AMENDED AND RESTATED
CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
CALLOWAY LABORATORIES, INC.

WHEREAS, the Office of Inspector General and Calloway Laboratories, Inc. (Calloway) (collectively referred to as the "Parties") entered into a Corporate Integrity Agreement on March 27, 2012; and

WHEREAS, the Parties desire to amend and restate the terms of the Corporate Integrity Agreement;

NOW, THEREFORE, the Parties agree to enter into this Amended and Restated Corporate Integrity Agreement, effective as of the date of the final signature.

I. PREAMBLE

Calloway Laboratories, Inc. (Calloway) 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, Calloway is entering into a Settlement Agreement with the United States.

Prior to the execution of this CIA, Calloway established a corporate compliance program. Calloway agrees to operate its compliance program in a manner that meets the requirements of this CIA during the term of this CIA. Calloway may modify the compliance program as appropriate, but at a minimum, Calloway shall ensure that the compliance program meets the requirements of this CIA.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Calloway under this CIA shall be five years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. *Specific Provisions.*

1. Arrangements Provisions:

   i. Arrangements Training provisions outlined in Section III.C.2 of this CIA shall remain in effect only through the original five-year period of the CIA, which was effective on March 27, 2012;

   ii. Arrangements Tracking Procedures outlined in Section III.D. of this CIA shall remain in effect only through the original five-year period of the CIA, which was effective on March 27, 2012; and

   iii. Arrangements Review provisions outlined in Section III.E of this CIA shall remain in effect only through the original five-year period of the CIA, which was effective on March 27, 2012.

2. Other Provisions:

Sections VII, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Calloway's final annual report; or (2) any additional materials submitted by Calloway 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 Calloway and any actual or potential source of health care business or referrals to Calloway or any actual or potential recipient of health care business or referrals from Calloway. 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 Calloway refers an individual for the furnishing or arranging for the furnishing of any item or service, or (2) from whom Calloway 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 Calloway 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 Calloway for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

2. "Focus Arrangements" means every Arrangement that:

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

b. is between Calloway 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 Calloway 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 (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading), officers, directors, and employees of Calloway; 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 Calloway excluding vendors whose sole connection with Calloway is selling or otherwise providing medical supplies or equipment to Calloway and who do not bill the Federal health care programs for such medical supplies or equipment; and

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 per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

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

5. "Laboratory Covered Persons" includes Covered Persons who perform job functions that relate to or affect the quality and accuracy of clinical testing and reporting.

6. "Reimbursement Covered Persons" includes Covered Persons involved in the preparation or submission of claims for reimbursement from any Federal health care program.

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Officer and Committee

1. *Compliance Officer*. Prior to or upon the Effective Date, Calloway shall appoint a Covered Person to serve as its Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for 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. The Compliance Officer shall be a member of senior management of Calloway, shall report directly to the Chief Executive Officer of Calloway, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Calloway, and shall be authorized to report on such matters to the Board of Directors at any time. Written documentation of the Compliance Officer's reports to the Board of Directors shall be made available to OIG upon request. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Calloway 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.

Calloway shall report to OIG, in writing, any change in the identity or position description of the Compliance Officer, or any actions or changes that would affect the

Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. *Compliance Committee*. Within 90 days after the Effective Date, Calloway shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of Calloway's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

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

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

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

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

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

At minimum, the resolution shall include the following language:

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

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

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

4. *Management Accountability and Certifications*: In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Calloway officers or employees ("Certifying Employees") are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Calloway business unit, department, or functional area is compliant with applicable Federal health care program and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Calloway's Chief Executive Officer/President, Chief Financial Officer, General Manager of Substance Abuse and Vice President Pain Care Sales, Director of Billing, Director of Laboratory Operations, Laboratory Director, and, to the extent that a Calloway business unit, department, or functional area performs functions related to government reimbursement, billing and claims, promotion, marketing, sales, contracting, Arrangements, or compliance and is not covered by one of the above certifications, such other appropriate executives, vice-presidents, and directors, as would be necessary to ensure that there is a certifying officer or employee covering each such business unit, department, or functional area.

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 [department or functional area], an area under my

supervision. My job responsibilities include ensuring compliance with regard to the _____ [insert name of the department or functional area.] To the best of my knowledge, except as otherwise described herein, the _____ [insert name of department or functional area] of Calloway is in compliance with all applicable Federal health care program requirements, and the obligations of the CIA."

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

B. Written Standards

1. *Code of Conduct*. Within 90 days after the Effective Date, Calloway shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. Calloway shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

a. Calloway's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;

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

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

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

Within 90 days after the Effective Date, each Covered Person shall certify, in writing or in electronic form, that he or she has received, read, understood, and shall abide by Calloway's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

Calloway shall periodically review the Code of Conduct 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 90 days after the Effective Date, Calloway shall implement written Policies and Procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA and Calloway's compliance with Federal health care program requirements. The Policies and Procedures also shall address:

a. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute) and 42 U.S.C. § 1395nn (Stark Law), and the regulations and other guidance documents related to these statutes, and business or financial arrangements or contracts that generate unlawful Federal health care program business in violation of the Anti-Kickback Statute or the Stark Law;

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

c. the Clinical Laboratory Improvement Amendments (CLIA) of 1988; and

d. all statutes, regulations, and manual provisions related to the provision and reimbursement for urine drug testing services.

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

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

C. Training and Education

1. *General Training*. Within 90 days after the Effective Date, Calloway shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain Calloway's:

a. CIA requirements; and

b. Compliance Program, including the Code of Conduct.

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Training.*

a. Arrangements Training. Within 90 days after the Effective Date, each Arrangements Covered Person shall receive at least three hours of Arrangements Training, in addition to the General Training required above. The Arrangements Training shall include a discussion of:

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. Calloway'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 Calloway's Arrangements to know the applicable legal requirements and Calloway'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.

New Arrangements Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Arrangements Covered Persons, or within 90 days after the Effective Date, whichever is later.

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

b. Laboratory Training. Within 90 days after the Effective Date, each Laboratory Covered Person shall receive at least two hours of Laboratory Training, in addition to the General Training required above. Laboratory Training shall include a discussion of:

i. policies, procedures, and other requirements applicable to the documentation, recording, and reporting of test results;

ii. the personal obligation of each individual involved in the laboratory testing process to ensure that the documentation, recording, and reporting of test results is accurate;

iii. applicable privacy, and compliance-related statutes, regulations, and program requirements and directives;

iv. the legal sanctions for violations of the Federal health care program requirements;

v. applicable pre-analytical, analytical, and post-analytical tasks;

vi. applicable statutes, regulations, requirements, and directives of the Federal health care programs. This should include, but not be limited to, correlating Federal health care program requirements related to commonly utilized codes and the tests performed by Laboratory Covered Persons associated with those commonly utilized codes; and

vii. examples of proper and improper data review, results certification, and, as applicable, documentation practices.

New Laboratory Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming a Laboratory Covered Person, or within 90 days after the Effective Date, whichever is later.

After receiving the initial Laboratory Training described in this section, each Laboratory Covered Person shall receive at least two hours of Laboratory Training, in addition to the General Training, in each subsequent Reporting Period.

c. Reimbursement Training. Within 90 days after the Effective Date, each Reimbursement Covered Person shall receive at least three hours of Reimbursement Training, in addition to the General Training required above. Reimbursement Training shall include a discussion of:

i. the Federal health care program requirements regarding the accurate coding and submission of claims;

ii. the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate;

iii. applicable reimbursement statutes, regulations, and program requirements and directives;

iv. the legal sanctions for violations of the Federal health care program requirements; and

v. examples of proper and improper claims submission practices.

New Reimbursement Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming a Reimbursement Covered Person, or within 90 days after the Effective Date, whichever is later.

After receiving the initial Reimbursement Training described in this section, each Reimbursement Covered Person shall receive at least two hours of Reimbursement Training, in addition to the General Training, in each subsequent Reporting Period.

3. *Board Member Training*. Within 90 days after the Effective Date, Calloway shall provide at least two hours of training to each member of the Board of Directors, in addition to the General Training. This training shall address the responsibilities of board members and corporate governance.

New members of the Board of Directors shall receive the Board Member Training described above within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later.

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

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

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

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

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

1. *Focus Arrangements Procedures*. Within 90 days after the Effective Date, Calloway shall create procedures reasonably designed to ensure that each existing and new or renewed Focus Arrangement does not violate the Anti-Kickback Statute and/or the Stark Law or the regulations, directives, and guidance related to these statutes (Focus Arrangements Procedures). These procedures shall include the following:

a. creating and maintaining a centralized tracking system for all existing and new or renewed Focus Arrangements (Focus Arrangements Tracking System);

b. tracking remuneration to and from all parties to Focus Arrangements;

c. tracking service and activity logs to ensure that parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangement(s) (if applicable);

d. monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Focus Arrangement(s) (if applicable);

e. establishing and implementing a written review and approval process for all Focus Arrangements, the purpose of which is to ensure that all new and existing or renewed Focus Arrangements do not violate the Anti-Kickback Statute and Stark Law, and that includes at least the following: (i) a legal review of all Focus Arrangements by counsel with expertise in the Anti-Kickback Statute and Stark Law, (ii) a process for specifying the business need or business rationale for all Focus Arrangements, and (iii) a process for determining and

documenting the fair market value of the remuneration specified in the Focus Arrangement;

f. requiring the Compliance Officer to review the Focus Arrangements Tracking System, internal review and approval process, and other Focus Arrangements Procedures on at least an annual basis and to provide a report on the results of such review to the Compliance Committee; and

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

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

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

b. Include in the written agreement a requirement that each party to a Focus Arrangement who meets the definition of a Covered Person shall complete the Arrangements Training required by Section III.C.2 of this CIA. Additionally, Calloway shall provide each party to the Focus Arrangement with a copy of its Code of Conduct and Stark Law and Anti-Kickback Statute Policies and Procedures;

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

3. *Records Retention and Access*. Calloway shall retain and make available to OIG, upon request, the Focus Arrangements Tracking System and all

supporting documentation of the Focus Arrangements subject to this Section and, to the extent available, all non-privileged communications related to the Focus Arrangements and the actual performance of the duties under the Focus Arrangements.

E. Review Procedures

1. *General Description*

a. *Engagement of Independent Review Organization*. Within 90 days after the Effective Date, Calloway shall engage an entity (or entities), such as an accounting, auditing, 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 Appendices A and C to this CIA, which is incorporated by reference.

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

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

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

3. *Claims Review.* An IRO shall review Calloway's coding, billing, and claims submission to the Medicare and state Medicaid programs and the reimbursement received (Claims Review) and shall prepare a Claims Review Report, as outlined in Appendix D to this CIA, which is incorporated by reference.

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

Prior to initiating a Validation Review, OIG shall notify Calloway 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, Calloway may request a meeting with OIG to: (a) discuss the results of any Claims Review or Arrangements Review submissions or findings; (b) present any additional information to clarify the results of the Claims Review or Arrangements Review or to correct the inaccuracy of the Claims Review or Arrangements Review; and/or (c) propose alternatives to the proposed Validation Review. Calloway agrees to provide any additional information as may be requested by OIG under this Section III.E.4 in an expedited manner. OIG will attempt in good faith to resolve any Claims Review or Arrangements Review issues with Calloway 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.

5. *Independence and Objectivity Certification*. The IRO shall include in its report(s) to Calloway 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 Appendices A and C to this CIA.

F. Disclosure Program

Within 90 days after the Effective Date, Calloway shall establish a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Calloway'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. Calloway shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Calloway 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, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews.

G. Ineligible Persons

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

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

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

b. "Exclusion Lists" include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.oig.hhs.gov); and

ii. the General Services Administration's System for Award Management (available through the Internet at http://www.sam.gov).

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

a. Calloway 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. Calloway shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on a monthly basis thereafter.

c. Calloway 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.F affects Calloway's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. Calloway understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that Calloway may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Calloway meets the requirements of Section III.G.

3. *Removal Requirement.* If Calloway has actual notice that a Covered Person has become an Ineligible Person, Calloway shall remove such Covered Person

from responsibility for, or involvement with, Calloway'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 Calloway 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, Calloway shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceedings

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

I. Repayment of Overpayments

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

2. *Repayment of Overpayments*

a. If, at any time, Calloway identifies or learns of any Overpayment, Calloway 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, Calloway shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies.

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

J. Reportable Events

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

a. a substantial Overpayment;

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

c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or

d. the filing of a bankruptcy petition by Calloway.

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

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

OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Section III.J.1.a*. For Reportable Events under Section III.J.1.a, the report to OIG shall be made within 30 days of the identification of the Overpayment, and shall include:

a. a description of the steps taken by Calloway to identify and quantify the Overpayment;

b. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

c. a description of Calloway's actions taken to correct the Reportable Event; and

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

Within 60 days of identification of the Overpayment, Calloway shall provide OIG with a copy of the notification and repayment to the payor required in Section III.H.2.

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

a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

b. a description of Calloway's actions taken to correct the Reportable Event;

c. any further steps Calloway plans to take to address the Reportable Event and prevent it from recurring; and

d. if the Reportable Event has resulted in an Overpayment, a description of the steps taken by Calloway to identify and quantify the Overpayment.

5. *Reportable Events under Section III.J.1.d*. For Reportable Events under Section III.J.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.

6. *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 Calloway to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. The requirements of Section III.I.2 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 Calloway identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then Calloway is not required by this Section III.J to submit the Reportable Event to CMS through the SRDP.

IV. SUCCESSOR LIABILITY; CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Sale of Business, Business Unit or Location.

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

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

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

3. the names of the Board members who are responsible for satisfying the Board of Directors compliance obligations described in Section III.A.3;

4. a copy of Calloway's Code of Conduct required by Section III.B.1;

5. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have

completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG upon request);

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

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

a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be made available to OIG upon request.

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

10. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendices A and C to this CIA; (d) a summary and description of any and all current and prior engagements and agreements between Calloway and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to Calloway;

11. a description of the process by which Calloway fulfills the requirements of Section III.G regarding Ineligible Persons;

12. a list of all of Calloway'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 Calloway currently submits claims;

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

14. the certifications required by Sections III.A.4 and V.C.

B. Annual Reports

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

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in Section III.A;

2. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available upon request);

3. the Board resolution required by Section III.A.3;

4. a summary of any changes or amendments to Calloway's Code of Conduct required by Section III.B.1 and the reason for such changes, along with a copy of the revised Code of Conduct;

5. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be made available to OIG upon request);

6. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy);

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

a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of individuals required to complete the initial and annual training, the percentage of individuals who actually completed the initial and annual training, and an explanation of any exceptions.

A copy of all training materials and the documentation to support this information shall be made available to OIG upon request;

8. 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;

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

10. Calloway'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;

11. a summary and description of any and all current and prior engagements and agreements between Calloway and the IRO (if different from what was submitted as part of the Implementation Report);

12. a certification from the IRO regarding its professional independence and objectivity with respect to Calloway;

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

14. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the

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

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

16. any changes to the process by which Calloway fulfills the requirements of Section III.G regarding Ineligible Persons;

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

18. a description of all changes to the most recently provided list of Calloway's locations (including addresses) as required by Section V.A.11; 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 Calloway currently submits claims; and

19. the certifications required by Sections III.A.4 and V.C.

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

C. Certifications

The Implementation Report and each Annual Report shall include a certification by the Compliance Officer that:

1. to the best of his or her knowledge, except as otherwise described in the report, Calloway is in compliance with all of the requirements of this CIA;

2. to the best of his or her knowledge, Calloway 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;

3. to the best of his or her knowledge, Calloway has fulfilled the requirements for New and Renewed Focus Arrangements under Section III.D.2 of the CIA;

4. 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; and

5. to the best of his or her knowledge, Calloway has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs.

D. Designation of Information

Calloway 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. Calloway 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

Calloway:
Robert J. Rossi, Esquire
Vice President &
Chief Compliance Officer
Calloway Laboratories, Inc.
12 Gill Street
Suite 4000
Woburn, MA 01801
Telephone: 781.224.9899

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, Calloway may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), in addition to a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Calloway's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Calloway's locations for the purpose of verifying and evaluating: (a) Calloway's compliance with the terms of this CIA; and (b) Calloway's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Calloway to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction.

Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Calloway's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Calloway shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Calloway's employees may elect to be interviewed with or without a representative of Calloway present.

VIII. DOCUMENT AND RECORD RETENTION

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

X. BREACH AND DEFAULT PROVISIONS

Calloway 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, Calloway 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 Calloway fails to establish and implement any of the following obligations as described in Section III:

   a. a Compliance Officer;

b. a Compliance Committee;

c. the Board of Directors compliance obligations;

d. the Certifying Employee certifications;

e. a written Code of Conduct;

f. written Policies and Procedures;

g. the training of Covered Persons, Arrangements Covered Persons, Laboratory Covered Persons, Reimbursement 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 Disclosure Program;

j. Ineligible Persons screening and removal requirements;

k. notification of Government investigations or legal proceedings; and

l. reporting of Reportable Events.

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 Calloway fails to engage and use an IRO, as required in Section III.E, and Appendices A-D.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Calloway 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 Calloway fails to submit any

Claims Review Report or Arrangements Review Report in accordance with the requirements of Section III.E and Appendices B and D.

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

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

Calloway 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 Calloway fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Calloway receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties

1. *Demand Letter*. Upon a finding that Calloway 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 Calloway of: (a) Calloway'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, Calloway 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 Calloway elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Calloway 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 Calloway 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 repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

b. a failure by Calloway to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.J;

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, and Appendices A - D.

2. *Notice of Material Breach and Intent to Exclude*. The parties agree that a material breach of this CIA by Calloway constitutes an independent basis for Calloway's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Calloway has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Calloway of: (a) Calloway'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*. Calloway shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. Calloway is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30 day period, but that: (i) Calloway has begun to take action to cure

the material breach; (ii) Calloway is pursuing such action with due diligence; and (iii) Calloway has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter*. If, at the conclusion of the 30 day period, Calloway fails to satisfy the requirements of Section X.D.3, OIG may exclude Calloway from participation in the Federal health care programs. OIG shall notify Calloway in writing of its determination to exclude Calloway. (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 Calloway'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, Calloway 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 Calloway 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, Calloway 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.

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 Calloway was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Calloway 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 Calloway to pay Stipulated Penalties, such

Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Calloway 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:

a. whether Calloway was in material breach of this CIA;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Calloway had begun to take action to cure the material breach within that period; (ii) Calloway has pursued and is pursuing such action with due diligence; and (iii) Calloway provided to OIG within that period a reasonable timetable for curing the material breach and Calloway has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Calloway, only after a DAB decision in favor of OIG. Calloway's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Calloway 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 Calloway 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. Calloway 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 Calloway, Calloway 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

Calloway 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 Calloway's obligations under this CIA based on a certification by Calloway 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 Calloway is relieved of its CIA obligations, Calloway will be required to notify OIG in writing at least 30 days in advance if Calloway 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 Calloway 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 CALLOWAY LABORATORIES, INC.

/Gail Marcus/ 5/6/2014

GAIL MARCUS
President and Chief Executive Officer
Calloway Laboratories, Inc.

DATE

/Robert J. Rossi, Esquire/ 05/06/2014

ROBERT J. ROSSI, Esquire
Vice President &
Chief Compliance Officer
Calloway Laboratories, Inc.

DATE

/John T. Bentivoglio, Esquire/ 5/7/2014

JOHN T. BENTIVOGLIO, Esquire
MITCHELL S. ETTINGER, Esquire
ALEXANDER R. COHEN, Esquire
Skadden, Arps, Slate, Meagher & Flom, LLP
Counsel for Calloway Laboratories, Inc.

DATE

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

/Robert K. DeConti/ 5/15/14

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

/Andrea L. Treese Berlin/ 5/1/14

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

/Geoffrey W. Hymans/ 5/9/14

GEOFFREY W. HYMANS DATE
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.E.2 of the CIA.

A. IRO Engagement

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

2. If Calloway 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, Calloway 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 Calloway at the request of OIG, whichever is later, OIG will notify Calloway if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Calloway may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Arrangements Review who are knowledgeable in the requirements of the Anti-Kickback Statute and the Stark Law and the regulations and other guidance documents related to these statutes; and

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

C. IRO Responsibilities

The IRO shall:

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

2. respond to all OIG inquires in a prompt, objective, and factual manner; and

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

D. IRO Independence and Objectivity

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

E. IRO Removal/Termination

1. *Provider and IRO*. If Calloway terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Calloway 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. Calloway must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO*. In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Calloway to engage a new IRO in accordance with Paragraph A of this Appendix. Calloway must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring Calloway to engage a new IRO, OIG shall notify Calloway 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, Calloway 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 Calloway prior to requiring Calloway to terminate the IRO. However, the final determination as to whether or not to require Calloway to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

ARRANGEMENTS REVIEW

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

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

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

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

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

4. recommendations to improve Calloway'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 Calloway during the Reporting Period. The IRO shall assess whether Calloway 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 Calloway'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 Calloway 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 Calloway 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 Calloway 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 Calloway's policies, procedures, and systems in place to ensure that all Focus Arrangements comply with the Focus Arrangements Procedures and Focus Arrangements Requirements.

APPENDIX C

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.E.3 of the CIA.

A. IRO Engagement

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

2. If Calloway 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, Calloway shall submit the information identified in Section V.A.8 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Calloway at the request of OIG, whichever is later, OIG will notify Calloway if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Calloway may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Claims Review who have expertise in the billing, coding, reporting, and other requirements of urine drug testing claims and in the general requirements of the Federal health care program(s) from which Calloway seeks reimbursement;

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

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

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

C. IRO Responsibilities

The IRO shall:

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

2. follow all applicable Medicare and Medicaid rules and reimbursement guidelines in making assessments in the Claims Review;

3. if in doubt of the application of a particular Medicare and Medicaid policy or regulation, request clarification from the appropriate authority (e.g., Medicare contractor);

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

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

D. IRO Independence and Objectivity

The IRO must perform the Claims Review 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 Calloway terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Calloway 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. Calloway must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Calloway to engage a new IRO in accordance with Paragraph A of this Appendix. Calloway must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring Calloway to engage a new IRO, OIG shall notify Calloway 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, Calloway 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 Calloway prior to requiring Calloway to terminate the IRO. However, the final determination as to whether or not to require Calloway to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX D

CLAIMS REVIEW

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

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

a. Overpayment: The amount of money Calloway has received in excess of the amount due and payable under any Federal health care program requirements which shall include any extrapolated Overpayments determined in accordance with Section A.3 of this Appendix D.

b. Paid Claim: A claim submitted by Calloway and for which Calloway has received reimbursement from the Medicare or Medicaid program.

c. Population: There will be two separate populations for the purposes of the Claims Review as follows:

i. Medicare Population: The Medicare Population shall be defined as all Paid Claims which were paid by Medicare during the 12-month period covered by the Claims Review, and

ii. Focus State Medicaid Population: The Focus State Medicaid Population shall be defined as all Paid Claims which were paid by the Medicaid program in the state selected by OIG (Focus State) during the 12-month period covered by the Claims Review. Sixty days prior to the IRO's initiation of the Discovery Sample, Calloway will provide to OIG a list of all states in which claims were paid to Calloway by the state Medicaid program. In addition to

identifying the state, Calloway will include an up-to-date reporting of the number of Paid Claims in that state and the total reimbursement received by Calloway from that state's Medicaid program. Thereafter, OIG will select the Focus State.

d. Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Samples shall be included as part of the net Overpayment calculation.)

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

2. *Discovery Samples.* The IRO shall conduct two Discovery Samples, reviewing a total of 200 randomly selected Paid Claims (Discovery Samples). In the first Discovery Sample the IRO shall randomly select and review a sample of 100 Paid Claims from the Medicare Population. In the second Discovery Sample the IRO shall randomly select and review a sample of 100 Paid Claims from the Focus State Medicaid Population. In both Discovery Samples the Paid Claims shall be reviewed based on the supporting documentation available at Calloway's office or under Calloway's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed.

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

3. *Full Sample(s)*. If either Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall select (an) additional sample(s) of Paid Claims (Full Sample(s)) from the appropriate population using commonly accepted sampling methods. The Paid Claims selected for the Full Sample(s) shall be reviewed based on supporting documentation available at Calloway or under Calloway's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, the IRO may use the Paid Claims sampled as part of the Discovery Sample, and the corresponding findings for those Paid Claims, as part of its Full Sample, if: (1) statistically appropriate and (2) the IRO selects the Full Sample Paid Claims using the seed number generated by the Discovery Sample. The findings of the Full Sample shall be used by the IRO to estimate the actual Overpayment in the Population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate.

4. *Systems Review*. If either of Calloway's Discovery Samples identify an Error Rate of 5% or greater, Calloway's IRO shall also conduct a Systems Review. The Systems Review shall consist of the following:

a. a review of Calloway's billing and coding systems and processes relating to claims submitted to Federal health care programs (including, but not limited to, the operation of the billing system, the process by which claims are coded, safeguards to ensure proper coding, claims submission and billing; and procedures to identify and correct inaccurate coding and billing);

b. for each claim in the Discovery Sample(s) and Full Sample(s) that resulted in an Overpayment, the IRO shall review the system(s) and process(es) that generated the claim and identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

5. *Other Requirements*

a. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Paid Claims selected as part of the Discovery Samples or Full Sample(s) (if applicable), and Calloway shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Discovery Samples or Full Sample(s) (if applicable). If the IRO accepts any supplemental documentation or materials from Calloway after the IRO has completed its initial review of the Discovery Samples or Full Sample(s) (if applicable) (Supplemental Materials), the IRO shall identify in the Claims Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Claims Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

b. Paid Claims without Supporting Documentation. Any Paid Claim for which Calloway cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Calloway for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

c. Use of First Samples Drawn. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, the Paid Claims selected in each first sample shall be used (i.e., it is not permissible to generate more than one list of random samples and then select one for use with the Discovery Samples or Full Sample(s)).

6. *Repayment of Identified Overpayments.* Calloway shall repay within 30 days any Overpayment(s) identified in the Discovery Samples, regardless of the Error Rate, and (if applicable) the Full Sample(s), including the IRO's estimate of the actual

Overpayment in the Population as determined in accordance with Section A.3 above, in accordance with payor refund policies. Calloway shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

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

1. *Claims Review Methodology*

   a. Claims Review Population. A description of the Population subject to the Claims Review.

   b. Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.

   c. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).

   d. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.

   e. Supplemental Materials. A description of any Supplemental Materials as required by A.5.a., above.

2. *Statistical Sampling Documentation*

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

b. A copy of the statistical software printout(s) estimating how many Paid Claims are to be included in the Full Sample, if applicable.

c. A description or identification of the statistical sampling software package used to select the sample and determine the Full Sample size, if applicable.

3. *Claims Review Findings*

a. Narrative Results

i. A description of Calloway's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.

ii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Discovery Samples, and the results of the Full Sample(s) (if any).

b. Quantitative Results

i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by Calloway (Claim Submitted) differed from what should have been the correct claim (Correct Claim), regardless of the effect on the payment.

ii. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to Calloway.

iii. Total dollar amount of all Overpayments in the Discovery Samples and the Full Sample(s) (if applicable).

iv. Total dollar amount of Paid Claims included in the Discovery Samples and the Full Sample(s) and the net Overpayment associated with the Discovery Samples and the Full Sample(s).

v. Error Rate in the Discovery Samples and the Full Sample(s).

vi. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim: Federal health care program billed, beneficiary health insurance claim number, date of service, code submitted (e.g., DRG, CPT code, etc.), code reimbursed, allowed amount reimbursed by payor, correct code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.

vii. If a Full Sample is performed, the methodology used by the IRO to estimate the actual Overpayment in the Population and the amount of such Overpayment.

c. Recommendations. The IRO's report shall include any recommendations for improvements to Calloway's billing and coding system based on the findings of the Claims Review.

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

a. the strengths and weaknesses in Calloway's billing systems and processes;

b. the strengths and weaknesses in Calloway's coding systems and processes; and

c. possible improvements to Calloway's billing and coding systems and processes to address the specific problems or weaknesses that resulted in the identified Overpayments.

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