CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
AND
MRI RADIOLOGY NETWORK, P.A.,
UNIVERSITY MRI OF BOCA RATON, INC.,
UNIVERSITY MRI OF BOCA RATON, L.L.C.,
WEST BOCA OPEN MRI, INC.,
EXPERT RADIOLOGY RESEARCH AND EDUCATIONAL FOUNDATION, INC.,
UNIVERSITY MRI LEASING, L.L.C.,
UNIVERSITY MRI RADIOLOGY ASSOCIATES, P.L.,
EXPERT RADIOLOGY NETWORK, P.A.,
NEUROSCIENCE ACQUISITION, L.L.C.,
UNIVERSITY MRI RESEARCH AND EDUCATIONAL FOUNDATION, L.L.C.,
UNIVERSITY IMAGE GUIDED THERAPY CENTER, L.L.C.,
AND
FRED L. STEINBERG, M.D.

I. PREAMBLE

MRI Radiology Network, P.A., University MRI of Boca Raton, Inc., University MRI of Boca Raton, L.L.C., West Boca Open MRI, Inc., Expert Radiology Research and Educational Foundation, Inc., University MRI Leasing, LLC., University MRI Radiology Associates, P.L., Expert Radiology Network, P.A., Neuroscience Acquisition, L.L.C., University MRI Research and Educational Foundation, L.L.C., University Image Guided Therapy Center, L.L.C., and Fred L. Steinberg, M.D. (collectively, "the UMRI-Related Entities"); hereby enter 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, the UMRI-Related Entities are entering into a Settlement Agreement with the United States.

This CIA applies to Steinberg, individually, each of the UMRI-Related Entities, and any entity in which Steinberg or any of the UMRI-Related Entities have an ownership or control interest at any time during the term of the CIA, as defined in 42 U.S.C. § 1320a-3(a)(3), and any other Covered Persons as defined in Section II.C. For so long as

Steinberg owns or has a control interest in each of the UMRI-Related Entities or any subsidiary of the UMRI-Related Entities, the integrity obligations set forth in this CIA may be satisfied by Steinberg on behalf of himself and the UMRI-Related Entities. If at any time during the term of this CIA, Steinberg acquires an ownership or a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), in any other entity that, at the time of the acquisition, was not required to abide by the terms of the CIA and that entity furnishes items or services that may be reimbursable, in whole or in part, by a Federal health care program, the integrity obligations of the CIA shall apply to such entity and such entity's Covered Persons for the remaining term of the CIA.

The UMRI-Related Entities represented to the OIG that, prior to the effective date of this CIA, the UMRI-Related Entities established a voluntary compliance program which includes a compliance officer, compliance committee, Code of Conduct, written policies and procedures, compliance training, annual claims audits, a confidential disclosure program, and disciplinary standards. The UMRI-Related Entities agree to continue operating its compliance program in accordance with the terms set forth below for the term of this CIA.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by the UMRI-Related Entities 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. Sections VII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) the UMRI-Related Entities' final annual report; or (2) any additional materials submitted by the UMRI-Related Entities 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 the UMRI-Related Entities and any actual or potential source of health care business or referrals to the UMRI-Related Entities or any actual or potential recipient of health care business or referrals from the UMRI-Related

Entities. The term "source" shall mean any physician, contractor, vendor, or agent and the term "health care business or referrals" shall be read to include referring, recommending, arranging for, ordering, leasing, or purchasing of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program; or

b. is between the UMRI-Related Entities 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 the UMRI-Related Entities for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6));

2. "Covered Persons" includes:

a. all owners, officers, directors, and employees of the UMRI-Related Entities; 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 the UMRI-Related Entities;

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.

3. "Arrangements Covered Persons" includes Covered Persons involved with the development, approval, management, or review of the UMRI-Related Entities' Arrangements, as such term is defined in Section II.C.1.

4. "Relevant Covered Persons" includes Covered Persons involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program.

III. CORPORATE INTEGRITY OBLIGATIONS

The UMRI-Related Entities shall maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* The UMRI-Related Entities represented to the OIG, that prior to the Effective Date, the UMRI-Related Entities appointed an individual to serve as Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer is 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 remain a member of senior management of the UMRI-Related Entities, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of the UMRI-Related Entities, and shall be authorized to report on such matters to the Board of Directors at any time. 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 the UMRI-Related Entities as well as for any reporting obligations created under this CIA.

The UMRI-Related Entities shall report to OIG, in writing, any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

2. *Compliance Committee.* The UMRI-Related Entities represented to the OIG that, prior to the Effective Date, the UMRI-Related Entities appointed a Compliance Committee and shall maintain a Compliance Committee for the term of the CIA. 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 the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

The UMRI-Related Entities 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.

B. Written Standards.

1. *Code of Conduct.* The UMRI-Related Entities represented to the OIG that, prior to the Effective Date, the UMRI-Related Entities developed, implemented, and distributed a written Code of Conduct to all Covered Persons. The UMRI-Related Entities shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. Within 90 days of the Effective Date, the UMRI-Related Entities shall review and revise the Code of Conduct to, at a minimum, set forth:

a. the UMRI-Related Entities' 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. the UMRI-Related Entities' requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with the UMRI-Related Entities' own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);

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

d. the possible consequences to both the UMRI-Related Entities and Covered Persons of failure to comply with Federal health care program requirements and with the UMRI-Related Entities' own Policies and Procedures and the failure to report such noncompliance; and

e. the right of all individuals to use the Disclosure Program described in Section III.F, and the UMRI-Related Entities'

commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 120 days after the Effective Date, each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the UMRI-Related Entities' Code of Conduct (revised as necessary to include the elements set forth above). New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

The UMRI-Related Entities shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. *Policies and Procedures.* The UMRI-Related Entities represent to the OIG that, prior to the Effective Date, the UMRI-Related Entities developed and implemented written Policies and Procedures regarding the operation of the UMRI-Related Entities' compliance program and its compliance with Federal health care program requirements. Within 90 days of the Effective Date, the UMRI-Related Entities shall review and revise the Policies and Procedures to, at a minimum, address:

a. the subjects relating to the Code of Conduct identified in Section III.B.1;

b. 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; and

c. the requirements set forth in Section III.D (Compliance with the Anti-Kickback Statute and Stark Law), including but not limited to the Arrangements Database, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals.

Within 120 days after the Effective Date, the relevant portions of the Policies and Procedures (revised as necessary to include the elements set forth above) shall be distributed to all Covered Persons whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), the UMRI-Related Entities shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all Covered Persons whose job functions relate to those Policies and Procedures.

C. Training and Education.

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

a. CIA requirements; and

b. the UMRI-Related Entities' Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 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. *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:

a. arrangements that potentially implicate the Anti-Kickback Statute or the Stark Law, as well as the regulations and other guidance documents related to these statutes;

b. the UMRI-Related Entities' policies, procedures, and other requirements relating to Arrangements, including but not limited to the Arrangements Database, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals required by Section III.D of the CIA;

c. the personal obligation of each individual involved in the development, approval, management, or review of the UMRI-Related Entities' Arrangements to know the applicable legal requirements and the UMRI-Related Entities' policies and procedures;

d. the legal sanctions under the Anti-Kickback Statute and the Stark Law; and

e. examples of violations of the Anti-Kickback Statute and the Stark Law.

New Arrangements Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Arrangements Covered Persons, or within 90 days after the Effective Date, whichever is later. An employee of the UMRI-Related Entities' who has completed the Arrangements Training shall review a new Arrangements Covered Person's work until such time as the new Arrangements Covered Person completes his or her Arrangements Training.

After receiving the initial Arrangements Training described in this Section, each Arrangements Covered Person shall receive at least one hour of Arrangements Training in each subsequent Reporting Period.

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

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

b. policies, procedures, and other requirements applicable to the documentation of medical records;

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

d. applicable reimbursement statutes, regulations, and Federal health care program requirements and directives;

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

f. examples of proper and improper claims submission practices.

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 90 days after the Effective Date, whichever is later. An employee of the UMRI-Related Entities' who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to the delivery of patient care items or services and/or the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes his or her Specific Training.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least one hour of Specific Training in each subsequent Reporting Period.

4. *Certification.* Each individual who is required to attend training shall certify, in writing, or in electronic form, if applicable, 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. These shall be made available to OIG, upon request.

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

6. *Update of Training.* The UMRI-Related Entities 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.* The UMRI-Related Entities may provide the training required under this CIA through appropriate computer-based training approaches.

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

a. creating and maintaining a database of all existing and new or renewed Arrangements that shall contain the information specified in Appendix A (Arrangements Database);

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

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

e. establishing and implementing a written review and approval process for all Arrangements, including but not limited to a legal review by counsel with expertise in the Anti-Kickback Statute and Stark Law and appropriate documentation of all internal controls, the purpose of which is to ensure that all new and existing or renewed Arrangements do not violate the Anti-Kickback Statute and Stark Law;

f. requiring the Compliance Officer to review the Arrangements Database, internal review and approval process, and other Arrangements Procedures on at least a quarterly 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 Section III.I (Reporting) when appropriate.

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

a. ensure that each Arrangement is set forth in writing and signed by the UMRI-Related Entities and the other parties to the Arrangement;

b. include in the written agreement a requirement that all individuals who meet the definition of Covered Persons shall comply with the UMRI-Related Entities' Compliance Program, including the training related to the Anti-Kickback Statute and the Stark Law. Additionally, the UMRI-Related Entities shall provide each party to the Arrangement with a copy of its Code of Conduct and Stark Law and Anti-Kickback Statute Policies and Procedures; and

c. include in the written agreement a certification by the parties to the 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.* The UMRI-Related Entities shall retain and make available to OIG, upon request, the Arrangements Database and all supporting documentation of the Arrangements subject to this Section and, to the extent available, all non-privileged communications related to the Arrangements and the actual performance of the duties under the Arrangements.

E. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, the UMRI-Related Entities shall

engage an individual or entity (or entities), such as an accounting, auditing, law, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the following reviews: (i) a review to assist the UMRI-Related Entities in assessing its compliance with the obligations pursuant to Section III.D of this CIA (Arrangements Review), (ii) a review to assist the UMRI-Related Entities in assessing and the UMRI-Related Entities' coding, billing, and claims submission to the Medicare program and the reimbursement received (Claims Review), and, if applicable, (iii) a review to analyze whether the UMRI-Related Entities sought payment for certain unallowable costs (Unallowable Cost Review). The IRO engaged by the UMRI-Related Entities to perform the Arrangements Review shall have expertise in the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and the Physician Self-Referral Law, 42 U.S.C. § 1395nn (the "Stark Law"). The IRO engaged by the UMRI-Related Entities to perform the Claims Review shall have expertise in the billing, coding, reporting, and other requirements applicable to the UMRI-Related Entities and in the general requirements of the Medicare program. If an Unallowable Cost Review is necessary, the IRO engaged by the UMRI-Related Entities to perform the Unallowable Costs Review shall have expertise in the cost reporting requirements applicable to the UMRI-Related Entities and in the general requirements of the Federal health care program(s) from which the UMRI-Related Entities seek reimbursement.

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

b. *Frequency of Arrangements Review*. The Arrangements Review shall be performed annually and shall cover each of the Reporting

Periods. The IRO(s) shall perform all components of each annual Arrangements Review.

c. *Frequency of Claims Review.* The Claims Review shall be performed annually and shall cover each of the Reporting Periods. The IRO(s) shall perform all components of each annual Claims Review.

d. *Frequency of Unallowable Cost Review.* If applicable, the IRO shall perform the Unallowable Cost Review for the first Reporting Period.

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

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

2. *Arrangements Review.* The IRO shall perform a review to assess whether the UMRI-Related Entities are complying with the Arrangements Procedures and Arrangements Requirements required by Sections III.D.1 and III.D.2 of this CIA. The IRO shall randomly select a sample of 10 Arrangements that were entered into or renewed during the Reporting Period. The IRO shall assess whether the UMRI-Related Entities have implemented the Arrangements Procedures and, for each selected Arrangement, the IRO shall assess whether the UMRI-Related Entities have complied with the Arrangements Procedures and Arrangements Requirements specifically with respect to that Arrangement. The IRO's assessment shall include, but is not limited to: (a) verifying that the Arrangement is listed in the Arrangements Database; (b) verifying that the 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; (c) verifying that the remuneration related to the Arrangement is properly tracked; (d) verifying that the service and activity logs are properly completed and reviewed (if applicable); (e) verifying that leased space, medical supplies, medical devices, and equipment, and other patient care items are

properly monitored (if applicable); (f) verifying that the Compliance Officer is reviewing the Arrangements Database, internal review and approval process, and other Arrangements Procedures on a quarterly basis and reporting the results of such review to the Compliance Committee; (g) verifying that effective responses are being implemented when violations of the Anti-Kickback Statute and Stark Law are discovered; and (h) verifying that the UMRI-Related Entities have met the requirements of Section III.D.2.

3. *Arrangements Review Report.* The IRO shall prepare a report based upon the Arrangements Review performed (Arrangements Review Report). The Arrangements Review Report shall include the IRO's findings with respect to: (a) whether the UMRI-Related Entities have generally implemented the Arrangements Procedures described in Section III.D.1; and (b) specific findings as to whether THE the UMRI-Related Entities have complied with the Arrangements Procedures and Arrangements Requirements with respect to each of the randomly selected Arrangements reviewed by the IRO. In addition, the Arrangements Review Report shall include any observations, findings and recommendations on possible improvements to the UMRI-Related Entities' policies, procedures, and systems in place to ensure that all Arrangements do not violate the Anti-Kickback Statute and Stark Law.

4. *Claims Review.* The Claims Review shall include a Discovery Sample of 50 Paid Claims and, if the Error Rate for the Discovery Sample is 5% or greater, a Full Sample. The applicable definitions, procedures, and reporting requirements are outlined in Appendix D to this CIA, which is incorporated by reference.

5. *Claims Review Report.* The IRO shall prepare a report based upon the Claims Review performed (Claims Review Report). Information to be included in the Claims Review Report is described in Appendix D.

6. *Repayment of Identified Overpayments.* In accordance with Section III.I.1, the UMRI-Related Entities shall repay within 30 days any Overpayment(s) identified in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. The UMRI-Related Entities shall make available to OIG any and all documentation and the associated documentation that reflects the refund of the Overpayment(s) to the payor.

7. *Unallowable Cost Review.* If applicable, the IRO shall conduct a review of the UMRI-Related Entities' compliance with the unallowable cost provisions of the Settlement Agreement. The IRO shall determine whether the UMRI-Related Entities have complied with its obligations not to charge to, or otherwise seek payment from, federal or state payors for unallowable costs (as defined in the Settlement Agreement) and

its obligation to identify to applicable federal or state payors any unallowable costs included in payments previously sought from the United States, or any state Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by the UMRI-Related Entities or any affiliates. To the extent that such cost reports, cost statements, information reports, or payment requests, even if already settled, have been adjusted to account for the effect of the inclusion of the unallowable costs, the IRO shall determine if such adjustments were proper. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous years.

8. *Unallowable Cost Review Report.* If applicable, the IRO shall prepare a report based upon the Unallowable Cost Review performed. The Unallowable Cost Review Report shall include the IRO's findings and supporting rationale regarding the Unallowable Costs Review and whether the UMRI-Related Entities have complied with its obligation not to charge to, or otherwise seek payment from, federal or state payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable federal or state payors any unallowable costs included in payments previously sought from such payor.

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

Prior to initiating a Validation Review, OIG shall notify the UMRI-Related Entities 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, the UMRI-Related Entities may request a meeting with OIG to: (a) discuss the results of any Arrangements Review, Claims Review, or Unallowable Cost Review submissions or findings; (b) present any additional information to clarify the results of the Arrangements Review,

Claims Review, or Unallowable Cost Review or to correct the inaccuracy of the Arrangements Review, Claims Review, Unallowable Cost Review; and/or (c) propose alternatives to the proposed Validation Review. The UMRI-Related Entities agree to provide any additional information as may be requested by OIG under this Section III.E.8 in an expedited manner. OIG will attempt in good faith to resolve any Arrangements Review, Claims Review, or Unallowable Cost Review issues with the UMRI-Related Entities 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.

10. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to the UMRI-Related Entities a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the Arrangements Review, Claims Review, or Unallowable Cost Review, and that it has concluded that it is, in fact, independent and objective.

F. Disclosure Program.

The UMRI-Related Entities represented to OIG that, prior to the Effective Date, the UMRI-Related Entities established and shall maintain 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 the UMRI-Related Entities' 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. The UMRI-Related Entities 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, the UMRI-Related Entities 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. The disclosure log shall be made available to OIG upon request.

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 ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

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

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.epls.gov).

c. "Screened Persons" include prospective and current owners, officers, directors, employees, contractors, and agents of the UMRI-Related Entities.

2. *Screening Requirements.* The UMRI-Related Entities shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements.

a. The UMRI-Related Entities shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Screened Persons to disclose whether they are Ineligible Persons.

b. The UMRI-Related Entities shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

c. The UMRI-Related Entities shall implement a policy requiring all Screened Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section affects the responsibility of (or liability for) the UMRI-Related Entities to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. The UMRI-Related Entities understand that items or services furnished by excluded persons are not payable by Federal health care programs and that the UMRI-Related Entities may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether the UMRI-Related Entities meet the requirements of this section III.G.

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

4. *Pending Charges and Proposed Exclusions.* If the UMRI-Related Entities have actual notice that a Screened Person is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Screened Person's employment or contract, the UMRI-Related Entities shall take all appropriate actions to ensure that the responsibilities of that Screened 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, the UMRI-Related Entities shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to the UMRI-Related Entities conducted or brought by a governmental entity or its agents involving an allegation that the UMRI-Related Entities have 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. The UMRI-Related Entities 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. Reporting.

1. *Overpayments.*

a. *Definition of Overpayments.* For purposes of this CIA, an "Overpayment" shall mean the amount of money the UMRI-Related Entities have received in excess of the amount due and payable under any Federal health care program requirements.

b. *Reporting of Overpayments.* If, at any time, the UMRI-Related Entities identify or learn of any Overpayment, the UMRI-Related Entities shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 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. Also, within 30 days after identification of the Overpayment, the UMRI-Related Entities shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, the UMRI-Related Entities 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, and, for Medicare contractors, shall include

the information contained on the Overpayment Refund Form, provided as Appendix E to this CIA. 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.

2. *Reportable Events.*

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

i. a substantial Overpayment;

ii. 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; or

iii. the filing of a bankruptcy petition by the UMRI-Related Entities.

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

b. *Reporting of Reportable Events.* If the UMRI-Related Entities determine (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, the UMRI-Related Entities shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

i. If the Reportable Event results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section III.I.1, and shall include all of the information on the Overpayment Refund Form, as well as:

(A) the payor's name, address, and contact person to whom the Overpayment was sent; and

(B) the date of the check and identification number (or electronic transaction number) by which the Overpayment was repaid/refunded;

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

iii. a description of the UMRI-Related Entities' actions taken to correct the Reportable Event; and

iv. any further steps the UMRI-Related Entities plan to take to address the Reportable Event and prevent it from recurring.

v. If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the filing and a description of any Federal health care program authorities implicated.

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, the UMRI-Related Entities change locations or close a business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, the UMRI-Related Entities 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 location.

B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, the UMRI-Related Entities purchase or establish a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, the UMRI-Related Entities shall notify OIG at least 30 days prior to such purchase or the operation of the new business unit or location. This notification shall include the address of the new business unit or location, phone number, fax number, the UMRI-Related Entities' Medicare number, the UMRI-Related Entities' identification number and/or supplier number, and the name and address of the contractor that issued

each number. Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location. In the event that, after the Effective Date, the UMRI-Related Entities propose to sell any or all of its business units or locations that are subject to this CIA, the UMRI-Related Entities shall notify OIG of the proposed sale at least 30 days prior to the sale of such business unit or location. This notification shall include a description of the 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 such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the Effective Date, the UMRI-Related Entities 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. a copy of the UMRI-Related Entities' Code of Conduct required by Section III.B.1;

4. a copy of all Policies and Procedures required by Section III.B.2;

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

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

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

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

7. a description of the Arrangements Database required by Section III.D.1.a;

8. a description of the internal review and approval process required by Section III.D.1.e;

9. a description of the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1;

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

11. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) a summary and description of any and all current and prior engagements and agreements between the UMRI-Related Entities and the IRO;

12. a certification from the IRO regarding its professional independence and objectivity with respect to the UMRI-Related Entities;

13. a description of the process by which the UMRI-Related Entities fulfill the requirements of Section III.G regarding Ineligible Persons;

14. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken in response to the screening and removal obligations set forth in Section III.G; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;

15. a list of all of the UMRI-Related Entities' 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

Provider number(s), provider identification number(s), and/or supplier number(s); and the name and address of each Medicare contractor to which the UMRI-Related Entities currently submits claims;

16. a description of the UMRI-Related Entities' corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

17. the certifications required by Section V.C.

B. Annual Reports. The UMRI-Related Entities shall submit to OIG annually a report with respect to the status of, and findings regarding, the UMRI-Related Entities' 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. 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);

3. 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);

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

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

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

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

5. a description of any changes to the Arrangements Database required by Section III.D.1.a;

6. a description of any changes to the internal review and approval process required by Section III.D.1.e;

7. a description of any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1;

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

9. the UMRI-Related Entities' response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.E;

10. a summary and description of any and all current and prior engagements and agreements between the UMRI-Related Entities and the IRO, if different from what was submitted as part of the Implementation Report;

11. a certification from the IRO regarding its professional independence and objectivity with respect to the UMRI-Related Entities;

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

13. 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;

14. a summary of the disclosures in the disclosure log required by Section III.F that: (a) relate to Federal health care programs; (b) allege abuse or neglect of patients; or (c) involve allegations of conduct that may involve illegal remunerations or inappropriate referrals in violation of the Anti-Kickback Statute or Stark law;

15. any changes to the process by which the UMRI-Related Entities fulfill the requirements of Section III.G regarding Ineligible Persons;

16. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken by the UMRI-Related Entities in response to the screening and removal obligations set forth in Section III.G; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;

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 the UMRI-Related Entities' locations (including addresses) as required by Section V.A.15; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare Provider number(s), provider identification number(s), and/or supplier number(s); and the name and address of each Medicare contractor to which the UMRI-Related Entities currently submits claims; and

19. the certifications required by Section V.C.

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

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that:

1. to the best of his or her knowledge, except as otherwise described in the applicable report, the UMRI-Related Entities are in compliance with all of the requirements of this CIA;

2. to the best of his or her knowledge, the UMRI-Related Entities have implemented procedures reasonably designed to ensure that all Arrangements do not violate the Anti-Kickback Statute and Stark Law, including the Arrangements Procedures required in Section III.D of the CIA;

3. to the best of his or her knowledge, the UMRI-Related Entities have fulfilled the requirements for New and Renewed 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, the UMRI-Related Entities have 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. The UMRI-Related Entities 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. The UMRI-Related Entities 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

THE UMRI-RELATED ENTITIES:

Therese Leonzal
Compliance Officer
for the UMRI-Related Entities
3848 FAU Boulevard, Suite 200
Boca Raton, FL 33431

Telephone: 561.826.1202
Facsimile: 561.826.1203

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, the UMRI-Related Entities 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), either instead of or 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 the UMRI-Related Entities' books, records, and other documents and supporting materials and/or conduct on-site reviews of any of the UMRI-Related Entities' locations for the purpose of verifying and evaluating: (a) the UMRI-Related Entities' compliance with the terms of this CIA; and (b) the UMRI-Related Entities' compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by the UMRI-Related Entities to OIG or its duly authorized representative(s) at all reasonable business hours for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of the UMRI-Related Entities' 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. The UMRI-Related Entities shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. The UMRI-Related Entities' employees may elect to be interviewed with or without a representative of the UMRI-Related Entities present.

VIII. DOCUMENT AND RECORD RETENTION

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

X. BREACH AND DEFAULT PROVISIONS

The UMRI-Related Entities are 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, the UMRI-Related Entities 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 the UMRI-Related Entities fails to establish and implement any of the following obligations as described in Section III:

a. a Compliance Officer;

b. a Compliance Committee;

c. a written Code of Conduct;

d. written Policies and Procedures;

e. the training of Covered Persons;

f. the Arrangements Procedures and/or Arrangements Requirements described in Sections III.D.1 and III.D.2;

g. a Disclosure Program;

h. Ineligible Persons screening and removal requirements; and

i. notification of Government investigations or legal proceedings.

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 the UMRI-Related Entities fail to engage an IRO, as required in Section III.E, and Appendixes B and C.

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 the UMRI-Related Entities fail 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 the UMRI-Related Entities fail to submit the annual Arrangements Review Report, Claims Review Report, and, if appropriate, Unallowable Cost Review Report in accordance with the requirements of Section III.E.

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

6. A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of the UMRI-Related Entities 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 the UMRI-Related Entities fail to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to the UMRI-Related Entities stating the specific grounds for its determination that the UMRI-Related Entities have failed to comply fully and adequately with the CIA

obligation(s) at issue and steps the UMRI-Related Entities shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the UMRI-Related Entities receive 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. The UMRI-Related Entities 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 the UMRI-Related Entities 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 the UMRI-Related Entities receive 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 the UMRI-Related Entities have failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify the UMRI-Related Entities of: (a) the UMRI-Related Entities' failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, the UMRI-Related Entities 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 the UMRI-Related Entities elect to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until the UMRI-Related Entities cure, 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 certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that the UMRI-Related Entities have materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

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

a. a failure by the UMRI-Related Entities to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.I;

b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or

d. a failure to engage and use an IRO in accordance with Section III.D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by the UMRI-Related Entities constitutes an independent basis for the UMRI-Related Entities' exclusion from participation in the Federal health care programs. Upon a determination by OIG that the UMRI-Related Entities have materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify the UMRI-Related Entities of: (a) the UMRI-Related Entities' material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure*. The UMRI-Related Entities 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. The UMRI-Related Entities are 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) the UMRI-Related Entities have begun to take action to cure the material breach; (ii) the UMRI-Related Entities are pursuing such action with due diligence; and (iii) the UMRI-Related Entities have provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter*. If, at the conclusion of the 30-day period, the UMRI-Related Entities fail to satisfy the requirements of Section X.D.3, OIG may exclude the UMRI-Related Entities from participation in the Federal health care programs. OIG shall notify the UMRI-Related Entities in writing of its determination to exclude the UMRI-Related Entities (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of the UMRI-Related Entities' receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, the UMRI-Related Entities 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 the UMRI-Related Entities 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, the UMRI-Related Entities 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 the UMRI-Related Entities were in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. The UMRI-Related Entities 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 the UMRI-Related Entities to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless the UMRI-Related Entities request 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 the UMRI-Related Entities were 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) the UMRI-Related Entities had begun to take action to cure the material breach within that period; (ii) the UMRI-Related Entities have pursued and are pursuing such action with due diligence; and (iii) the UMRI-Related Entities provided to OIG within that period a reasonable timetable for curing the material breach and the UMRI-Related Entities have 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 the UMRI-Related Entities, only after a DAB decision in favor of OIG. The UMRI-Related Entities' election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude the UMRI-Related Entities 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 the UMRI-Related Entities 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. The UMRI-Related Entities shall waive their 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 the UMRI-Related Entities, the UMRI-Related Entities 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

The UMRI-Related Entities and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of the UMRI-Related Entities;

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

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

D. OIG may agree to a suspension of the UMRI-Related Entities' obligations under the CIA in the event of the UMRI-Related Entities' cessation of participation in Federal health care programs. If the UMRI-Related Entities withdraw from participation in Federal health care programs and are relieved of their CIA obligations by OIG, the UMRI-Related Entities shall notify OIG at least 30 days in advance of the UMRI-Related Entities' intent to reapply as a participating the UMRI-Related Entities or supplier with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the CIA should be reactivated or modified.

E. OIG may, in its sole discretion, agree to a suspension of some or all of Steinberg's obligations under the CIA in the event that Steinberg becomes an employee of an entity other than the UMRI-Related Entities.

F. The undersigned the UMRI-Related Entities signatory represents and warrants that he is authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

G. 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
MRI RADIOLOGY NETWORK, P.A.,
UNIVERSITY MRI OF BOCA RATON, INC.,
WEST BOCA OPEN MRI, INC.,
EXPERT RADIOLOGY RESEARCH AND EDUCATIONAL FOUNDATION, INC.,
UNIVERSITY MRI LEASING, L.L.C.,
UNIVERSITY MRI RADIOLOGY ASSOCIATES, P.L.,
EXPERT RADIOLOGY NETWORK, P.A.,
NEUROSCIENCE ACQUISITION, L.L.C,
UNIVERSITY MRI RESEARCH AND EDUCATIONAL FOUNDATION, L.L.C.
AND
FRED L. STEINBERG, M.D.

4/1/08

FRED L. STEINBERG, M.D.
Individually
and on behalf of the UMRI-Related Entities

DATE

4/2/08

ERIC DUBELIER, ESQ.
ReedSmith, LLP
Counsel for Fred L. Steinberg
and the UMRI-Related Entities

DATE

9/2/08

THOMAS W. GREESON, ESQ.
ReedSmith, LLP
Counsel for Fred L. Steinberg
and the UMRI-Related Entities

DATE

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

4/10/08

GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

DATE

APPENDIX A

ARRANGEMENTS DATABASE

The UMRI-Related Entities shall create and maintain an Arrangements Database to track all new and existing Arrangements in order to ensure that each Arrangement does not violate the Anti-Kickback Statute and Stark Law. The Arrangements Database shall contain certain information to assist the UMRI-Related Entities in evaluating whether each Arrangement violates the Anti-Kickback Statute and Stark Law, including but not limited to the following:

1. Each party involved in the Arrangement;

2. The type of Arrangement (e.g., physician employment contract, medical directorship, lease agreement);

3. The term of the Arrangement, including the effective and expiration dates and any automatic renewal provisions;

4. The amount of compensation to be paid pursuant to the Arrangement and the means by which compensation is paid;

5. The methodology for determining the compensation under the Arrangements, including the methodology used to determine the fair market value of such compensation;

6. Whether the amount of compensation to be paid pursuant to the Arrangement is determined based on the volume or value of referrals between the parties;

7. Whether each party has fulfilled the requirements of Section III.D.2; and

8. Whether the Arrangement satisfies the requirements of an Anti-Kickback Statute safe harbor and/or a Stark Law exception or safe harbor, as applicable.

APPENDIX B

INDEPENDENT REVIEW ORGANIZATION FOR ARRANGEMENTS REVIEW

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

A. IRO Engagement.

The UMRI-Related Entities 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 written notice of the identity of the selected IRO, OIG will notify the UMRI-Related Entities if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, the UMRI-Related Entities may continue to engage the IRO.

If the UMRI-Related Entities engage 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, the UMRI-Related Entities shall submit the information identified in Section V.A.11 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify the UMRI-Related Entities if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, the UMRI-Related Entities may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Arrangements Review engagement who are knowledgeable in the requirements of the Anti-Kickback Statute and the Stark Law; 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 Section III.E of the CIA.

D. IRO Independence and Objectivity.

The IRO must perform the Arrangements Review in a professionally independent and objective fashion, taking into account any other business relationships or engagements that may exist between the IRO and the UMRI-Related Entities.

E. IRO Removal/Termination.

1. *Provider.* If the UMRI-Related Entities terminate the IRO during the course of the engagement, the UMRI-Related Entities must submit a notice explaining the reasons to OIG no later than 30 days after termination. The UMRI-Related Entities must engage a new IRO in accordance with Paragraph A of this Appendix.

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 the UMRI-Related Entities to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring the UMRI-Related Entities to engage a new IRO, OIG shall notify the UMRI-Related Entities 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, the UMRI-Related Entities may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. The UMRI-Related Entities shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with the UMRI-Related Entities prior to requiring the UMRI-Related Entities to terminate the IRO. However, the final determination as to whether or not to require the UMRI-Related Entities to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX C

INDEPENDENT REVIEW ORGANIZATION FOR CLAIMS REVIEW

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

A. IRO Engagement.

The UMRI-Related Entities 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 written notice of the identity of the selected IRO, OIG will notify the UMRI-Related Entities if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, the UMRI-Related Entities may continue to engage the IRO.

If the UMRI-Related Entities engage 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, the UMRI-Related Entities shall submit the information identified in Section V.A.11 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify the UMRI-Related Entities if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, the UMRI-Related Entities may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Claims Review and Unallowable Cost Review, if applicable engagement who have expertise in the billing, coding, reporting, and other requirements of radiology and diagnostic imaging claims and in the general requirements of the Federal health care program(s) from which the UMRI-Related Entities seek 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 (e.g., CCA, CCS, CCS-P, CPC,

RRA, etc.) 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 Claim Review and Unallowable Cost Review, if applicable, in accordance with the specific requirements of the CIA;

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

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

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 B to the CIA.

D. IRO Independence and Objectivity.

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

E. IRO Removal/Termination.

1. *Provider.* If the UMRI-Related Entities terminate the IRO during the course of the engagement, the UMRI-Related Entities must submit a notice explaining the reasons to OIG no later than 30 days after termination. The UMRI-Related Entities must engage a new IRO in accordance with Paragraph A of this Appendix.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as

described in Paragraph C, OIG may, at its sole discretion, require the UMRI-Related Entities to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring the UMRI-Related Entities to engage a new IRO, OIG shall notify the UMRI-Related Entities 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, the UMRI-Related Entities may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. The UMRI-Related Entities shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with the UMRI-Related Entities prior to requiring the UMRI-Related Entiteis to terminate the IRO. However, the final determination as to whether or not to require the UMRI-Related Entities to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX D
CLAIMS REVIEW

A. Claims Review.

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

a. Overpayment: The amount of money the UMRI-Related Entities have received in excess of the amount due and payable under any Federal health care program requirements.

b. Item: Any discrete unit that can be sampled (e.g., code, line item, beneficiary, patient encounter, etc.).

c. Paid Claim: A code or line item submitted by the UMRI-Related Entities and for which the UMRI-Related Entities have received reimbursement from the Medicare program.

d. Population: For the first Reporting Period, the Population shall be defined as all Items for which a code or line item has been submitted by or on behalf of the UMRI-Related Entities and for which the UMRI-Related Entities have received reimbursement from Medicare (i.e., Paid Claim) during the 12-month period covered by the first Claims Review.

For the remaining Reporting Periods, the Population shall be defined as all Items for which the UMRI-Related Entities have received reimbursement from Medicare (i.e., Paid Claim) during the 12-month period covered by the Claims Review.

To be included in the Population, an Item must have resulted in at least one Paid Claim.

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

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

2. *Discovery Sample.* The IRO shall randomly select and review a sample of 50 Paid Claims submitted by or on behalf of the UMRI-Related Entities (Discovery Sample). The Paid Claims shall be reviewed based on the supporting documentation available at the UMRI-Related Entities' office(s) or under the UMRI-Related Entities' 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 the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, the UMRI-Related Entities should, as appropriate, further analyze any errors identified in the Discovery Sample. The UMRI-Related Entities recognize that OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample or any other segment of the universe.)

3. *Full Sample.* If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall select an additional sample of Paid Claims (Full Sample) using commonly accepted sampling methods. The Full Sample shall be designed to: (1) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate; and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims selected for the Full Sample shall be reviewed based on supporting documentation available at the UMRI-Related Entities or under the UMRI-Related Entities' 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 UMRI-Related Entities may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 50 Items, as part of its Full Sample, if: (1) statistically appropriate and (2) the UMRI-Related Entities select the Full Sample Items using the seed number generated by the Discovery Sample. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from the UMRI-Related Entities to the appropriate Federal health care program payor, including the Medicare contractor (e.g., carrier, fiscal intermediary, or DMERC/DME MAC), for appropriate follow-up by that payor.

4. *Systems Review*. If the UMRI-Related Entities' Discovery Sample identifies an Error Rate of 5% or greater, the UMRI-Related Entities' IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO shall perform a "walk through" of the system(s) and process(es), that generated the claim to 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. Paid Claims without Supporting Documentation. For the purpose of appraising Items included in the Claims Review, any Paid Claim for which the UMRI-Related Entities cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by the UMRI-Related Entities for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

b. Replacement Sampling. Considering the Population shall consist only of Paid Claims and that Items with missing documentation cannot be replaced, there is no need to utilize alternate or replacement sampling units.

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 associated with the Items selected in each first sample (or first sample for each strata, if applicable) shall be used (i.e., it is not permissible to generate more than one list of random samples and then select one for use with the Discovery Sample or Full Sample).

B. Claims Review Report. 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. Sampling Unit. A description of the Item as that term is utilized for the Claims Review.

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

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

d. Sampling Frame. A description of the sampling frame, which is the totality of Items from which the Discovery Sample and, if any, Full Sample has been selected and an explanation of the methodology used to identify the sampling frame. In most circumstances, the sampling frame will be identical to the Population.

e. 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).

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

2. *Statistical Sampling Documentation.*

a. The number of Items appraised in the Discovery Sample and, if applicable, in the Full Sample.

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

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

d. 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 the UMRI-Related Entities' 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 Sample, and the results of the Full Sample (if any).

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by the UMRI-Related Entities (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 the UMRI-Related Entities.

iii. Total dollar amount of all Overpayments in the sample.

iv. Total dollar amount of paid Items included in the sample and the net Overpayment associated with the sample.

v. Error Rate in the sample.

vi. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure 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. (See Attachment 1 to this Appendix.)

4. *Systems Review*. Observations, findings, and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s).

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.

Claim Review Results

Federal Health Care Program Billed	Bene HIC #	Date of Service	Procedure Code Submitted	Procedure Code Reimbursed	Allowed Amount Reimbursed	Correct Procedure Code (IRO determined)	Correct Allowed Amt Reimbursed (IRO determined)	Dollar Difference between Amt Reimbursed and Correct Allowed Amt

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

Date:_____
Contractor Deposit Control #_____ Date of Deposit: _____
Contractor Contact Name:_____Phone #_____
Contractor Address:_____
Contractor Fax:_____

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.

PROVIDER/PHYSICIAN/SUPPLIERNAME_____
ADDRESS_____
PROVIDER/PHYSICIAN/SUPPLIER #_____CHECK NUMBER#_____
CONTACT PERSON:_____PHONE #_____ AMOUNT OF CHECK $_____ CHECK DATE_____

REFUND INFORMATION

For each Claim, provide the following:
Patient Name_____HIC #_____
Medicare Claim Number_____Claim Amount Refunded $_____
Reason Code for Claim Adjustment:_____ (Select reason code from list below. Use one reason per claim)

(Please list all claim numbers involved. Attach separate sheet, if necessary)

*Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling, please indicate methodology and formula used to determine amount and reason for overpayment:*_____

For Institutional Facilities Only:
Cost Report Year(s) _____
(If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)
For OIG Reporting Requirements:
Do you have a Corporate Integrity Agreement with OIG? Yes No

Reason Codes:

Billing/Clerical Error
01 - Corrected Date of Service
02 - Duplicate
03 - Corrected CPT Code
04 - Not Our Patient(s)
05 - Modifier Added/Removed
06 - Billed in Error
07 - Corrected CPT Code

MSP/Other Payer Involvement
08 - MSP Group Health Plan Insurance
09 - MSP No Fault Insurance
10 - MSP Liability Insurance
11 - MSP, Workers Comp.(Including Black Lung
12 - Veterans Administration

Miscellaneous
13 - Insufficient Documentation
14 - Patient Enrolled in an HMO
15 - Services Not Rendered
16 - Medical Necessity
17 - Other (Please Specify)
_____