

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
*INNOVATIVE RESOURCE GROUP, LLC, D/B/A APS HEALTHCARE MIDWEST***

I. PREAMBLE

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

II. TERM AND SCOPE OF THE CIA

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

B. Sections VII, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) IRG’s final annual report; or (2) any additional materials submitted by IRG pursuant to OIG’s request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. “Disease Management” refers to IRG’s coordination of care for eligible participants through member outreach and engagement activities, and the reporting thereon, under a contract between IRG and a state Medicaid agency for the purposes of enhancing the member’s health condition, self-management, and care coordination. Such activities include, for example, enrollment, assessment, and contact with members, as well as IRG’s tracking and reporting of member engagements to a state Medicaid agency. The term “Disease Management” is inclusive of services provided by

both medical and non-medical staff, and includes the more intensive level of these member outreach and engagement services that is sometimes called case management.

2. “Covered Persons” includes:
 - a. all officers, directors, and employees of IRG; and
 - b. all contractors, subcontractors, agents, and other persons who provide Disease Management services on behalf of IRG pursuant to its Disease Management contracts with state Medicaid programs, excluding vendors whose sole connection with IRG is selling or otherwise providing supplies, equipment, utilities, administrative software development, office support services, and physical plant leased space services, to IRG and who do not bill the Federal health care programs for such supplies, equipment, utilities, or services.

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. “Relevant Covered Persons” includes Covered Persons involved in the provision of Disease Management services relating to or under a contract between IRG and a state Medicaid agency, and Covered Persons involved in the collection, assembly and submission of data or invoices to state Medicaid agencies or their agents, relating to IRG’s Disease Management functions.

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Officer and Committee

1. *Compliance Officer.* Within 90 days after the Effective Date, IRG shall appoint an individual to serve as its Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of IRG, shall report directly to the President of IRG, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of IRG, 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 IRG as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

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

2. *Compliance Committee.* Within 90 days after the Effective Date, IRG shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., executives of relevant departments, such as clinical quality, human resources, operations and information systems). 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 IRG's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly.

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

3. *Board of Directors Compliance Obligations.* The Board of Directors (Board) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA.

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

- a. meeting at least quarterly to review and oversee IRG's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. ensuring that IRG adopts and implements policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and Federal health care program requirements; and
- c. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board summarizing its review and oversight of IRG's compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

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

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

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

B. Written Standards

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

- a. IRG's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate invoices consistent with such requirements;
- b. IRG's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with IRG's own Policies and Procedures;
- c. the requirement that all of IRG's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by IRG, suspected violations of any Federal health care program requirements or of IRG's own Policies and Procedures; and
- d. the right of all individuals to use the Disclosure Program described in Section III.E, and IRG's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

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

IRG 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.* Within 90 days after the Effective Date, IRG shall implement written Policies and Procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA. In particular, IRG shall develop and implement policies and procedures that will promote compliance with the standards applicable to Disease Management functions set forth in IRG's Medicaid contract(s); ensure accuracy of data submission relating to those Disease Management functions; and promote compliance with all Federal health care program requirements.

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

At least annually (and more frequently, if appropriate), IRG shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, any such revised Policies and Procedures shall be distributed to all Covered Persons.

C. Training and Education

1. *General Training.* Within 90 days after the Effective Date, IRG shall provide at least two hours of General Training to each Covered Person, except that a Covered Person who has completed such training since September 1, 2010, shall only be required to receive information about the existence of this CIA and a summary of its provisions within 90 days after the Effective Date. This General Training, at a minimum, shall explain IRG's:

- a. CIA requirements; and
- b. Compliance Program, including the Code of Conduct.

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

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

- a. policies, procedures, and other requirements applicable to the provision of Disease Management services, disenrollment of members, and the documentation and submission of reports relating to such activities which are required under the applicable Disease Management contract to the relevant state Medicaid agency;
- b. the personal obligation of each individual to ensure the accuracy of information, files and data compiled in relation to and pursuant to IRG's Disease Management contracts with state Medicaid agencies;
- c. applicable statutes, regulations, and Federal health care program requirements and directives;
- d. the legal sanctions for violations of the Federal health care program requirements; and
- e. examples of proper and improper Disease Management 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.

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

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

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

4. *Certification.* Each individual who is required to attend training shall certify, in writing, or in electronic form, 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.

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

6. *Update of Training.* IRG 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 or the Systems or Compliance Reviews, and any other relevant information.

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

D. Review Procedures

1. *General Description*

- a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, IRG shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform the reviews listed in this Section III.D. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

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

2. *Systems and Compliance Review.* The IRO shall review and evaluate any provisions relating to Disease Management contained in IRG's contracts with state Medicaid agencies and IRG's systems, processes, policies, and procedures with respect to the performance of Disease Management services under such contracts. The IRO shall conduct Systems Reviews according to the terms set out in Appendix B to this CIA, which is incorporated by reference. The IRO shall further conduct Compliance Reviews according to the terms set out in Appendix B to this CIA, in order to evaluate IRG's compliance with the contracts, systems, processes, policies, and procedures reviewed and evaluated in the Systems Review(s). The IRO shall prepare an annual Systems Review Report or Compliance Review Report as applicable, as outlined in Appendix B.

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

Prior to initiating a Validation Review, OIG shall notify IRG 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, IRG may request a meeting with OIG to: (a) discuss the results of any Systems or Compliance Review submissions or findings; (b) present any additional information to clarify the results of the Systems or Compliance Review or to correct the inaccuracy of the Systems or Compliance Review; and/or (c) propose alternatives to the proposed Validation Review. IRG agrees to provide any additional information as may be requested by OIG under this Section III.D.3 in an expedited manner. OIG will attempt in good faith to resolve any Systems or Compliance Review issues with IRG prior to conducting a Validation Review. However, the final

determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to IRG a certification or sworn affidavit that it has evaluated its professional independence and objectivity and has concluded that it is, in fact, independent and objective.

E. Disclosure Program

Within 90 days after the Effective Date, IRG shall establish a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with IRG's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. IRG 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, IRG 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.

F. Ineligible Persons

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

- a. an “Ineligible Person” shall include an individual or entity who:
 - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
 - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. “Exclusion Lists” include:
 - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and
 - ii. the General Services Administration’s List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).

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

- a. IRG shall screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.
- b. IRG shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

- c. IRG shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

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

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

4. *Pending Charges and Proposed Exclusions.* If IRG has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, IRG shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings

Within 30 days after discovery, IRG shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to IRG conducted or brought by a governmental entity or its agents involving an allegation that IRG has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. IRG 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.

H. Reportable Events

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

- a. 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;
- b. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.F.1.a; or
- c. the filing of a bankruptcy petition by IRG.

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

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

3. *Reportable Events under Section III.H.1.a and b.* For Reportable Events under Section III.H.1.a and III.H.1.b, the report to OIG shall include:

- a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- b. a description of IRG’s actions taken to correct the Reportable Event; and
- c. any further steps IRG plans to take to address the Reportable Event and prevent it from recurring.

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

5. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves only a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by IRG to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG.

IV. CHANGES TO BUSINESS UNITS, LOCATIONS, OR DISEASE MANAGEMENT CONTRACTS

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, IRG changes locations or closes a business unit or location related to the furnishing of items or services that may be paid for or reimbursed by Federal health care programs, IRG 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, IRG purchases or establishes a new business unit or location related to the furnishing of items or services that may be paid for or reimbursed by Federal health care programs, IRG 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, and the location's Medicare and state Medicaid program provider number and/or supplier number(s) if applicable; and the name and address of each Medicare program contractor and state Medicaid agency division to which IRG currently submits claims or with which IRG is currently contracted. 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, IRG proposes to sell any or all of its business units or locations that are subject to this CIA, IRG 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.

D. Creation or Termination of Disease Management Contract. In the event that, after the Effective Date, IRG enters into a new Disease Management contract with a state or federal health care program, or subcontracts to perform Disease Management services for an entity that contracted with a state or federal health care program, IRG shall notify OIG of the new Disease Management contract as soon as possible, but no later than 30 days after the effective date of the contract or subcontract. In the event that, after the Effective Date, a Disease Management contract between IRG and a state or federal health care program or a subcontract to perform Disease Management services for an entity that contracted with a state or federal health care program is terminated before the expiration date identified in the contract by either party, IRG shall notify OIG of the terminated contract as soon as possible, but no later than 30 days after the termination date of the contract or subcontract. This notification shall include, for contracts, the name of the contracting state or federal health care program, and for subcontracts, the names and contact information of the contractor from whom IRG subcontracted; a brief description of the terms of the new contract if applicable; and the date of termination of the contract if applicable. This CIA shall be binding on the new contract or subcontract, unless otherwise determined and agreed to in writing by the OIG, except that the IRO review provisions in Section III.D and Appendix B shall apply only to Disease Management contracts and not subcontracts. IRG shall not be obligated to provide notice to OIG under this Paragraph when a Disease Management contract or subcontract expires by its own terms and is not renewed.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the Effective Date, IRG 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 IRG's Code of Conduct required by Section III.B.1;
4. 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);
5. a summary of all Policies and Procedures required by Section III.B (copies of the Policies and Procedures shall be made available to OIG upon request);
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; and
 - b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

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

7. a description of the Disclosure Program required by Section III.E;
8. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; (d) a summary and description of any and all current and prior engagements and agreements between IRG and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to IRG;
9. a description of the process by which IRG fulfills the requirements of Section III.F regarding Ineligible Persons;
10. a list of all of IRG's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare and state

Medicaid program provider number and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which IRG currently submits claims or invoices for payment;

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

12. the certifications required by Section V.C.

B. Annual Reports. IRG shall submit to OIG annually a report with respect to the status of, and findings regarding, IRG's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

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

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

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

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

5. 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);

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

- a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
- b. the number of individuals required to complete the initial and annual training, the percentage of individuals who actually completed the initial and annual training, and an explanation of any exceptions.

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

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

8. IRG's response to the reports prepared pursuant to Section III.D, along with corrective action plan(s) related to any issues raised by the reports;

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

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

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

12. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care programs (the complete disclosure log shall be made available to OIG upon request);

13. any changes to the process by which IRG fulfills the requirements of Section III.F regarding Ineligible Persons;

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

15. a description of all changes to the most recently provided list of IRG's locations (including addresses) as required by Section V.A.10; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare and state Medicaid program provider number(s) and/or supplier number(s), if applicable; and the name and address of each Medicare program contractor and state Medicaid agency division to which IRG currently submits claims or with which IRG is currently contracted for Disease Management services; and

16. 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 each Annual Report shall include a certification by the Compliance Officer that:

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

2. 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

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

D. Designation of Information. IRG 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. IRG 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

IRG:

Michael J. Williamson, Esq.
Compliance Officer
44 S. Broadway, Suite 1200
White Plains, NY 10601-4411
Telephone: 914.288.4643

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

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

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

X. BREACH AND DEFAULT PROVISIONS

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

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, IRG 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 IRG 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, Relevant Covered Persons, and Board Members;
- f. a Disclosure Program;
- g. Ineligible Persons screening and removal requirements;
- h. notification of Government investigations or legal proceedings; and
- i. reporting of Reportable Events.

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

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

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

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

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of IRG 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 IRG fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to IRG stating the specific grounds for its determination that IRG has failed to comply fully and adequately with the CIA obligation(s) at issue and steps IRG shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after IRG receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1- 6 of this Section.

B. Timely Written Requests for Extensions. IRG 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 IRG 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 IRG receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties

1. *Demand Letter.* Upon a finding that IRG has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify IRG of: (a) IRG's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, IRG 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 IRG elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until IRG cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

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

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

D. Exclusion for Material Breach of this CIA

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

- a. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- b. a failure by IRG to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.H;

- 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, Appendix A, and Appendix B.

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

3. *Opportunity to Cure.* IRG 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. IRG is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30 day period, but that: (i) IRG has begun to take action to cure the material breach; (ii) IRG is pursuing such action with due diligence; and (iii) IRG has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, IRG fails to satisfy the requirements of Section X.D.3, OIG may exclude IRG from participation in the Federal health care programs. OIG shall notify IRG in writing of its determination to exclude IRG. (This letter shall be referred to as the "Exclusion Letter.") Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of IRG's 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, IRG 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 IRG 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, IRG 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 IRG was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. IRG 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 IRG to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless IRG requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

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

- a. whether IRG was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) IRG had begun to take action to cure the material breach within that period; (ii) IRG has pursued and is pursuing such action with due diligence; and (iii) IRG provided to OIG within that period a reasonable timetable for curing the material breach and IRG has followed the timetable.

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

IRG and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of IRG.

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

E. The undersigned IRG 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.

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

ON BEHALF OF INNOVATIVE RESOURCE GROUP, LLC,
D/B/A APS HEALTHCARE MIDWEST

/Jerome V. Vaccaro/

2/18/2011

JEROME V. VACCARO
President
Innovative Resource Group, LLC

DATE

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

/Gregory E. Demske/

2/18/11

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

DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

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

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

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Systems or Compliance Review who have expertise in publications or other guidance issued by the applicable State Medicaid program agency or by the Department of Health and Human Services (HHS) relating to the Disease Management functions performed by IRG, and the Disease Management process, including but not limited to patient assessment, continuing patient care and contact, and patient enrollment or disenrollment.

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

3. 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 System and Compliance Review in accordance with the specific requirements of the CIA;

2. follow all applicable Medicaid rules and applicable contract provisions in conducting the System or Compliance Review;

3. if in doubt of the application of a particular Medicaid policy or regulation or contract term, request clarification from the appropriate authority;

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

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

D. IRO Independence and Objectivity

The IRO must perform the System and Compliance Reviews 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 IRG.

E. IRO Removal/Termination

1. *Provider and IRO.* If IRG terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, IRG must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. IRG must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the prior IRO or at least 60 days prior to the end of the current Reporting Period, whichever is earlier.

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

Prior to requiring IRG to engage a new IRO, OIG shall notify IRG 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, IRG may present additional information regarding the IRO's qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with IRG prior to requiring IRG to terminate the IRO. However, the final determination as to whether or not to require IRG to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

DISEASE MANAGEMENT REVIEW

I. Disease Management Review, General Description

As specified more fully below, IRG shall retain an IRO to perform reviews of IRG's Disease Management functions under contracts between IRG and state Medicaid agencies (Disease Management Review). The Disease Management Review shall consist of two components – a systems review (the “Systems Review”) and a compliance review (the “Compliance Review”). IRG may engage, at its discretion, a single IRO to perform both components of the Disease Management Review, provided that the entity has the necessary expertise and capabilities to perform both.

The IRO shall perform the Disease Management Review, consisting of a Systems Review and a Compliance Review, annually to cover each of the five Reporting Periods. The IRO shall randomly select one Disease Management contract for each Reporting Period on which to perform the Disease Management Review. Once a Disease Management contract has been selected for the Disease Management Review in a Reporting Period, it will not be considered in the pool from which the IRO randomly selects subsequent Disease Management contracts for review.¹ The IRO shall perform all components of the Disease Management Review.

II. Disease Management Systems Review

A. Systems Review. The IRO shall perform the Systems Review in each Reporting Period. The IRO shall perform all components of the Systems Review.

The Systems Review shall be a review of IRG's contracts, systems, processes, policies, and procedures relating to Disease Management functions. Specifically, the Systems Review will consider the selected Disease Management contract for the performance of Disease Management functions (hereafter, “Selected State DM Contract”), and IRG's systems, processes, policies, and procedures relating to the performance of the Disease Management functions under the Selected State DM Contract (hereafter, “IRG Policies”).

¹ Where IRG has two Disease Management contracts with the same state Medicaid agency, and the contracts are substantially similar, both contracts shall be removed from the pool for purposes of subsequent selection of Disease Management contracts for review.

The Population for purposes of the Systems Review includes the Selected State DM Contract as defined above and its corresponding IRG Policies. Specifically, the IRO shall include in its review:

1. the Selected State DM Contract, including amendments, formal and informal communications with the State agency, and associated documents regarding IRG's responsibilities with respect to Disease Management functions under the Selected State DM Contract, within the control of IRG;
2. IRG Policies and associated documents related to performance of Disease Management functions;
3. IRG's organizational structure related to performance of Disease Management functions;
4. IRG's staffing policies and procedures related to Disease Management functions;
5. the form and content of information and materials related to the Selected State DM Contract disseminated to participating members, providers, or other entities necessary to coordination of care and Disease Management functions;
6. the manner in which IRG performs its Disease Management functions;
7. the manner in which IRG handles and responds to any and all contacts from participating members and providers;
8. the manner in which IRG reports any and all information required under the Selected State DM Contract to the State, and the content of such reports, as well as any and all additional communications pertaining to the Selected State DM Contract between IRG and the State;
9. IRG Policies used to track and/or analyze its performance of Disease Management functions under the Selected State DM Contract, including but not limited to IRG Policies used to track and/or analyze (1) its attempts and success at contacting members, (2) phone calls or other communications from members to IRG, and (3)

whether and when members are assessed and/or a plan of care is created for each member;

10. Any publications or other guidance issued by the applicable State Medicaid program agency or by the Department of Health and Human Services (HHS) relating to the Disease Management functions performed by IRG;

11. IRG Policies regarding any and all reporting of data, information, analysis, or outcomes relating to the Selected State DM Contract within IRG or to its parent company; and

12. IRG Policies regarding the collection, recording, and storage of member information relating to Disease Management functions in member records (hereafter, "Member Records"), such as:

- a. Name, contact information, primary language, and demographic information;
- b. eligibility, enrollment, or participation under the State DM Contract, as well as consent or lack thereof to participation or enrollment as appropriate;
- c. medical history, diagnoses, prescription and over the counter drugs, and any disease-specific information regarding risk, treatment needs, and key triggers;
- d. member's provider contact information;
- e. assessments, plans of care, or other evaluations of the member;
- f. tracking record of contacts to or from member, successful or attempted;
- g. notes created by IRG personnel relevant to the member;
- h. formal or informal complaints or inquiries by the member; and

- i. any and all documents by IRG sent to the member or received by IRG in relation to the member (e.g., emergency room records).

B. Systems Review Report. The IRO shall prepare a Systems Review Report as described in this Appendix for each Systems Review performed. The following information shall be included in the Systems Review Report.

1. Systems Review Objective. A clear statement of the objective intended to be achieved by the Systems Review.
2. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Systems Review and any personnel interviewed.
3. Review Protocol. A narrative description of how the Systems Review was conducted and what was evaluated.
4. Description of Reviewed State DM Contracts and IRG Policies. A detailed description of the Selected State DM Contract under review and its corresponding IRG Policies, including but not limited to, a description of the IRG Policies in place to assess and contact members, as well as Selected State DM Contract provisions that apply to member assessment and contact, if applicable.
5. Review Findings. Findings and supporting rationale regarding weaknesses in IRG Policies relating to the Selected State DM Contract, if any, as well as recommendations for improvement, if any;
6. Credentials. The names and credentials of the individuals who: (1) designed the procedures and the review methodology utilized for the Systems Review and (2) performed the Systems Review.

III. Compliance Review

A. Compliance Review. The IRO shall perform the Compliance Review in each Reporting Period. The IRO shall perform all components of each Compliance Review.

In each Reporting Period, the IRO shall select the same Selected State DM Contract and its corresponding IRG Policies reviewed in the Systems Review (hereafter, “Selected System”), to form the basis of the Compliance Review for that Reporting Period. As described more fully below, the Compliance Review shall include a review of records relating to a sample of member assessments and contacts made under the Selected System. The purpose of the Compliance Review shall be to analyze IRG’s compliance with the applicable terms of the Selected State DM Contract, and, in the absence of specific requirements in the Selected State DM Contract, with the corresponding IRG Policies.

1. IRO Review of Discovery Sample of Member Records. The IRO shall randomly select and review a sample of 50 Member Records for each Selected System. The Member Records shall be reviewed based on the supporting documentation available at IRG’s office or under IRG’s control, and the Member Records shall be reviewed for their compliance with the Selected Systems as established by the Systems Review and Systems Review Report in II.A and II.B. Specifically, the IRO shall focus on whether the Member Records are in compliance with the contractual or internal requirements regarding the timing and documentation of member assessments, member contacts, and member enrollment or disenrollment, if applicable. Member Records for each Selected System shall be analyzed separately for their compliance with the applicable Selected System.

2. IRO Review of Larger Sample of Member Records. For each Selected System, if 95% or more of the Member Records are found to be in compliance with the applicable Selected System as established by the Systems Review, no additional sampling is required. If, in either Selected System, fewer than 95% of the Member Records sampled are found to be in compliance with the Selected System, that Selected System will undergo further sampling. Specifically, the IRO shall randomly select and review a sample of 100 additional Member Records for the Selected System(s), in a manner consistent with the methodology set forth in III.A.1.

B. Compliance Review Report. The IRO shall prepare an Compliance Review Report as described in this Appendix for each Compliance Review performed. The following information shall be included in the Compliance Review Report.

1. Compliance Review Objective. A clear statement of the objective intended to be achieved by the Compliance Review.

2. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Compliance Review and any personnel interviewed.
3. Compliance Review Sample. A description of the Selected System and the Member Records subject to the Compliance Review.
4. Review Protocol. A narrative description of how the Systems Review was conducted and what was evaluated.
5. Description of Applicable Provisions of Selected Systems. A detailed description of the Selected System, including but not limited to contractual or internal requirements regarding the timing and documentation of member assessments, member contacts, and member enrollment or disenrollment, if applicable, that were used to analyze whether Member Records were in compliance with the requirements of the Selected System.
6. Review Findings. Findings and supporting rationale regarding compliance of IRG with the Selected System, and any recommendations for improvement associated with such findings, including what the IRO identifies as potential causes of any weaknesses or noncompliance;
7. Credentials. The names and credentials of the individuals who: (1) designed the procedures and the review methodology utilized for the Systems Review and (2) performed the Systems Review.

C. Disclosure to States. IRG will disclose the Compliance Review Report to the appropriate State with whom IRG has contracted to perform Disease Management functions under the Selected State DM Contract applicable to that Selected System.