CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
HEALTH DIAGNOSTIC LABORATORY, INC.

I. PREAMBLE

Health Diagnostic Laboratory, Inc. (HDL) 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, HDL 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 HDL 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) HDL's final annual report; or (2) any additional materials submitted by HDL 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 HDL and any actual or potential source of health care business or referrals to HDL or any actual or potential recipient of health care business or referrals from HDL. 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 HDL refers an individual for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part by a Federal health care program, or (2) from whom HDL 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 HDL 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 HDL for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

2. "Focus Arrangements" means every Arrangement that:

a. is between HDL and any actual source of health care business or referrals to HDL and involves, directly or indirectly, the offer, payment, or provision of anything of value; or

b. is between HDL 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 HDL for designated health services (as defined at 42 U.S.C. §1395nn(h)(6)).

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

3. "Covered Persons" includes:

a. all owners who are natural persons and who have an ownership interest of 5 percent or greater, officers, directors, and employees of HDL; and

b. all contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of HDL excluding vendors whose sole connection with HDL is selling or otherwise providing medical supplies or equipment to HDL and who do not bill the Federal health care programs for such medical supplies or equipment.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours during a Reporting Period, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during a Reporting Period.

4. "Arrangements Covered Persons" includes each Covered Person who is involved with the development, approval, management, or review of HDL's Arrangements.

5. "Government Reimbursed Tests" refers to all HDL tests that are marketed or provided by HDL and reimbursed by Federal health care programs.

6. "Promotional Functions" includes: (a) the marketing, advertising, or promoting of Government Reimbursed Tests; and (b) the preparation or external dissemination of promotional materials or information about, or the provision of promotional services relating to, Government Reimbursed Tests, including those functions relating to HDL's review and approval processes for promotional materials and any applicable review committee(s).

7. "Promotional Covered Persons" includes each Covered Person who is involved with the development, approval, management, or review of HDL's Promotional Functions (including any sales force members).

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Officer and Committee

1. *Compliance Officer.* HDL has appointed a Covered Person to serve as its Compliance Officer and shall maintain a Compliance Officer, who is a Covered Person, for the term of the CIA. The Compliance Officer shall be a member of senior management of HDL, shall report directly to the Chief Executive Officer of HDL, 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 HDL. 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 a Compliance Committee of the Board of Directors of HDL (Board Compliance Committee), and shall be authorized to report on such matters to the Board Compliance Committee at any time. Written documentation of the Compliance Officer's reports to the Board Compliance Committee shall be made available to OIG upon request; and

c. monitoring the day-to-day compliance activities engaged in by HDL 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.

HDL 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. *Executive Compliance Committee.* HDL has appointed an Executive Compliance Committee. The Executive 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., personnel of relevant departments, such as

billing, human resources, and operations). The Compliance Officer shall chair the Executive Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of HDL's risk areas and shall oversee monitoring of internal and external audits and investigations). The Executive Compliance Committee shall meet at least quarterly. The minutes of the Executive Compliance Committee meetings shall be made available to OIG upon request.

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

3. *Board Compliance Committee.* The Board Compliance Committee 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 Compliance Committee must include independent (i.e., non-executive) members.

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

a. meeting at least quarterly to review and oversee HDL's compliance program, including but not limited to the performance of the Compliance Officer and Executive Compliance Committee;

b. submitting to the OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period; and

c. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board Compliance Committee, summarizing its review and oversight of HDL's compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

"The Compliance Committee of the Board of Directors (the Board Compliance Committee) has made a reasonable inquiry into the operations of HDL's Compliance

Program including the performance of the Compliance Officer and the Executive Compliance Committee. Based on its inquiry and review, the Board Compliance Committee has concluded that, to the best of its knowledge, HDL has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA."

If the Board Compliance Committee is unable to provide such a conclusion in the resolution, the Board Compliance Committee 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 HDL.

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

4. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain HDL employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable HDL 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: President and Chief Executive Officer, Chief Scientific Officer, Chief Commercial Officer, Chief Medical Officer, Chief Compliance Officer, Senior Vice President of Billing, Operations, Coding and Compliance, Vice President of Clinical Affairs, and Vice President of Marketing and Public Relations. 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 HDL policies, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the [insert name of department] of HDL 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.

B. Written Standards

1. *Code of Conduct.* Within 120 days after the Effective Date, HDL shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. HDL 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. HDL's commitment to full compliance with all Federal health care program requirements, including the submission of claims for items or services furnished to Medicare and Medicaid program beneficiaries consistent with such requirements;

b. HDL's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with HDL's own Policies and Procedures;

c. the requirement that all of HDL's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by HDL, suspected violations of any Federal health care program requirements or of HDL's own Policies and Procedures; and

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

HDL 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, HDL 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 HDL's compliance with Federal health care program

requirements. The Policies and Procedures also shall address at a minimum the following:

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. all statutes, regulations, and other guidance related to the provision of and reimbursement for blood testing services;

d. appropriate ways to conduct Promotional Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Anti-Kickback Statute;

e. the dissemination of materials and information by HDL sales representatives about Government Reimbursed Tests and the manner in which HDL sales representatives respond to requests for information about (i) the medical necessity of Government Reimbursed Tests, and (ii) the use of standard or custom requisition templates (Panels). These Policies and Procedures shall require that sales representatives use only materials that have been reviewed and approved by HDL;

f. the development and review by appropriate qualified personnel (e.g., personnel of relevant departments, such as operations or legal) of promotional materials and information intended to be disseminated outside HDL to ensure that legal, regulatory, and medical concerns are properly addressed during HDL's review and approval process and are elevated when appropriate. The Policies and Procedures shall be designed to ensure that such materials and information comply with all applicable Federal health care program requirements. The Policies and Procedures shall require the review by appropriate qualified personnel of all promotional

materials prior to the distribution or use of such materials; and

g. the distribution of materials and tools for the collection, processing, and handling of specimens for Government Reimbursed Tests (Specimen Materials and Tools). This shall include a review of the bases upon, and circumstances under, which providers may receive Specimen Materials and Tools from HDL.

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

At least annually (and more frequently, if appropriate), HDL 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 120 days after the Effective Date, HDL shall develop a written plan (Training Plan) that outlines the steps HDL will take to ensure that:

a. all Covered Persons receive adequate training regarding (i) HDL's CIA requirements and Compliance Program, including the Code of Conduct (General Training) and, (ii) to the extent relevant to their responsibilities, Federal health care program requirements related to the submission of claims for items or services furnished to Medicare and Medicaid program beneficiaries;

b. all Arrangements Covered Persons receive adequate 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) HDL'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 HDL's Arrangements to know the applicable legal requirements and HDL'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; and

c. all Promotional Covered Persons receive adequate training regarding: (i) all applicable Federal health care program requirements relating to Promotional Functions; (ii) HDL's Policies and Procedures and other requirements applicable to Promotional Functions; (iii) HDL's policy regarding the distribution of Specimen Materials and Tools; (iv) the personal obligation of each individual involved in Promotional Functions to comply with all applicable Federal health care program and other applicable legal requirements; (v) the legal sanctions under the Anti-Kickback Statute and the Stark Law; and (vi) proper and improper practices related to Promotional Functions.

The Training Plan shall include information regarding the training topics, the identification of Covered Persons, Arrangements Covered Persons, and Promotional 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 HDL's Training Plan, OIG will notify HDL of any comments or objections to the Training Plan. Absent notification by the OIG that the Training Plan is unacceptable, HDL may implement its Training Plan. HDL shall furnish training to its Covered Persons, Arrangements Covered Persons, and Promotional Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Board Member Training.* Within 120 days after the Effective Date, HDL shall provide at least two hours of training to each member of the Board of Directors. This training shall address the HDL'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 120 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.* HDL 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 Arrangements Transactions Review, Arrangements Systems Review, or Promotional Functions Systems Review, and any other relevant information. Any updates to the Training Plan must be submitted to the OIG prior to the implementation of the revised Training Plan. Within 30 days of OIG's receipt of any updates or revisions to HDL's Training Plan, OIG will notify HDL of any comments or objections to the revised Training Plan. Absent notification from the OIG that the revised Training Plan is unacceptable, HDL may implement the revised Training Plan.

6. *Computer-based Training.* HDL may provide the training required under this CIA through appropriate computer-based training approaches. If HDL 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 120 days after the Effective Date, HDL 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 Executive 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, HDL shall comply with the following requirements (Focus Arrangements Requirements):

a. ensure that each Focus Arrangement is set forth in writing and signed by HDL 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. Additionally, HDL shall provide each party to the Focus Arrangement with a copy of its Code of Conduct and Stark Law and Anti-Kickback Statute Policies and Procedures; and

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

3. *Records Retention and Access*. HDL 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 120 days after the Effective Date, HDL shall engage an individual or entity (or entities), such as an accounting, auditing, law, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this Section III.E. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

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

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

2. *IRO Reviews*. The IRO shall perform an Arrangements Systems Review, Arrangements Transactions Review, and Promotional Functions Systems Review (generally referred to as an "IRO Review") and prepare a report for each Review (IRO Review Report) as outlined in Appendix B to this CIA, which is incorporated by reference.

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

Prior to initiating a Validation Review, OIG shall notify HDL of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, HDL may request a meeting with OIG to: (a) discuss the results of any IRO Review submissions or findings; (b) present any additional information to clarify the results of the IRO Review or to correct the inaccuracy of the IRO Review; and/or (c) propose alternatives to the proposed Validation Review. HDL agrees to provide any additional information as may be requested by OIG under this Section III.E.3 in an expedited manner. OIG will attempt in good faith to resolve any IRO Review issues with HDL prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

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

F. Risk Assessment and Internal Review Process

Within 120 days after the Effective Date, HDL shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with Arrangements (as defined in Section II.C.1 above), Promotional Functions (as defined in Section II.C.7 above), and the appropriate submission of claims for items or services furnished to Medicare and Medicaid program beneficiaries. 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. HDL shall maintain the risk assessment and internal review process for the term of the CIA. Copies of any internal audit work plans, internal audit reports, and corrective action plans prepared in connection with the risk assessment and internal review process shall be made available to OIG upon request.

G. Disclosure Program

HDL has established a Disclosure Program that includes a mechanism (including 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 HDL'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. HDL has publicized and shall continue to 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, HDL 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.* HDL shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

a. HDL 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. HDL shall screen all Covered Persons against the Exclusion Lists within 120 days after the Effective Date and thereafter shall screen against the LEIE on a monthly basis and screen against SAM on an annual basis.

c. HDL 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 Section III.H affects HDL'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. HDL understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that HDL may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether HDL meets the requirements of Section III.H.

3. *Removal Requirement.* If HDL has actual notice that a Covered Person has become an Ineligible Person, HDL shall remove such Covered Person from responsibility for, or involvement with, HDL'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 HDL 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, HDL shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of services rendered to any beneficiary or patient, or any claims submitted to any Federal health care program.

I. Notification of Government Investigation or Legal Proceedings

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

J. Repayment of Overpayments

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

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

2. *Reporting of Reportable Events.* If HDL determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, HDL 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 of the identification of the Overpayment 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 HDL to identify and quantify the Overpayment; and

d. a description of HDL's actions taken to correct the Reportable Event and prevent it from recurring.

Within 60 days of identification of the Overpayment, HDL 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 HDL'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 HDL 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 HDL 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 only a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by HDL 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 only the Stark Law that is disclosed to CMS pursuant to the SRDP. If HDL identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then HDL is not required by this Section III.K to submit the Reportable Event to CMS through the SRDP.

L. Internal Monitoring Program

Within 120 days after the Effective Date, HDL shall establish an Internal Monitoring Program (IMP) to evaluate and monitor HDL's interactions with health care professionals (HCPs).

1. *Compliance Review Program.* HDL compliance personnel or their designees (Monitoring Personnel) shall conduct direct field observations (Observations) of HDL sales representatives to assess whether (i) those sales representatives understand and comply with the Policies and Procedures required by the CIA, and (ii) the messages delivered and materials distributed to HCPs are consistent with applicable legal requirements and with HDL's Policies and Procedures. These Observations shall be full-day ride-alongs with field sales representatives, and each Observation shall consist of directly observing all meetings between a sales representative and HCPs during the workday. HDL shall conduct at least 10 Observations annually so long as HDL has at least 20 sales representatives and, if HDL has fewer than 20 sales representatives, at least one Observation annually of at least 50% of HDL's sales force. The Observations shall be scheduled throughout the year, judgmentally selected by Monitoring Personnel, and conducted across the United States.

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

a. the identity of the reviewed sales representative;

b. the identity of the Monitoring Personnel who conducted the Observation;

c. the date and duration of the Observation;

d. an overall assessment of compliance with and understanding of HDL's Policies and Procedures;

e. the identification of any potential non-compliance with the Policies or Procedures; and

f. such other elements as HDL's Compliance Department may require.

Monitoring Personnel conducting the Observations shall have access to all relevant records and information of HDL necessary to assess HDL's interactions with HCPs and to identify potential or actual compliance violations. Results from the Observations shall be compiled and reported to the Compliance Officer for review and remediation as appropriate. Potential violations of Federal health care program requirements shall be reported to the Compliance Office for appropriate follow-up activity.

2. *Reporting and Follow-up.* In the event that a compliance issue is identified during any Observation, HDL shall investigate the incident. As part of the formal investigation procedures, findings shall be made and all necessary and appropriate responsive action (including disciplinary action) and corrective action shall be taken. The Compliance Officer shall disclose Reportable Events pursuant to Section III.K above, if applicable. The Compliance Office shall maintain records of any compliance issues identified during an Observation and any corrective action.

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

M. Cooperation

Upon reasonable notice and request, HDL shall cooperate with all OIG investigations relating to the Covered Conduct in the Settlement Agreement entered into between the United States and HDL contemporaneously with this CIA, and understands that full cooperation includes: (1) prompt and truthful disclosures, upon reasonable notice and request, to OIG and (2) truthful testimony in administrative hearings and/or court proceedings. HDL, upon reasonable notice, will make reasonable efforts to facilitate access to, and encourage the cooperation of, its current and former directors, officers, and employees for interviews and testimony relating to the Covered Conduct, and will furnish to OIG, upon reasonable request, all documents and records in its possession, custody, or control relating to the Covered Conduct. Section III.M shall not require and shall not be construed as a waiver of any applicable attorney-client or work product privileges.

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, HDL 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, HDL 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, HDL 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, HDL shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the business, business unit or location.

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

In the event that, after the Effective Date, HDL 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, HDL 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 HDL currently submits claims. Each new business, business unit or location and all Covered Persons at each new business, business unit or location shall be subject to the applicable requirements of this CIA, unless otherwise agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

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

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

2. the names and positions of the members of the Executive Compliance Committee required by Section III.A.2;

3. the names of the members of the Board Compliance Committee described in Section III.A.3;

4. the names and positions of the Certifying Employees required by Section III.A.4;

5. a copy of HDL's Code of Conduct required by Section III.B.1;

6. a summary of all Policies and Procedures required by Section III.B.2 (copies of the Policies and Procedures shall be made available to OIG upon request);

7. 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);

8. 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;

9. 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 Appendix A to this CIA; (d) a summary and description of any and all current and prior engagements and agreements between HDL and the IRO(s); and (e) a certification from the IRO(s) regarding its professional independence and objectivity with respect to HDL;

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

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

12. a certification that HDL has conducted the screening required by Section III.H regarding Ineligible Persons, or a description of why HDL cannot provide such a certification;

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

14. a list of all of HDL'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 HDL currently submits claims;

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

16. the certifications required by Section V.C.

B. Annual Reports

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

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; any change in the membership of the Executive Compliance Committee described in Section III.A.2, any change in the membership of the Board Compliance Committee 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 Board (written documentation of such reports shall be made available to OIG upon request);

3. the Board resolution required by Section III.A.3 and a description of the documents and other materials reviewed by the Board, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution;

4. a summary of any changes or amendments to HDL'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);

5. a copy of HDL'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 HDL 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.

6. 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;

7. a complete copy of all reports prepared pursuant to Section III.E, along with a copy of the IRO(s)' engagement letter;

8. HDL's response to the reports prepared pursuant to Section III.E, 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 HDL and the IRO(s), if different from what was submitted as part of the Implementation Report;

10. a certification from the IRO(s) regarding its professional independence and objectivity with respect to HDL;

11. 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;

12. a copy of HDL's internal audit work plans and a list of all reviews completed during the Reporting Period pursuant to Section III.F;

13. 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 remunerations or inappropriate referrals in violation of the Anti-Kickback Statute or Stark law (the complete disclosure log shall be made available to OIG upon request);

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

15. 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;

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

17. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: Medicare, Medicaid (report each applicable state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report;

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

19. a summary of the IMP and the results of the IMP required by Section III.L, including a summary of the Observations and copies of any reports from Observations in which a compliance issue was identified, and a description of the

action(s) that HDL took as a result of such determination;

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

21. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 90 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, HDL 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, HDL is in compliance with all of the requirements of this CIA;

b. to the best of his or her knowledge, HDL 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, HDL 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.

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

D. Designation of Information

HDL 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. HDL 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

HDL: Chief Compliance Officer
Health Diagnostic Laboratory, Inc.
737 N. 5th Street, Suite 400
Richmond, VA 23219
Telephone: 804.343.2718

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

VIII. DOCUMENT AND RECORD RETENTION

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

X. BREACH AND DEFAULT PROVISIONS

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

a. a Compliance Officer;

b. an Executive Compliance Committee;

c. the Board Compliance Committee obligations, including the resolution from the Board Compliance Committee;

d. the management certification obligations;

e. a written Code of Conduct;

f. written Policies and Procedures;

g. the development and/or implementation of a Training Plan for the training of Covered Persons, Arrangements Covered Persons, Promotional 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;

o. reporting of Reportable Events;

p. the IMP 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 HDL fails to engage and use an IRO, as required in Section III.E and Appendix A.

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

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

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

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

HDL 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 HDL 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 HDL 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 HDL 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 HDL of: (a) HDL'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, HDL 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 HDL elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until HDL 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 HDL 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 HDL 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, and Appendix B.

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

diligence; and (iii) HDL has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, HDL fails to satisfy the requirements of Section X.D.3, OIG may exclude HDL from participation in the Federal health care programs. OIG shall notify HDL in writing of its determination to exclude HDL. (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 HDL's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. After the end of the period of exclusion, HDL 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 HDL 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, HDL 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 HDL was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. HDL 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 HDL to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless HDL 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 HDL was in material breach of this CIA and, if so, whether:

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

HDL 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 HDL's obligations under this CIA based on a certification by HDL that it is no longer providing health care items or services that will be billed to any Federal health care program and that it does not have any ownership or control interest, as defined in 42 U.S.C. §1320a-3, in any entity that bills any Federal health care program. If HDL is relieved of its CIA obligations, HDL will be required to notify OIG in writing at least 30 days in advance if HDL 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. The undersigned HDL 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.

E. 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 HDL

/Joseph P. McConnell/

3/26/2015

JOSEPH P. MCCONNELL
President, CEO, and Co-Founder
Health Diagnostic Laboratory, Inc.

DATE

/Douglas L. Sbertoli/

3/26/2015

DOUGLAS L. SBERTOLI
Executive Vice President
Director of Business Affairs
Corporate Counsel
Health Diagnostic Laboratory, Inc.

DATE

/Laura G. Hoey/

3/26/2015

LAURA G. HOEY
MICHAEL B. LAMPERT
BRIEN T. O'CONNOR
Ropes & Gray LLP

DATE

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

/Robert K. DeConti/

3/31/15

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

DATE

/Katherine E. Matos/

3/31/15

KATHERINE E. MATOS
Senior Counsel
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U. S. Department of Health and Human Services

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/Lisa G. Veigel/

3/31/15

LISA G. VEIGEL
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DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. HDL shall engage one or more IROs that possess the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO(s) 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 HDL in response to a request by OIG, whichever is later, OIG will notify HDL if the IRO(s) is/are unacceptable. Absent notification from OIG that the IRO(s) is/are unacceptable, HDL may continue to engage the IRO(s).

2. If HDL engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, HDL 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 HDL at the request of OIG, whichever is later, OIG will notify HDL if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, HDL may continue to engage the IRO.

B. IRO Qualifications

The IRO(s) shall:

1. assign individuals to conduct the IRO Reviews who have expertise in the laboratory industry, including applicable Federal health care program requirements;

2. assign individuals to conduct the IRO Reviews 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

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

C. IRO Responsibilities

The IRO(s) shall:

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

2. follow all applicable Federal health care program requirements in making assessments in each IRO Review;

3. if in doubt of the application of a particular Federal health care program, policy or regulation, request clarification from the appropriate authority;

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 B to the CIA.

D. IRO Independence and Objectivity

The IRO(s) must perform the Reviews in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office.

E. IRO Removal/Termination

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

2. *OIG Removal of IRO(s).* 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 may, at its sole discretion, require HDL to engage a new IRO in accordance with Paragraph A of this Appendix. HDL must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring HDL to engage a new IRO, OIG shall notify HDL of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, HDL may present additional information regarding the IRO's qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with HDL prior to requiring HDL to terminate the IRO. However, the final determination as to whether or not to require HDL to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

INDEPENDENT REVIEW ORGANIZATION REVIEW

The IRO Reviews shall consist of three components: an Arrangements Systems Review, an Arrangements Transactions Review, and a Promotional Functions Systems Review. The IRO shall perform all components of each IRO Review. If there are no material changes to HDL's systems, processes, policies, and procedures relating to Arrangements or Promotional Functions, the Arrangements Systems Review or Promotional Functions Systems Review shall be performed for the first and fourth Reporting Periods. If HDL materially changes the Arrangements or Promotional Functions systems, processes, policies and procedures, the IRO shall perform a Systems Review for the materially changed system 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 HDL's systems, processes, policies, and procedures relating to the initiation, review, approval, and tracking of Arrangements. Specifically, the IRO shall review the following:

1. HDL'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. HDL's systems, policies, processes, and procedures for tracking remuneration to and from all parties to Focus Arrangements;

3. HDL'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. HDL'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. HDL'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. HDL'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 HDL, 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, HDL's internal review and approval process, and other Arrangements systems, process, policies, and procedures;

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

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

C. Arrangements Transactions Review. The Arrangements Transactions Review shall consist of a review by the IRO of 50 randomly selected Focus Arrangements that were entered into or renewed by HDL during the Reporting Period. The IRO shall assess whether HDL 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 HDL'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 HDL 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 HDL 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 HDL 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 HDL's policies, procedures, and systems in place to ensure that all Focus Arrangements comply with the Focus Arrangements Procedures and Focus Arrangements Requirements.

E. Promotional Functions Systems Review. The Promotional Functions Systems Review shall be a review of HDL's systems, processes, policies, and procedures relating to the following:

1. Promotional Functions activities;

2. HDL's internal review and approval of information and materials relating to Promotional Functions that are disseminated to individuals or entities outside HDL;

3. incentive compensation for Promotional Covered Persons who are sales representatives or their managers and whether HDL's financial incentives inappropriately motivate such individuals to engage in the improper promotion of Government Reimbursed Tests. This shall include a review of the bases upon which compensation is determined.

4. Specimen Materials and Tools (as described in Section III.B.2.h of the CIA). This shall include a review of the bases upon, and circumstances under, which providers may receive Specimen Materials and Tools from HDL; and

5. 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.

F. Promotional Functions Systems Review Report. The IRO shall prepare a report based upon each Promotional Functions Systems Review performed. The Promotional Functions 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 HDL's systems, policies, processes, and procedures relating to the items identified in Section E above;

3. findings and supporting rationale regarding strengths and weaknesses in HDL's systems, processes, policies, and procedures relating to Promotional Functions described in Section E above; and

4. recommendations to improve HDL's systems, policies, processes, or procedures relating to Promotional Functions described in Section E above.