clinical Officer, Chief Scientific Officer, Chief Marketing Officer, Chief People Officer, Chief Information Officer, General Counsel, President of RxAnte, General Manager of Analytics, General Manager of Pharmacogenetic Testing, and all regional vice presidents. For each Reporting Period, each Certifying Employee shall sign a certification that states:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of department] with all applicable Federal health

care program requirements, obligations of the Corporate Integrity Agreement, and Millennium policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] of Millennium is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement. 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 certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above.

Within 90 days after the Effective Date, Millennium 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 90 days after the Effective Date, Millennium shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. Millennium 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. Millennium’s commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;
- b. Millennium’s requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Millennium’s own Policies and Procedures;
- c. the requirement that all of Millennium’s Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Millennium, suspected

violations of any Federal health care program requirements or of Millennium's own Policies and Procedures; and

- d. the right of all individuals to use the Disclosure Program described in Section III.G, and Millennium's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 90 days after the Effective Date, Millennium shall distribute the Code of Conduct to all Covered Persons. Millennium 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, Millennium 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 Millennium's compliance with Federal health care program requirements. Throughout the term of this CIA, Millennium shall enforce and comply with its Policies and Procedures and shall make such compliance an element of evaluating the performance of all employees. The Policies and Procedures shall address:

- a. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute) and 42 U.S.C. § 1395nn (Stark Law), and the regulations and other guidance documents related to these statutes, and business or financial arrangements or contracts that generate unlawful Federal health care program business in violation of the Anti-Kickback Statute or the Stark Law;
- b. the requirements set forth in Section III.D (Compliance with the Anti-Kickback Statute and Stark Law);
- c. the Federal health care program requirements regarding the accurate submission of claims for urine drug testing, genetic testing, and any other Government Reimbursed Service. In particular, Millennium shall design and implement Policies and Procedures designed to prevent Millennium from submitting claims for Government Reimbursed Services that are not medically reasonable and necessary, including but not

limited to communication to physicians that all orders should be medically reasonable and necessary given the patient's clinical condition and a requirement that referral sources must submit to Millennium diagnostic information for all tests ordered as documentation of the medical necessity of each service ordered. Further, Millennium shall implement and enforce Policies and Procedures designed to ensure that its claims for Federal health care program reimbursement for Government Reimbursed Services are consistent with coverage rules, including National and Local Coverage Determinations;

- d. the use of requisition forms (as used in this document, the term "requisition forms" includes both paper and electronic requisition forms) that include all appropriate information to inform ordering physicians of the importance of medical reasonableness and necessity of each test potentially ordered. Specifically, Millennium's Policies and Procedures shall include the following requirements:
 - i. All requisition forms shall boldly state that Medicare will only pay for tests that are medically reasonable and necessary based on the clinical condition of each individual patient;
 - ii. Each requisition form shall list all potential tests clearly and distinctly, and the form must require the physician to request (by notation) each ordered test individually (except for test panels established by CMS or other payor billing codes or policies);
 - iii. Each requisition form shall state that physicians may not order tests under custom profiles, standing orders (unless the physician has established a specific standing order for an individual patient for a defined period of time based upon a determination of the medical reasonableness and necessity of doing so), or panels (except for test panels established by CMS or other payor billing codes or policies);

- iv. In addition to applicable billing rules, Millennium shall not submit claims to Federal health care programs for any test unless Millennium has received a valid requisition form;
 - v. Each requisition form shall identify any tests ordered that are subject to applicable National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), and provide instructions on how ordering physicians can access additional information regarding those NCDs and LCDs, including links to the applicable NCDs and LCDs on the CMS web site;
 - vi. Each requisition form shall advise that tests submitted for Medicare and Medicaid reimbursement must meet program requirements or the claim may be denied;
 - vii. Confirmatory and quantitative tests must be listed separately on the requisition forms, which must indicate that each test should be ordered only where it is medically necessary to have information that screening with qualitative immunoassays alone will not provide; and
 - viii. To the extent tests are not offered individually, they shall be available by writing in the “Special Instructions” section of the requisition form.
- e. the importance of medical reasonableness and necessity in Millennium’s claim submission, sales and marketing, and communication with customers;
 - f. the materials and information that may be distributed by Millennium, through its sales representatives (including any contract sales force) or otherwise, about Government Reimbursed Services and the manner in which Millennium sales representatives respond to requests for information

about the medical reasonableness and necessity of Government Reimbursed Services. These Policies and Procedures shall require that sales representatives: (i) use only materials that have been reviewed and approved by Millennium; and (ii) respond to the physician on questions regarding medical reasonableness and necessity of Government Reimbursed Services as previously approved by the Chief Clinical Officer, and to refer the physician to the Chief Clinical Officer in all other instances, as required by Millennium Policies and Procedures;

- f. the materials and information that may be distributed by the Chief Clinical Officer and the mechanisms through, and manner in which, the Chief Clinical Officer receives and responds to requests for information about the uses of Government Reimbursed Services; the form and content of information disseminated by Millennium in response to such requests; and the internal review process for the information disseminated;
- g. speaker activities by creating a Speaker Activities Program. With regard to speaker programs, Millennium shall implement a process to require all speakers to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance obligations for the speakers (including requirements regarding the use of Millennium approved materials and requirements that speakers emphasize the importance of medical reasonableness and necessity). Millennium shall establish a centralized, electronic system to initiate and track all speaker programs that includes controls designed to ensure that speaker programs are used for legitimate and lawful purposes. The controls shall also be designed to ensure that there is a legitimate need for the speaker programs.

Millennium shall ensure that speakers are paid according to a centrally managed, pre-set rate structure determined based on a fair-market value analysis conducted by an independent

individual or entity. Millennium shall maintain a comprehensive list of speaker program attendees through its centralized system. In addition, Millennium shall use its centralized system to handle all logistics and spending associated with speaker programs, including the tracking and review of the aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with speaker programs. Millennium shall require certifications by sales representatives or other Millennium personnel that a speaker program complied with Millennium requirements, or in the event of non-compliance, Millennium shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation; and

- h. disciplinary policies and procedures, including corrective action plans as appropriate, for violations of Millennium's Policies and Procedures.

Within 90 days after the Effective Date, the Policies and Procedures shall be distributed to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Millennium 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. *Training Plan.* Within 90 days after the Effective Date, Millennium shall develop a written plan (Training Plan) that outlines the steps Millennium will take to ensure that:
 - a. all Covered Persons receive adequate training (General Training) regarding Millennium's CIA requirements and Compliance Program, including the Code of Conduct and applicable Policies and Procedures;

- b. all Reimbursement Covered Persons receive adequate training (Reimbursement Training) regarding:
 - i. the Federal health care program requirements regarding the accurate coding and submission of claims,
 - ii. the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate, meet Millennium's Policies and Procedures requirements, and comply with all applicable reimbursement statutes, regulations, and program requirements and directives;
 - iii. the legal sanctions for violations of the Federal health care program requirements; and
 - iv. examples of proper and improper claims submission practices (Reimbursement Training);

- c. Arrangements Covered Persons receive adequate training (Arrangements Training) regarding:
 - i. 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;
 - ii. Millennium'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;
 - iii. the personal obligation of each individual involved in the development, approval, management, or review of Millennium's Arrangements to know the applicable legal requirements and Millennium's policies and procedures;

- iv. the legal sanctions under the Anti-Kickback Statute and the Stark Law; and
 - v. examples of violations of the Anti-Kickback Statute and the Stark Law.
- d. all Sales and Marketing Covered Persons receive adequate training (Sales and Marketing Training) regarding:
- i. contacts, relationships, and actions that potentially implicate the Anti-Kickback Statute or the Stark Law, as well as the regulations and other guidance documents related to these statutes;
 - ii. Millennium's policies, procedures, and other requirements relating to Sales and Marketing Materials and Activities, including discussion of the implications of remuneration to and from sources of health care business or referrals;
 - iii. the personal obligation of each individual involved Sales and Marketing to know the applicable legal requirements and Millennium's policies and procedures;
 - iv. the legal sanctions under the Anti-Kickback Statute and the Stark Law; and
 - v. examples of Sales and Marketing practices that violate the Anti-Kickback Statute and the Stark Law.

The Training Plan shall include information regarding the training topics, the identification and categorization of Covered Persons, Reimbursement Covered Persons, Arrangements Covered Persons, and Sales and Marketing Covered Persons required to attend each training session, the length of the training, the schedule for training, and the format of the training. Within 30 days of the OIG's receipt of Millennium's Training Plan, OIG will notify Millennium of any comments or objections to the Training Plan. Absent notification by the OIG that the Training Plan is unacceptable, Millennium may implement its Training Plan. Millennium shall furnish training to its Covered Persons, Reimbursement Covered Persons, and Arrangements Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Board Member Training.* Within 90 days after the Effective Date, Millennium shall provide at least two hours of training to each member of the Board of Directors. This training shall address the Millennium's CIA requirements and Compliance Program (including the Code of Conduct), 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 an outside compliance expert hired by the Board 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 90 days after the Effective Date, whichever is later.

3. *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.

4. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area.

5. *Update of Training Plan.* Millennium shall review the Training Plan annually, and, where appropriate, update the Training Plan to reflect changes in Federal health care program requirements, any issues discovered during internal audits, the Claims Review, or the Arrangements Review, and any other relevant information. Any updates to the Training Plan must be reviewed and approved by the OIG prior to the implementation of the revised Training Plan. Within 30 days of OIG's receipt of any updates or revisions to Millennium's Training Plan, OIG will notify Millennium of any comments or objections to the revised Training Plan. Absent notification from the OIG that the revised Training Plan is unacceptable, Millennium may implement the revised Training Plan.

6. *Computer-based Training.* Millennium may provide the training required under this CIA through appropriate computer-based training approaches. If Millennium chooses to provide computer-based training, it shall make available

appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

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

1. *Focus Arrangements Procedures.* Within 90 days after the Effective Date, Millennium 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.J and III.K when appropriate.

2. *New or Renewed Focus 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, Millennium shall comply with the following requirements (Focus Arrangements Requirements):

- a. Ensure that each Focus Arrangement is set forth in writing and signed by Millennium 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 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. Additionally, Millennium 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;
- 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. *Records Retention and Access.* Millennium 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 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 Independent Review Organization.* Within 90 days after the Effective Date, Millennium shall engage an entity (or entities), such as an accounting, auditing, law, or consulting firm (hereinafter “Independent Review Organization(s)” or “IRO(s)”), to perform the reviews listed in this Section III.E. The applicable requirements relating to the IRO(s) are outlined in Appendices A-D to this CIA, which are incorporated by reference.
- b. *Retention of Records.* The IRO and Millennium shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Millennium) related to the reviews.
- c. *Responsibilities and Liabilities.* Nothing in this Section III.E affects Millennium’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 False Claims Act, the Anti-Kickback Statute, and/or the Stark Law.

2. *Claims Review.* The IRO shall review Millennium’s coding, billing, and claims submission to the Medicare and state Medicaid programs and the reimbursement received (Claims Review) and shall prepare a Claims Review Report, as outlined in Appendix C to this CIA, which is incorporated by reference.

3. *Arrangements Review.* The IRO shall perform an Arrangements Review and prepare an Arrangements Review Report as outlined in Appendix D to this CIA, which is incorporated by reference.

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

Prior to initiating a Validation Review, OIG shall notify Millennium in writing of its intent to do so and provide an explanation of the reasons OIG has determined a Validation Review is necessary. Millennium 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 Claims Review and/or Arrangements Review or to correct the inaccuracy of the Claims Review and/or 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.

5. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Millennium a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.E and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendices A and B to this CIA.

F. Risk Assessment and Internal Review Process

Within 120 days after the Effective Date, Millennium shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries (including, but not limited to, monitoring ordering patterns to identify and address situations where referral sources may be ordering tests that are not medically reasonable and necessary), Arrangements (as defined in Section II.C.1 above), and Sales and Marketing of Government Reimbursed Services. The risk assessment and internal review process should require compliance, legal, and department leaders, at least annually, to: (1) identify and prioritize risks, (2) develop

internal audit work plans related to the identified risk areas, (3) implement the internal audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. Millennium shall maintain the risk assessment and internal review process for the term of the CIA.

G. Disclosure Program

Within 90 days after the Effective Date, Millennium 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 Millennium'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. Millennium 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, Millennium 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.

H. 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.* Millennium shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. Millennium 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. Millennium shall screen all current Covered Persons against the Exclusion Lists within 90 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. Millennium 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.H affects Millennium'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. Millennium understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that Millennium may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Millennium meets the requirements of Section III.H.

3. *Removal Requirement.* If Millennium has actual notice that a Covered Person has become an Ineligible Person, Millennium shall remove such Covered Person from responsibility for, or involvement with, Millennium'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 Millennium 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, Millennium 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.

I. Notification of Government Investigation or Legal Proceeding

Within 30 days after discovery, Millennium shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Millennium conducted or brought by

a governmental entity or its agents involving an allegation that Millennium 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. Millennium 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 proceeding, if any.

J. Overpayments

1. *Definition of Overpayments.* For purposes of this CIA, an “Overpayment” shall mean the amount of money Millennium 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, Millennium 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, Millennium identifies any Overpayment, Millennium 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, Millennium 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.

K. 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.H.1.a; or
- d. the filing of a bankruptcy petition by Millennium.

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

2. *Reporting of Reportable Events.* If Millennium determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Millennium shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Section III.K.1.a.* For Reportable Events under Section III.K.1.a, the report to OIG shall be made within 30 days after making a 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 Millennium to identify and quantify the Overpayment; and
- d. a description of Millennium's actions taken to correct the Reportable Event and prevent it from recurring.

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

4. *Reportable Events under Section III.K.1.b.* For Reportable Events under Section III.K.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 Millennium'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 Millennium to identify and quantify the Overpayment.

5. *Reportable Events under Section III.K.1.c.* For Reportable Events under Section III.K.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 Millennium 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.K.1.d.* For Reportable Events under Section III.K.1.d, the report to the 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 solely a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by Millennium 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.J.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 solely the Stark Law that is disclosed to CMS pursuant to the SRDP. If Millennium identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then Millennium is not required by this Section III.J to submit the Reportable Event to CMS through the SRDP.

L. Field Force Monitoring.

Within 120 days after the Effective Date, Millennium shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor its sales personnel's interactions with healthcare professionals (HCPs) and healthcare institutions (HCIs). The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales personnel's interactions with HCPs and HCIs and to identify potential improper conduct or violations of Millennium's Policies and Procedures. As described in more detail below, the FFMP shall consist of direct field observations (Observations) of sales personnel .

1. *Sales Representative Observations.* Representatives of the compliance department (Monitoring Personnel) shall conduct observations of field sales representatives (including any contract sales personnel) to assess whether the messages delivered and materials distributed to HCPs and HCIs are consistent with applicable legal requirements, and with Millennium's Policies and Procedures, and to ensure that sales representatives are not making any statements regarding medical reasonableness and necessity outside the scope of Millennium's Policies and Procedures (but, rather, are referring matters related to medical reasonableness and necessity not covered by Millennium's Policies and Procedures to the Chief Clinical Officer, as appropriate). These observations shall be full day ride-alongs with field sales representatives (Observations), and each Observation shall consist of directly observing all meetings between a sales representative and HCPs and HCIs during the workday. The Observations shall be scheduled throughout the year, judgmentally selected by Monitoring Personnel, include a review of each Government Reimbursed Service, and be conducted across the United States.

At the completion of each Observation, Monitoring Personnel shall prepare a report which includes:

- a. the identity of the sales representative;
- b. the identity of the Monitoring Personnel who conducted the Observation;
- c. the date and duration of the Observation;
- d. the Government Reimbursed Service(s) promoted during the Observation;

- e. an overall assessment of compliance with Millennium Policies and Procedures; and
- f. the identification of any conduct inconsistent with Millennium's Policies and Procedures or any other improper conduct by the field sales representative.

Monitoring Personnel shall conduct at least 50 Observations in each Reporting Period.

2. *Reporting and Follow-up.* Monitoring Personnel shall have access to all relevant records and information necessary to assess field representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations. Results from the FFMP shall be compiled and reported to the Compliance Officer for review and remediation as appropriate. Potential violations related to improper promotion of a Government Reimbursed Service or potential violations of Federal health care program or CLIA requirements shall be reported to the Compliance Officer for appropriate follow-up activity. In the event that a compliance issue, including but not limited to any potential improper promotion or noncompliance with Millennium's Policies and Procedures, is identified during any portion of the FFMP, the Compliance Officer shall investigate the incident consistent with established Policies and Procedures for the handling of investigations. As part of the investigative procedures, findings shall be made and all necessary and appropriate responsive action (including disciplinary action) and corrective action shall be taken, including the disclosure of Reportable Events pursuant to Section III.K above, as applicable. Any compliance issues identified during the FFMP and any corrective action shall be recorded in the files of the Compliance Officer.

Millennium shall include a summary of the FFMP and the results of the FFMP as part of each Annual Report. As part of each Annual Report, Millennium also shall provide the OIG with copies of the Observation report for any instances in which it was determined that improper promotion occurred and a description of the action(s) that Millennium took as a result of such determinations. Millennium shall make the Observation reports for all other Observations available to the OIG upon request.

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, Millennium 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, Millennium 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, Millennium 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, Millennium shall notify OIG of this fact as soon as possible, but no later than 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, Millennium 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, Millennium 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, phone number, 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 Millennium 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 determined and agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

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

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the name, address, phone number, and position description of the Chief Clinical Officer required by Section III.A, and the job responsibilities the Chief Clinical Officer;
3. the names and positions of the members of the Compliance Committee required by Section III.A;
4. the names of the Board members who are responsible for satisfying the Board of Directors compliance obligations described in Section III.A.3;
5. the names and positions of the Certifying Employees required by Section III.A.4;
6. a copy of Millennium's Code of Conduct required by Section III.B.1;
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) and a copy of all current requisition forms;
8. the Training Plan required by Section III.C.1 and a description of the Board of Directors training required by Section III.C.2 (including a summary of the topics covered, the length of the training, and when the training was provided);
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 IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendices A and B to this CIA; (d) a summary and description of any and all current and prior engagements and agreements between Millennium and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to Millennium;

11. a description of the risk assessment and internal review process required by Section III.F;

12. a description of the Disclosure Program required by Section III.G;

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

14. a copy of Millennium's policies and procedures regarding the identification, quantification and repayment of Overpayments required by Section III.J;

15. a description of the Field Force Monitoring Program required by Section III.L;

16. a list of all of Millennium's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare 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 Millennium currently submits claims;

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

18. the certifications required by Section V.C.

B. Annual Reports

Millennium shall submit to OIG annually a report with respect to the status of, and findings regarding, Millennium'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 and Chief Clinical Officer; any change in the membership of the Compliance Committee described in Section III.A, 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.4;
2. the dates of each report made by the Compliance Officer to the Chief Executive Officer and Board (written documentation of such reports shall be made available to OIG upon request);
3. the dates of each report made by the Chief Clinical Officer to the Chief Executive Officer and Board (written documentation of such reports shall be made available to OIG upon request);
4. 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;
5. a summary of any changes or amendments to Millennium'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) and a copy of all current requisition forms;
6. a copy of Millennium's Training Plan developed under Section III.C and the following information regarding each type of training required by the Training Plan: a description of the training, including a summary of the topics covered; the length of sessions, a schedule of training sessions, a general description of the categories of individuals required to complete the training, and the process by which Millennium ensures that all designated employees receive appropriate training. A copy of all training materials and the documentation to support this information shall be made available to OIG upon request.

7. 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;

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

9. a summary and description of any and all current and prior engagements and agreements between Millennium and the IRO (if different from what was submitted as part of the Implementation Report) and a certification from the IRO regarding its professional independence and objectivity with respect to Millennium;

10. a description of the risk assessment and internal review process required by Section III.F., a summary of any changes to the process and a description of the reasons for such changes;

11. a summary of all internal audits performed pursuant to Section III.F during the Reporting Period and any corrective action plans developed in response to those internal audits. Copies of the internal audit reports and corrective actions plans shall be made available to OIG upon request;

12. a summary of the disclosures in the disclosure log required by Section III.G that: (a) relate to Federal health care programs; or (b) involve allegations of conduct that may involve illegal remuneration 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);

13. a certification that Millennium has completed the screening required by Section III.H regarding Ineligible Persons;

14. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.I. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

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

16. 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;

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

18. a summary of any changes or amendments to Millennium's Field Force Monitoring Program required by Section III.L;

19. a summary describing any audits conducted during the applicable Reporting Period by a Medicare or state Medicaid program contractor or any government entity or contractor, involving a review of Federal health care program claims, and Millennium's response/corrective action plan (including information regarding any Federal health care program refunds) relating to the audit findings;

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

21. 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, Millennium shall include the certifications of Certifying Employees as required by Section III.A.4;

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, Millennium is in compliance with all of the requirements of this CIA;
- b. to the best of his or her knowledge, Millennium 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, Millennium has fulfilled the requirements for New and Renewed Focus Arrangements under Section III.D.2 of the 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.

D. Designation of Information

Millennium 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. Millennium shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services

Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

Millennium:

Michael Myers, Esq.
Chief Compliance Officer
Millennium Health, LLC
15330 Avenue of Science
San Diego, CA 92128
Telephone: 858.451.3535
Facsimile: 858.217.1910
Michael.Myers@millenniumhealth.com

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

Millennium shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Millennium's Covered Persons may elect to be interviewed with or without a representative of Millennium present.

VIII. DOCUMENT AND RECORD RETENTION

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

X. BREACH AND DEFAULT PROVISIONS

Millennium 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, Millennium 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 Millennium fails to establish and implement any of the following obligations as described in Sections III and IV:

- a. a Compliance Officer;
- b. a Chief Clinical Officer;

- b. a Compliance Committee;
- c. the Board of Directors compliance obligations;
- d. the management certification obligations;
- e. a written Code of Conduct;
- f. written Policies and Procedures as described in Section III.B.2;
- g. the development and/or implementation of a Training Plan for the training of Covered Persons, Reimbursement Covered Persons, Sales and Marketing Covered Persons, Arrangements Covered Persons, and Board Members;
- h. the Focus Arrangements Procedures and/or Focus Arrangements Requirements described in Sections III.D.1 and III.D.2;
- i. a risk assessment and internal review process as required by Section III.F;
- j. a Disclosure Program;
- k. Ineligible Persons screening and removal requirements;
- l. notification of Government investigations or legal proceedings;
- m. policies and procedures regarding the repayment of Overpayments;
- n. the repayment of Overpayments as required by Section III.J and Appendix C;
- o. reporting of Reportable Events;

- p. a Field Force Monitoring Program as required by Section III.L; 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 Millennium fails to engage and use an IRO, as required by Section III.E and Appendices A-D.

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 Millennium 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 Millennium fails to submit any Claims Review Report or Arrangements Review Report in accordance with the requirements of Section III.E, Appendix B, and Appendix D.

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

6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of Millennium as part of its Implementation Report, any 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 Millennium fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Millennium stating the specific grounds for its determination that Millennium has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Millennium shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date Millennium 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

Millennium 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 Millennium 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 Millennium 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 Millennium 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 Millennium of: (a) Millennium'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, Millennium 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 Millennium elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Millennium 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 Millennium 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 Millennium to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.K;
- 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 an IRO in accordance with Section III.E, Appendix A, or Appendix B.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Millennium constitutes an independent basis for Millennium'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 Millennium has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Millennium of: (a) Millennium'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.* Millennium 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) Millennium has begun to take action to cure the material breach; (ii) Millennium is pursuing such action with due diligence; and (iii) Millennium has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Millennium fails to satisfy the requirements of Section X.D.3, OIG may exclude Millennium from participation in the Federal health care programs. OIG shall notify Millennium in writing of its determination to exclude Millennium. (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 Millennium’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, Millennium 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 Millennium 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, Millennium 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 Millennium was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Millennium 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 Millennium to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Millennium 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 Millennium was in material breach of this CIA and, if so, whether:

- a. Millennium 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 Millennium's receipt of the Notice of Material Breach: (i) Millennium had begun to take action to cure the material breach; (ii) Millennium pursued such action with due diligence; and (iii) Millennium 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 Millennium, only after a DAB decision in favor of OIG. Millennium's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Millennium 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 Millennium 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. Millennium 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 Millennium, Millennium 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

Millennium 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 Millennium's obligations under this CIA based on a certification by Millennium that it is no longer providing health care items or services that will be billed to any Federal health care program and 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 Millennium is relieved of its CIA obligations, Millennium shall be required to notify OIG in writing at least 30 days in advance if Millennium 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) Millennium'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 Millennium 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 MILLENNIUM

/Brock Hardaway/

BROCK HARDAWAY
Chief Executive Officer
Millennium Health, LLC
/Michael K. Loucks/

10/15/15
DATE

MICHAEL K. LOUCKS
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/Joseph Savage, Jr./

10/15/15
DATE

JOSEPH F. SAVAGE, JR.
Goodwin Procter
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Boston, MA 02109

10/15/15
DATE

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

/Robert K. DeConti/

ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services
/Andrea L. Treese Berlin/

10/16/15

DATE

ANDREA L. TREESE BERLIN
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services

10/8/15

DATE

APPENDIX A

CLAIMS REVIEW

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. Millennium shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.8 of the CIA or any additional information submitted by Millennium in response to a request by OIG, whichever is later, OIG will notify Millennium if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Millennium may continue to engage the IRO.

2. If Millennium engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, Millennium shall submit the information identified in Section V.A.8 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Millennium at the request of OIG, whichever is later, OIG will notify Millennium if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Millennium may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Claims Review who have expertise in the relevant billing, coding, claims submission, medical documentation, medical reasonableness and necessity, and other applicable Medicare and state Medicaid program requirements, including National and Local Coverage Determinations and program guidance;

2. assign individuals to design and select the Claims Review sample who are knowledgeable about the appropriate statistical sampling techniques;

3. assign individuals to conduct the coding review portions of the Claims Review who have a nationally recognized coding certification and who have maintained this certification (e.g., completed applicable continuing education requirements); and

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

C. IRO Responsibilities

The IRO shall:

1. perform each Claims Review in accordance with the specific requirements of the CIA;

2. follow all applicable Medicare and state Medicaid program rules and reimbursement guidelines in making assessments in the Claims Review, including, but not limited to, consideration of medical reasonableness and necessity and National and Local Coverage Determinations and program guidance;

3. request clarification from the appropriate authority (e.g., Medicare contractor), if in doubt of the application of a particular Medicare or state Medicaid program policy or regulation (including, but not limited to, National and Local Coverage Determinations and program guidance) or medical reasonableness and necessity;

4. respond to all OIG inquiries in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendix C to the CIA.

D. IRO Independence and Objectivity

The IRO must perform the Claims Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

E. IRO Removal/Termination

1. *Millennium and IRO.* If Millennium terminates its' IRO or if the IRO withdraws from the engagement during the term of the CIA, Millennium must submit a notice explaining (a) its reasons for termination of the IRO or (b) the IRO's reasons for its withdrawal to OIG, no later than 30 days after termination or withdrawal. Millennium must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Millennium in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Millennium shall have 30 days from the date of OIG's written notice to provide information regarding the 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 Millennium regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Millennium in writing that Millennium shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Millennium must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require Millennium to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

ARRANGEMENTS REVIEW INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. Millennium shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.9 of the CIA or any additional information submitted by Millennium in response to a request by OIG, whichever is later, OIG will notify Millennium if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Millennium may continue to engage the IRO.

2. If Millennium engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, Millennium shall submit the information identified in Section V.A.9 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Millennium at the request of OIG, whichever is later, OIG will notify Millennium if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Millennium may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. 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 and other guidance documents related to these statutes; and

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

C. IRO Responsibilities

The IRO shall:

1. perform each 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 Appendix D to the CIA.

D. IRO Independence and Objectivity

The IRO must perform the Arrangements Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

E. IRO Removal/Termination

1. *Millennium and IRO.* If Millennium terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Millennium must submit a notice explaining (a) its reasons for termination of the IRO or (b) the IRO's reasons for its withdrawal to OIG, no later than 30 days after termination or withdrawal. Millennium must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Millennium in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Millennium shall have 30 days from the date of OIG's written notice to provide information regarding the 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 Millennium regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Millennium in writing that Millennium shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Millennium must engage a new IRO within 60 days of its receipt of OIG's written notice.

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

APPENDIX C

CLAIMS REVIEW

A. Claims Review. The IRO shall perform the Claims Review annually to cover each of the five Reporting Periods. The IRO shall perform all components of each Claims Review.

1. *Definitions*. For the purposes of the Claims Review, the following definitions shall be used:

- a. Overpayment: The amount of money Millennium has received in excess of the amount due and payable under Medicare or any state Medicaid program requirements as determined by the IRO in connection with the claims reviews performed under this Appendix C, including any extrapolated Overpayments determined in accordance with Section A.3 of this Appendix C.
- b. Paid Claim: A claim for laboratory testing submitted by Millennium and for which Millennium has received reimbursement from the Medicare program or the selected state Medicaid program.² Each Paid Claim shall include all laboratory testing claims submitted by Millennium for the same Medicare or state Medicaid program beneficiary on the same date of service (*i.e.* a Paid Claim will consist of all laboratory testing claims per beneficiary per encounter).

2 For each Reporting Period, one state Medicaid program will be included in the Paid Claims reviewed. It is currently anticipated that the following state Medicaid claims will be included in the noted Reporting Period:

<u>Reporting Period</u>	<u>State</u>
1	North Carolina
2	Florida
3	Georgia
4	Oklahoma
5	Kentucky

However, the state Medicaid program selected for inclusion in each Reporting Period's Paid Claims is subject to change with a 60 day notice at the end of each Reporting Period. A change in the selected state is at the sole discretion of the OIG.

- c. Population: The Population shall be defined as all Paid Claims during the 12-month period covered by the Claims Review.
- d. Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample shall be included as part of the net Overpayment calculation.)

The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Paid Claims in the sample.

2. *Discovery Sample*. The IRO shall randomly select and review a sample of 350 Paid Claims (Discovery Sample). The Paid Claims reviewed shall be comprised of three strata as follows: 150 Medicare urine drug testing Paid Claims, 100 Medicaid urine drug testing Paid Claims, and 100 genetic testing Paid Claims. The IRO shall determine the Error Rate (defined above) for each strata separately. The Paid Claims shall be reviewed based on the supporting documentation available at Millennium or under Millennium's control and applicable billing and coding regulations and guidance to determine whether the tests were properly ordered and performed (including, but not limited to determining: 1) whether the diagnosis information included on the requisition form or otherwise obtained from the ordering physician supports the medical necessity of the test(s) ordered, 2) that the test(s) ordered on the requisition form match(es) the test(s) performed, 3) determining that the test(s) ordered and performed match(es) the test(s) included in each Paid Claim, and 4) whether the claim was correctly coded, submitted, and reimbursed.

If the Error Rate (as defined above) for each strata in the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, Millennium should, as appropriate, further analyze any errors identified in the Discovery Sample. Millennium recognizes that OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample or any other segment of the universe.)

3. *Full Sample.* If the Discovery Sample indicates that the Error Rate for any strata is 5% or greater, the IRO shall select an additional sample of Paid Claims for that strata (Full Sample) using commonly accepted sampling methods. The Paid Claims selected for the Full Sample shall be reviewed based on supporting documentation available at Millennium or under Millennium's control and applicable billing and coding regulations and guidance to determine whether the test(s) were properly ordered and performed (including, but not limited to determining: 1) whether the diagnosis information included on the requisition form or otherwise obtained from the ordering physician supports the medical necessity of the test(s) ordered, 2) that the test(s) ordered on the requisition form match(es) the test(s) performed, 3) determining that the test(s) ordered and performed match(es) the test(s) included in each Paid Claim, and 4) whether the claim was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, the IRO may use the Paid Claims sampled as part of the Discovery Sample, and the corresponding findings for those Paid Claims, as part of its Full Sample, if: (1) statistically appropriate and (2) the IRO selects the Full Sample Paid Claims using the seed number generated by the Discovery Sample. The findings of the Full Sample shall be used by the IRO to estimate the actual Overpayment in the Population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from Millennium to the appropriate Federal health care program payor (e.g., Medicare contractor), for appropriate follow-up by that payor.

4. *Systems Review.* If Millennium's Discovery Sample identifies an Error Rate of 5% or greater for any strata, Millennium's IRO shall also conduct a Systems Review related to the Paid Claims in that strata. The Systems Review shall consist of the following:

- a. a review of Millennium's billing and coding systems and processes relating to claims submitted to Federal health care programs (including, but not limited to, the operation of the billing system, the process by which claims are coded, safeguards to ensure proper coding, claims submission and billing; and procedures to identify and correct inaccurate coding and billing);
- b. for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO shall review the system(s) and

process(es) that generated the claim and identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

5. *Other Requirements.*

- a. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Paid Claims selected as part of the Discovery Sample or Full Sample (if applicable), and Millennium shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Discovery Sample or Full Sample (if applicable). If the IRO accepts any supplemental documentation or materials from Millennium after the IRO has completed its initial review of the Discovery Sample or Full Sample (if applicable) (Supplemental Materials), the IRO shall identify in the Claims Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Claims Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.
- b. Paid Claims without Supporting Documentation. Any Paid Claim for which Millennium cannot produce required documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Millennium for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.
- c. Use of First Samples Drawn. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, the Paid Claims selected in each first sample shall be used (*i.e.*, it is not permissible to generate more than one list of random samples and then select one for use with the Discovery Sample or Full Sample).

6. *Repayment of Identified Overpayments.* Millennium shall repay within 30 days any Overpayment(s) identified in the Discovery Sample, regardless of the Error Rate, and (if applicable) the Full Sample, including the IRO's estimate of the actual Overpayment in the Population as determined in accordance with Section A.3 above, in accordance with payor refund policies. Millennium shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

B. Claims Review Report. The IRO shall prepare a Claims Review Report as described in this Appendix for each Claims Review performed. The following information shall be included in the Claims Review Report for each Discovery Sample and Full Sample (if applicable).

1. *Claims Review Methodology.*

- a. Claims Review Population. A description of the Population subject to the Claims Review.
- b. Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.
- c. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Claims Review (e.g., requisition forms, Local Coverage Determinations (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).
- d. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.
- e. Supplemental Materials. A description of any Supplemental Materials as required by A.5.a., above.

2. *Statistical Sampling Documentation.*

- a. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.

- b. A copy of the statistical software printout(s) estimating how many Paid Claims are to be included in the Full Sample, if applicable.
 - c. A description or identification of the statistical sampling software package used to select the sample and determine the Full Sample size, if applicable.
3. *Claims Review Findings.*
- a. Narrative Results.
 - i. A description of Millennium's ordering and referral process, including a description of how requisition forms are received, documented, reviewed, and monitored.
 - ii. A description of Millennium's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.
 - iii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any).
 - b. Quantitative Results.
 - i. For each strata, the total number and percentage of instances in which the IRO determined that the Paid Claims submitted by Millennium (Claim Submitted) differed from what should have been the correct claim (Correct Claim), regardless of the effect on the payment.
 - ii. For each strata, the total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to Millennium.
 - iii. Total dollar amount of all Overpayments (by strata) in the Discovery Sample and the Full Sample (if applicable).

- iv. Total dollar amount of Paid Claims (by strata) included in the Discovery Sample and the Full Sample and the net Overpayment associated with each strata in the Discovery Sample and the Full Sample.
 - v. Error Rate for each strata in the Discovery Sample and the Full Sample.
 - vi. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim: Federal health care program billed, beneficiary health insurance claim number, date of service, code submitted (e.g., DRG, CPT code, etc.), code reimbursed, allowed amount reimbursed by payor, correct code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.
 - vii. If a Full Sample is performed, the methodology used by the IRO to estimate the actual Overpayment in the Population for that strata and the amount of such Overpayment.
- c. Recommendations. The IRO's report shall include any recommendations for improvements to Millennium's billing and coding system and/or lab test ordering system based on the findings of the Claims Review.

4. *Systems Review Findings*. The IRO shall prepare a Systems Review Report based on the Systems Review performed (if applicable) that shall include the IRO's observations, findings, and recommendations regarding:

- a. the strengths and weaknesses in Millennium's billing systems and processes;
- b. the strengths and weaknesses in Millennium's coding systems and processes;

- c. the strengths and weaknesses in Millennium's laboratory test ordering systems and processes; and
- d. possible improvements to Millennium's billing, coding, and ordering systems and processes to address the specific problems or weaknesses that resulted in the identified Overpayments.

5. *Credentials.* The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review and (2) performed the Claims Review.

APPENDIX D

ARRANGEMENTS REVIEW

The Arrangements Review shall consist of two components: a systems review and a transactions review. The IRO shall perform all components of each Arrangements Review. If there are no material changes to Millennium's systems, processes, policies, and procedures relating to Arrangements, the Arrangements Systems Review shall be performed for the first and fourth Reporting Periods. If Millennium materially changes the Arrangements systems, processes, policies and procedures, the 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 Millennium's systems, processes, policies, and procedures relating to the initiation, review, approval, and tracking of Arrangements. Specifically, the IRO shall review the following:

1. Millennium'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. Millennium's systems, policies, processes, and procedures for tracking remuneration to and from all parties to Focus Arrangements;
3. Millennium's systems, policies, processes, and procedures for 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);
4. Millennium'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. Millennium'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. Millennium'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 Millennium, 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 on the Focus Arrangements Tracking System, Millennium's internal review and approval process, and other Arrangements systems, process, policies, and procedures;

8. Millennium'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. Millennium'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 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 Millennium'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 Millennium's systems, processes, policies, and procedures relating to Arrangements described in Section A.1-9 above; and

4. recommendations to improve Millennium'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 100 randomly selected Focus Arrangements that were entered into or renewed by Millennium during the Reporting Period. The IRO shall assess whether Millennium 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 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 Millennium's centralized tracking system in a manner that permits the 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 tracked;
4. verifying that the service and activity logs are properly completed and reviewed (if applicable);
5. verifying that leased space, medical supplies, medical devices, and equipment, and other patient care items are properly monitored (if applicable); and
6. verifying that the Focus Arrangement satisfies the Focus Arrangements Requirements of Section III.D.2 of the CIA.

D. Arrangements Transaction Review Report. The IRO shall prepare a report based on each Arrangements Transactions Review performed. The Arrangements Transaction 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 IRO in performing the Arrangements Transaction Review.
- c. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Focus Arrangements selected as part of the Arrangements Transaction Review and Millennium shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Focus Arrangements. If the IRO accepts any supplemental documentation or materials from Millennium after the IRO has completed its initial review of the Focus Arrangements (Supplemental Materials), the IRO shall identify in the Arrangements Transaction Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Arrangements Transaction Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

2. *Review Findings.* The IRO's findings with respect to whether Millennium has complied with the Focus Arrangements Procedures and Focus Arrangements Requirements with respect to each of the randomly selected Focus Arrangements reviewed by the IRO. In addition, the Arrangements Transactions Review Report shall include observations, findings and recommendations on possible improvements to Millennium's policies, procedures, and systems in place to ensure that all Focus Arrangements comply with the Focus Arrangements Procedures and Focus Arrangements Requirements.