CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
INDEPENDENT HEALTH ASSOCIATION

I. PREAMBLE

Independent Health Association (IHA) 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, IHA is entering into a Settlement Agreement with the United States.

IHA represents that, prior to this CIA, IHA voluntarily established a compliance program which provides for a Compliance Officer, a Compliance Committee structure with Board oversight, a compliance training and education program, a confidential disclosure reporting hotline, auditing and monitoring activities, and various policies and procedures designed and implemented to ensure IHA's compliance with Medicare Advantage organization requirements. IHA shall continue its compliance program through the term of the CIA and shall do so in accordance with the terms set forth below. IHA may modify its compliance program, as it deems appropriate, but at a minimum, IHA shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

II. EFFECTIVE DATE, TERM, AND DEFINITIONS

A. Effective Date. The "Effective Date" of this CIA shall be the signature date of the final signatory to this CIA.

B. Term. The term of this CIA shall be five years from the Effective Date, except that Sections VII and X shall continue for 120 days after OIG's receipt of: (1) IHA's final Annual Report or (2) any additional documentation relating to the final Annual Report requested by OIG, whichever is later. In addition, if OIG issues a Stipulated Penalties Demand Letter pursuant to Section X.C.1 or a Notice of Material Breach and Intent to Exclude pursuant to Section X.E.2 prior to the expiration of the 120 day period, then Section X shall remain in effect until the Stipulated Penalties Review described in Section X.E.2 or the Exclusion Review described in Section X.E.3 is completed, and IHA complies with the decision.

C. Definitions.

1. "Arrangements" means:

a. every arrangement or transaction that involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of

value and is between IHA and (i) any actual or potential source of health care business or referrals of Medicare beneficiaries to IHA or (ii) any actual or potential recipient of health care business or referrals from IHA; and

b. "Source of health care business or referrals" means any individual or entity that refers, recommends, arranges for, orders, leases, or purchases any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program.

c. "Recipient of health care business or referrals" means any individual or entity (a) to whom IHA refers an individual for the furnishing or arranging for the furnishing of any item or service, or (b) from whom IHA purchases, leases or orders or arranges for or recommends the purchasing, leasing, or ordering of any good, facility, item, or service, for which payment may be made in whole or in part by a Federal health care program.

2. "Certifying Covered Persons" means the following: Chief Operating Officer, Senior Vice President-Government Programs, Chief Financial Officer, Vice President - Medicare Programs, and the Director of Risk Adjustment.

3. "Covered Persons" means: (a) all owners who are natural persons, (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading), officers, board members, and employees of IHA who are engaged in, supervise, or oversee personnel who are engaged in IHA's Medicare Advantage business; (b) all contractors who furnish patient care items or services or perform billing, coding, or Risk Adjustment Activities functions on behalf of IHA. Covered Persons do not include active Medicare providers who are contracted with IHA pursuant to 42 C.F.R. sec. 422.200 et seq. to furnish Medicare-covered items and services unless such providers are IHA employees.

4. "Risk Adjustment Activities" means (a) creating, obtaining, reviewing, auditing, developing or maintaining protocols or systems to create, obtain, review, or audit risk adjustment data (as defined at 42 C.F.R. § 422.310); or (b) submitting, developing, or maintaining protocols or systems to submit risk adjustment data or deletes to CMS.

5. "Disclosure Program" means a program that enables individuals to disclose to the Compliance Officer or some other person who is not in the disclosing individual's chain of command any potential violations of criminal, civil, or administrative law related to the Federal health care programs or any issues or questions associated with IHA's policies, conduct, practices, or procedures.

6. "Exclusion Lists" means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available at http://www.oig.hhs.gov) and state Medicaid program exclusion lists that are publicly available.

7. "Ineligible Person" means an individual or entity who: (a) is currently excluded from participation in any Federal health care program or (b) has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a) (mandatory exclusion) but has not yet been excluded from participation in any Federal health care program.

7. "Overpayment" means any funds that IHA receives or retains under any Federal health care program to which IHA, after applicable reconciliation, is not entitled under such Federal health care program.

8. "Reportable Event" means: (a) a substantial Overpayment; (b) a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which criminal penalties or civil monetary penalties under Section 1128A or 1128B of the Social Security Act (the "Act") or exclusion under Section 1128 of the Act may be authorized; (c) the employment of or contracting with a Covered Person who is an Ineligible Person; or (d) the filing of a bankruptcy petition by IHA.

9. "Reporting Period" means each one-year period during the term of this CIA, beginning with the one-year period following the Effective Date.

10. "Training Plan" means a written plan that outlines the steps IHA will take to ensure that Covered Persons receive training on a periodic basis during the term of the CIA regarding IHA's CIA requirements and compliance program and the applicable Federal health care program requirements, including the requirements of 42 U.S.C. § 1320a-7b(b) (the Anti-Kickback Statute) and 42 U.S.C. § 1395nn (the Stark Law).

11. "Transition Plan" means a plan to address whether and how IHA's compliance program will continue to include the compliance program requirements set forth in Section III of the CIA, following the end of the CIA's term.

III. COMPLIANCE PROGRAM REQUIREMENTS

IHA shall establish and maintain a compliance program that includes the following elements:

A. Compliance Officer, Compliance Committee, Board Oversight, and Management Certifications.

1. *Compliance Officer*. Within 90 days after the Effective Date, IHA shall appoint a Compliance Officer who is an employee and a member of senior management of IHA. The Compliance Officer shall report directly to the Chief Executive Officer of IHA and shall not be or be subordinate to the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for IHA. The Compliance Officer shall be authorized to report to the Board of Directors of IHA (Board) regarding compliance matters at any time. The Compliance Officer shall be responsible for, without limitation:

a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements;

b. making at least quarterly reports regarding compliance matters to the Board Committee;

c. monitoring the day-to-day compliance activities engaged in by IHA; and

d. all reporting requirements of this CIA.

The Compliance Officer shall not have any noncompliance job responsibilities that, in OIG's discretion, may interfere or conflict with the Compliance Officer's ability to perform the duties outlined in this CIA.

IHA shall report to OIG, in writing, any changes in the identity, duties, or job responsibilities of the Compliance Officer within five business days after such a change.

2. *Compliance Committee*. Within 90 days after the Effective Date, IHA shall appoint a Compliance Committee that is chaired by the Compliance Officer. The Compliance Committee shall include, at a minimum, the members of senior management necessary to meet the requirements of this CIA. The Compliance Committee shall be responsible for, among other things, reviewing the policies and procedures required by Section III.B below at least annually, reviewing the training required by Section III.C below at least annually, implementation and oversight of the risk assessment and internal review process required by Section III.E below, and the development and implementation of the Transition Plan required by Section III.J below. The Compliance Committee shall meet at least quarterly.

IHA shall report to OIG, in writing, any changes to the membership of the Compliance Committee within 15 business days after such a change.

3. *Board Oversight.* The Board Risk and Compliance Committee ("Board Committee") shall be responsible for the review and oversight of IHA's compliance with Federal health care program requirements and the requirements of this CIA. The Board must include at least one independent (e.g, non-owner, non-employee, and non-executive) member.

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

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

b. submitting to OIG a description of the materials it reviewed and any additional steps taken, such as the engagement of an independent advisor or other third-party resources, in its oversight

of the compliance program and in support of making the resolution below during each Reporting Period; and

c. for each Reporting Period of the CIA, adopting a resolution approved by each member of the Board Committee regarding its review and oversight of IHA's compliance with Federal health care program requirements and the requirements of this CIA.

At minimum, the resolution shall include the following language:

> "The Board Risk and Compliance Committee has made a reasonable inquiry into the operations of IHA'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, IHA has implemented an effective compliance program to meet Federal health care program requirements and the requirements of IHA's Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services."

If the Board Committee is unable to adopt such a resolution, the Board Committee shall provide a written explanation of the reasons why it is unable to adopt the resolution and the steps the Board Committee is taking to implement an effective compliance program at IHA.

IHA shall report to OIG, in writing, any changes in the membership of the Board Committee, within 15 business days after such a change.

4. *Management Certifications.* The Certifying Covered Persons shall monitor compliance within the divisions or departments for which they are responsible and annually certify that the applicable IHA division or department is in compliance with applicable Federal health care program requirements and the requirements of this CIA. For each Reporting Period, each Certifying Covered Person shall certify as follows:

> "I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of division or department], an area under my supervision. My job responsibilities include ensuring [insert name of division or department]'s compliance with all applicable Federal health care program requirements, requirements of the Corporate Integrity Agreement, and IHA's policies and procedures. To the best of my knowledge, the [insert name of division or department] is in compliance with all applicable Federal health care program requirements and the requirements of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States."

If any Certifying Covered Person is unable to provide this certification, the Certifying Covered Person shall provide a written explanation of the reasons why he or she is unable to provide the certification.

Within 90 days after the Effective Date, IHA shall develop and implement a written process for Certifying Covered Persons to follow for the purpose of completing the certification required by this section (e.g., reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc. prior to the Certifying Covered Person making the required certification).

B. Written Standards. Within 90 days after the Effective Date, IHA shall develop and implement written policies and procedures (Policies and Procedures) that address the following: (1) the operation of IHA's compliance program, including the compliance program requirements outlined in this CIA; (2) IHA's compliance with Federal health care program requirements, including but not limited to compliance with the Anti-Kickback Statute, and the regulations and other guidance documents related to this statute; (3) a written review and approval process for Arrangements, the purpose of which is to ensure that all Arrangements do not violate the Anti-Kickback Statute and (4) the identification, quantification, and repayment of Overpayments. IHA shall enforce its Policies and Procedures and make compliance with its Policies and Procedures an element of evaluating the performance of all Covered Persons. The Policies and Procedures shall be made available to all Covered Persons.

The Compliance Committee shall review the Policies and Procedures at least annually and update the Policies and Procedures as necessary. Any new or revised Policies and Procedures shall be made available to all Covered Persons. All Policies and Procedures shall be made available to OIG upon request.

C. Training and Education.

1. *Covered Persons Training.* Within 90 days after the Effective Date, IHA shall develop a Training Plan that includes the following information: (a) training topics: (b) categories of Covered Persons required to attend each training session; (c) length of the training session(s); (d) schedule for training; and (e) format of the training. The Compliance Committee shall review the Training Plan at least annually and update the Training Plan as necessary.

2. *Board Training*. Within 90 days after the Effective Date, members of the Board Committee shall receive training regarding their responsibilities for corporate governance and review and oversight of the compliance program. The training shall address the specific responsibilities of health care board members, including the risks, oversight areas, and approaches to conducting effective oversight of a health care entity and shall include a discussion of the OIG's guidance on board member responsibilities. Each member of the Board Committee also shall receive the training described in Section III.C.1.

New members of the Board Committee shall receive the training described in this Section III.C.2 within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later. The Compliance Committee shall review the Board Committee training at least annually and update the Board Committee training as necessary.

3. *Training Records*. IHA shall make available to OIG, upon request, training materials and records verifying that the training described in Sections III.C.1 and III.C.2 has been provided.

D. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization*. Within 90 days after the Effective Date, IHA shall engage an entity (the "Independent Review Organization" or "IRO") that meets the qualifications and requirements outlined in Appendix A to this CIA, which is incorporated by reference, to perform the reviews described in this Section III.D.

b. *Retention of Records*. The IRO and IHA shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports exchanged between the IRO and IHA related to the reviews described in this Section III.D.

c. *Access to Records and Personnel.* IHA shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.D and that all records furnished to the IRO are accurate and complete.

2. *Record Review.* The IRO shall review medical records from a sample of Medicare Advantage enrollees to determine whether any associated Hierarchical Condition Categories (HCCs) for the members were appropriately reimbursed (Record Review) and shall review IHA's associated controls for such risk adjustment data. IHA shall prepare a Record Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Independence and Objectivity Certification*. The IRO shall include in its report(s) to IHA a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.D and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this CIA. The IRO's certification shall include a summary of all current and prior engagements between IHA and the IRO.

E. Risk Assessment and Internal Review Process. Within 90 days after the Effective Date, IHA shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with IHA's offering of Federal Health Care Program Plans, including but not limited to the risks associated with Risk Adjustment Activities, the submission of Medicare Advantage risk adjustment data and the Anti-Kickback Statute risks associated with Arrangements. The Compliance Committee shall be responsible for implementation and oversight of the risk assessment and internal review process. The risk assessment and internal review process shall be conducted at least annually and shall require IHA to: (1) identify and prioritize risks, (2) develop work plans or audit plans (as appropriate) related to the identified risk areas, (3) implement the work plans and audit plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track

the implementation of the work plans and any corrective action plans and assess the effectiveness of such plans.

F. Disclosure Program. Within 90 days after the Effective Date, IHA shall establish a Disclosure Program. IHA shall appropriately publicize the existence of the Disclosure Program (e.g., via periodic e-mails to employees or by posting the information in prominent common areas). The Disclosure Program shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program shall prohibit retaliation against Covered Persons relating to use of the Disclosure Program and IHA shall not retaliate against Covered Persons for use of the Disclosure Program. The Compliance Officer (or designee) shall conduct a review of each disclosure received through the Disclosure Program, including gathering all relevant information from the disclosing individual, and ensure that appropriate follow-up is conducted.

The Compliance Officer (or designee) shall record all disclosures (whether or not related to a potential violation of criminal, civil, or administrative law related to the Federal health care programs) in a written disclosure log within two business days of receipt of the disclosure. The disclosure log shall include the following information: (1) a summary of each disclosure received (whether anonymous or not), (2) the date the disclosure was received, (3) the individual or department responsible for reviewing the disclosure, (4) the status of the review, (5) any corrective action taken in response to the review, and (6) the date the disclosure was resolved.

G. Ineligible Persons.

1. *Screening Requirements.* IHA shall:

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

c. require all Covered Persons to disclose immediately to the Compliance Officer (or designee) if they become an Ineligible Person.

2. *Removal Requirement*. If IHA has actual notice that a Covered Person has become an Ineligible Person, IHA 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 for in whole or part, directly or indirectly, by any Federal health care program(s) from which the Covered Person has been excluded, at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s). Items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and IHA may be liable for overpayments and/or

criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether IHA meets the requirements of Section III.G.

H. Notification of Government Investigation or Legal Proceeding. IHA shall notify OIG, in writing, of any ongoing investigation or legal proceeding by a governmental entity or its agents involving an allegation that IHA has committed a crime or has engaged in fraudulent activities, within 30 days of IHA receiving notice of such investigation or legal proceeding. This notification shall include a description of the allegation(s), the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Within 30 days after resolution of the matter, IHA shall notify OIG, in writing, of the resolution of the investigation or legal proceeding.

I. Reportable Events. IHA shall notify OIG, in writing, within 30 days after determining that a Reportable Event exists, as follows:

1. *Substantial Overpayment.* The report to OIG shall include:

   a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions, or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;

   b. the Federal health care programs affected by the Reportable Event;

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

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

Within 60 days of identification of the substantial Overpayment, IHA shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations and Centers for Medicare and Medicaid Services (CMS) guidance, and provide OIG with documentation of the repayment.

2. *Probable Violation of Law.* The report to OIG shall include:

   a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;

b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event;

c. the Federal health care programs affected by the Reportable Event;

d. a description of the steps taken by IHA to identify and quantify any Overpayments; and

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

If the Reportable Event involves an Overpayment, within 60 days of identification of the Overpayment, IHA shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations and CMS guidance, and provide OIG with documentation of the repayment.

3. *Ineligible Person.* The report to OIG shall include:

a. the identity of the Ineligible Person and the job duties performed by that individual;

b. the dates of the Ineligible Person's employment or contractual relationship;

c. a description of the Exclusion Lists screening that IHA completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the screening process that led to the hiring or contracting with the Ineligible Person;

d. a description of how the Ineligible Person was identified; and

e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

4. *Bankruptcy.* The report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program requirements implicated.

J. Transition Plan. Prior to the end of the fourth Reporting Period, IHA shall develop a Transition Plan that is reviewed and approved by the Board. The Transition Plan shall be implemented following the end of the CIA's term. A copy of IHA's approved Transition Plan shall be included in IHA's fourth Annual Report.

IV. SUCCESSOR LIABILITY

If, after the Effective Date, IHA proposes to (a) sell any or all of its business, business units, or locations (whether through a sale of assets, sale of stock, or other type of transaction) relating to the furnishing of items or services that may be reimbursed by a Federal health care

program; or (b) purchase or establish a new business, business unit, or location relating to the furnishing of items or services that may be reimbursed by a Federal health care program, the CIA shall be binding on the purchaser of any business, business unit, or location and any new business, business unit, or location (and all Covered Persons at each new business, business unit, or location) shall be subject to the requirements of this CIA, unless otherwise determined and agreed to in writing by OIG. IHA shall notify OIG, in writing, of such sale or purchase within 30 days following the closing of the transaction and shall notify OIG, in writing, within 30 days of establishing such new business, business unit, or location.

If IHA wishes to obtain a determination by OIG that a proposed purchaser or proposed acquisition will not be subject to the CIA requirements, IHA must notify OIG in writing at least 30 days in advance of the proposed sale or purchase. This notification shall include a description of the business, business unit, or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

V. IMPLEMENTATION REPORT AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the Effective Date, IHA shall submit a written report (Implementation Report) to OIG that includes, at a minimum, the following information:

1. the name, business address, business phone number, and position description of the Compliance Officer required by Section III.A.1, and a detailed description of any noncompliance job responsibilities;

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

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

4. the names and positions of the Certifying Covered Persons required by Section III.A.4 and a copy of the written process for Certifying Covered Persons to follow in order to complete the certification required by Section III.A.4;

5. a list of the Policies and Procedures required by Section III.B;

6. the Training Plan required by Section III.C.1 and a description of the Board training required by Section III.C.2 (including a summary of the topics covered, the length of the training, and when the training was provided);

7. 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; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to IHA that includes a summary of all current and prior engagements between IHA and the IRO;

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

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

10. a description of the Ineligible Persons screening and removal process required by Section III.G;

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

12. a list of all of IHA's subsidiaries that hold coordinated care plan (CCP) contracts, their locations, and the states in which plans are offered; and a list of all other IHA locations (including mailing addresses), the corresponding name under which each location is doing business, and the location's contract number or, if applicable, Medicare and state Medicaid program provider number and/or supplier number(s); and

13. a certification by the Compliance Officer and Chief Executive Officer that:

a. to the best of his or her knowledge, except as otherwise described in the report, IHA has implemented and is in compliance with all of the requirements of this CIA;

b. 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

c. he or she understands that the certification is being provided to and relied upon by the United States.

B. Annual Reports. IHA shall submit to OIG a written report (Annual Report) for each of the five Reporting Periods that includes, at a minimum, the following information:

1. any change in the identity, position description, or noncompliance job responsibilities of the Compliance Officer; a current list of the Compliance Committee members, a current list of the Board members who are responsible for satisfying the Board compliance requirements, and a current list of the Certifying Covered Persons, along with the identification of any changes made during the Reporting Period to the Compliance Committee, Board, or Certifying Covered Persons;

2. the dates of each meeting of the Compliance Committee (copies of the meeting minutes shall be made available to OIG upon request);

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

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

5. a description of any changes to the written process for Certifying Covered Persons to follow in order to complete the certification required by Section III.A.4;

6. the certifications of Certifying Covered Persons required by Section III.A.4;

7. a list of any new or revised Policies and Procedures required by Section III.B. developed during the Reporting Period;

8. a description of any changes to the Training Plan required by Section III.C, and a summary of all training furnished to Covered Persons and Board members during the Reporting Period;

9. a complete copy of all reports prepared pursuant to Section III.D and IHA's response to the reports, along with corrective action plan(s) related to any issues raised by the report, and documentation of IHA's refund of the Estimated Overpayment (as defined in Appendix B to this CIA);

10. a certification from the IRO regarding its professional independence and objectivity with respect to IHA, including a summary of all current and prior engagements between IHA and the IRO;

11. a description of any changes to the risk assessment and internal review process required by Section III.E, including the reason(s) for such changes;

12. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) risk areas identified, (b) work plans and internal audit plans developed, (c) internal audits performed, (d) corrective action plans developed in response to internal audits, and (e) steps taken to track the implementation of the work plans and corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;

13. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs, including at least the following information: (a) a description of the disclosure, (b) the date the disclosure was received, (c) the resolution of the disclosure, and (d) the date the disclosure was resolved. The complete disclosure log shall be made available to OIG upon request;

14. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G, including the reason(s) for such changes;

15. a summary of any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H that includes a description of the allegation(s), the

identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

16. a summary of all Reportable Events required to have been reported pursuant to Section III.I during the Reporting Period;

17. (in the fourth Annual Report), a copy of the Transition Plan required by Section III.J;

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

19. a description of all changes to the most recently provided list of IHA's locations (including addresses) as required by Section V.A.12;

20. a description of any changes to IHA's corporate structure, including any parent and sister companies, subsidiaries, and their respective lines of business; and

21. a certification by the Compliance Officer and Chief Executive Officer that:

a. to the best of his or her knowledge, except as otherwise described in the report, IHA has implemented and is in compliance with all of the requirements of this CIA;

b. 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

c. he or she understands that the certification is being provided to and relied upon by the United States.

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. Designation of Information. IHA 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. IHA 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

All notifications and reports required under this CIA shall be submitted using the following contact information:

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
Email Address: officeofcounsel@oig.hhs.gov

IHA:

Nicole Britton
511 Farber Lakes Drive
Buffalo, NY
Telephone: 716-635-4874
Email Address: Nicole.britton@independenthealth.com

Unless otherwise requested by OIG, all notifications and reports required by this CIA shall be submitted electronically. OIG shall notify IHA in writing of any changes to the OIG contact information listed above. IHA shall notify OIG in writing within two business days of any changes to the IHA contact information listed above.

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 conduct interviews, examine and/or request copies of or copy IHA's books, records, and other documents and supporting materials, and conduct on-site reviews of any of IHA's locations, for the purpose of evaluating: (a) IHA's compliance with the requirements of this CIA and (b) IHA's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by IHA to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. For purposes of this provision, OIG or its duly authorized representative(s) may interview any of IHA's owners who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading), employees, contractors, and Board members 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. IHA shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon

OIG's request. IHA's owners who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading), employees, contractors, and Board members may elect to be interviewed with or without a representative of IHA present.

VIII. DOCUMENT AND RECORD RETENTION

IHA 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 IHA prior to any release by OIG of information submitted by IHA pursuant to this CIA and identified upon submission by IHA as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, IHA shall have the rights set forth at 45 C.F.R. § 5.42(a).

X. BREACH AND DEFAULT PROVISIONS

A. Stipulated Penalties. OIG may assess:

1. A Stipulated Penalty of up to $2,500 for each day IHA fails to comply with Section III.A;

2. A Stipulated Penalty of up to $2,500 for each day IHA fails to comply with Section III.B;

3. A Stipulated Penalty of up to $2,500 for each day IHA fails to comply with Section III.C;

4. A Stipulated Penalty of up to $2,500 for each day IHA fails to comply with Section III.D;

5. A Stipulated Penalty of up to $2,500 for each day IHA fails to comply with Section III.E;

6. A Stipulated Penalty of up to $2,500 for each day IHA fails to comply with Section III.F;

7. A Stipulated Penalty of up to $2,500 for each day IHA fails to comply with Section III.G;

8. A Stipulated Penalty of up to $2,500 for each day IHA fails to comply with Section III.H;

9. A Stipulated Penalty of up to $2,500 for each day IHA fails to comply with Section III.I;

10. A Stipulated Penalty of up to $2,500 for each day IHA fails to comply with Section III.J;

11. A Stipulated Penalty of up to $2,500 for each day IHA fails to comply with Section IV;

12. A Stipulated Penalty of up to $2,500 for each day IHA fails to comply with Section V;

13. A Stipulated Penalty of up to $2,500 for each day IHA fails to comply with Section VII;

14. A Stipulated Penalty of up to $2,500 for each day IHA fails to comply with Section VIII; or

15. A Stipulated Penalty of up to $50,000 for each false certification or false statement made to OIG by or on behalf of IHA under this CIA.

B. Timely Written Requests for Extensions. IHA 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. 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 IHA fails to meet the revised deadline set by OIG. 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 IHA 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*. If OIG determines that a basis for Stipulated Penalties under Section X.A exists, OIG shall notify IHA of: (a) IHA's failure to comply and (b) OIG's demand for payment of Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 15 business days after the date of the Demand Letter, IHA shall either: (a) 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.

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.

D. Exclusion for Material Breach.

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

a. failure to comply with any of the requirements of this CIA for which OIG has previously issued a demand for Stipulated Penalties under Section X.C, unless such Stipulated Penalty was overturned by an ALJ on appeal pursuant to the procedures described in Section X.E below;

b. failure to comply with Section III.A.1;

c. failure to comply with Section III.D;

d. failure to comply with Section III.I;

e. failure to comply with Section V;

f. failure to respond to a Demand Letter in accordance with Section X.C;

g. a false statement or false certification made to OIG by or on behalf of IHA under this CIA;

h. failure to pay Stipulated Penalties within 20 days after an ALJ issues a decision ordering IHA to pay the Stipulated Penalties or within 20 days after the HHS Departmental Appeals Board (DAB) issues a decision upholding the determination of OIG; or

i. failure to come into compliance with a requirement of this CIA for which OIG has demanded Stipulated Penalties, pursuant to the deadlines listed in Section X.E.2.

2. *Notice of Material Breach and Intent to Exclude*. The parties agree that a material breach of this CIA by IHA constitutes an independent basis for IHA's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than five years for each material breach. Upon a preliminary determination by OIG that IHA has materially breached this CIA, OIG shall notify IHA of: (a) IHA's material breach and (b) OIG's intent to exclude IHA. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Response to Notice*. IHA shall have 30 days from the date of the Notice of Material Breach and Intent to Exclude to submit any information and documentation for OIG to consider before it makes a final determination regarding exclusion.

4. *Exclusion Letter*. If OIG determines that exclusion is warranted, OIG shall notify IHA in writing of its determination to exclude IHA. (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 the Exclusion Letter. The effect of the exclusion shall be that no Federal health care program payment may be made for any items or services furnished, ordered, or prescribed by IHA, including administrative and management services, except as stated in regulations found at 42 C.F.R. §1001.1901(c). The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, IHA 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 issuing a Demand Letter or Exclusion Letter to IHA, and as an agreed-upon remedy for the resolution of disputes arising under this CIA, IHA 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. 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 DAB, in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21, but only to the extent this CIA does not provide otherwise. Notwithstanding the language in 42 C.F.R. § 1005: (a) the request for a hearing involving Stipulated Penalties shall be made within 15 business days after the date of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after the date of the Exclusion Letter and (b) no discovery shall be available to the parties. The procedures relating to the filing of a request for a hearing can be found at https://www.hhs.gov/about/agencies/dab/different-appeals-at-dab/appeals-to-alj/procedures/index.html.

2. *Stipulated Penalties Review*. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether IHA was in full and timely compliance with the requirements of this CIA for which OIG demands payment and (b) the period of noncompliance. IHA shall have the burden of proving its full and timely compliance. If the ALJ upholds the OIG's determination that IHA has breached this CIA and orders IHA to pay Stipulated Penalties, IHA must (a) come into compliance with the requirement(s) that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 20 days after the ALJ issues a decision, unless IHA properly and timely requests review of the ALJ decision by the DAB. If the ALJ decision is properly and timely appealed to the DAB and the DAB upholds the determination of OIG, IHA must (a) come into compliance with the requirement(s) that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 20 days after the DAB issues its decision.

3. *Exclusion Review*. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be whether IHA was in material breach of this CIA. If the ALJ sustains the OIG's determination of material breach, the exclusion shall take effect 20 days after the ALJ issues the decision. 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. IHA 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 IHA, IHA 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. 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 and IHA agrees not to seek additional review of the DAB's decision (or the ALJ's decision if not appealed) in any judicial forum.

XI. EFFECTIVE AND BINDING AGREEMENT

IHA and OIG agree as follows:

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

B. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) IHA's responsibility to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program requirements.

C. The undersigned IHA signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacities and that they are authorized to execute this CIA.

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

ON BEHALF OF IHA

/Michael W. Cropp, MD/ December 13, 2024
MICHAEL W. CROPP, M.D., M.B.A. DATE
Chief Executive Officer
Independent Health

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

/Susan Gillin/ 12/13/24
SUSAN E. GILLIN DATE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

/Sarah Kessler/ 12/13/24
SARAH KESSLER DATE
Senior Counsel
Office of Counsel to the Inspector General
U.S. Department of Health and Human Services

/Geeta Taylor/ 12/13/24
GEETA TAYLOR DATE
Senior Counsel
Office of Counsel to the Inspector General
U.S. Department of Health and Human Services

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. IHA 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 E. Within 30 days after OIG receives the information identified in Section V.A.7 of the CIA or any additional information submitted by IHA in response to a request by OIG, whichever is later, OIG will notify IHA if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, IHA may continue to engage the IRO.

2. If IHA engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, IHA shall submit the information identified in Section V.A.7 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 IHA at the request of OIG, whichever is later, OIG will notify IHA if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, IHA may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Records Review who have expertise in the Federal health care program requirements applicable to the records and data being reviewed;

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

3. assign individuals to conduct the coding review portions of the Record Review who are certified coders and who are experienced in risk adjustment data validation, and the review of a variety of medical record layouts, electronic medical record entries, and handwritten medical record documentation; 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 Records Review in accordance with the specific requirements of the CIA;

2. follow all applicable Federal health care program rules and reimbursement guidelines in making assessments in the Records Review;

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

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. IHA Responsibilities

IHA shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in III.D of this CIA and that all records furnished to the IRO are accurate and complete.

E. IRO Independence and Objectivity

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

F. IRO Removal/Termination

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

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

APPENDIX B

RECORD REVIEW

A. Record Review. The IRO shall perform the Record Review for each of the five Reporting Periods. The Record Review shall be conducted on one IHA Medicare Advantage coordinated care plan (CCP) contract, excluding specialized MA plans for special needs, for each Reporting Period. The CCP contract selected for review shall be referred to as the "Subject Plan." The IRO shall perform all parts of the Record Review.

1. *Definitions*.

   a. "CMS's Criteria for Risk Adjustment Eligible Diagnoses" means CMS's requirements for diagnoses submissions including, but not limited to, Part 422 of Title 42 and Chapter 7 of CMS's Medicare Managed Care Manual.

   b. "Data Submission Period" means the year for which MA organizations may submit diagnoses for CMS to use to calculate an enrollee's risk score for the subsequent Payment Year.

   c. "Mapped Diagnoses" means diagnosis data submitted by Subject Plans for risk adjustment when such diagnosis map to Hierarchical Condition Categories (HCCs) that affected CMS's payment for the Risk Adjustment Members for the Payment Year.

   d. "Mapped Diagnoses Resulting From Chart Reviews" means Mapped Diagnoses that resulted from a retrospective review of enrollees' medical record documentation to identify risk adjusting diagnoses that (1) providers did not originally submit to the Medicare Advantage Organization ("MAO") or (2) providers submitted to the MAO in error.

   e. "Mapped Diagnoses Resulting From an hHRA" means Mapped Diagnoses that resulted from a home-based Health Risk Assessment (hHRA).

   f. "Payment Year" means the calendar year following a particular Data Submission Period; final reconciliation for a Payment Year typically occurs in July of the year following the Payment Year. The first Payment Year under the CIA will correlate with the 2022 Data Submission Period.

   g. "Population" means all Risk Adjustment Members for a particular Payment Year.

   h. "Population Subset" means all Risk Adjustment Members for a particular Payment Year that are within a subset of the total Population as determined below. In OIG's discretion, OIG will select a Population Subset (e.g., Risk Adjustment Members who had an hHRA during the Data Submission Period or Risk Adjustment Members Subject to a Chart

Review) for the Record Review and shall notify IHA and the IRO of its selection of the Population Subset at least 90 days prior to the end of the Reporting Period. IHA, or its IRO on behalf of IHA, may submit proposals identifying suggestions for the Population Subset to be reviewed at least 120 days prior to the end of the Reporting Period. In connection with creating the Population Subset, OIG will review proposals submitted by IHA or its IRO, and may consider information furnished to OIG regarding the results of IHA's internal risk assessment and internal auditing, or other information obtained by OIG. The determination of what manner to create the Population Subset shall be made at the sole discretion of OIG.

In the first and third Reporting Periods, the Population Subset shall be Risk Adjustment Members Subject to a Chart Review.

i. "Overpayment" means the amount of money IHA has received in excess of the amount due and payable under Medicare program requirements, as determined by the IRO in connection with the Record Review performed under this Appendix.

j. "Record Review Sample" means the random sample of 100 Risk Adjustment Members from the Population Subset from the Subject Plan.

k. "Risk Adjustment Data" means data described in 42 C.F.R. 310.

l. "Risk Adjustment Member" means a Medicare Advantage (MA) enrollee who (1) was continuously enrolled in a Subject Plan from January of the Data Submission Period through January of the Payment Year; (2) had at least one Mapped Diagnosis; (3) had non-End Stage Renal Disease status from January of the Data Submission Period through January of the Payment Year; (4) had non-hospice status from January of the Data Submission Period through January of the Payment Year; and (5) was enrolled in Medicare Part B coverage during the full Data Submission Period.

m. "Risk Adjustment Member Subject to a Chart Review" means a Risk Adjustment Member whose medical record documentation was subjected to a retrospective review to identify one or more Mapped Diagnoses that (1) providers did not originally submit to IHA or (2) providers submitted to IHA in error.

n. "Error Rate" means the percentage of net Overpayments identified in the Record Review. The net Overpayment shall be calculated by subtracting all underpayments identified in the Record Review Sample from all Overpayments identified in the Record Review Sample. The Error Rate is calculated by dividing the net Overpayment amount for the sampled Risk

Adjustment Members in the Record Review Sample by the amount CMS paid for such Risk Adjustment Members.

2. *Selection of Subject Plan*. At least 180 days before the end of the Reporting Period, IHA shall provide OIG with a list of its CCP contracts for the prior Payment Year. For each CCP contract, the list shall identify for the Payment Year: (1) the number of enrollees with at least one HCC; (2) the average risk score for all of the enrollees; (3) the adjusted medical loss ratio; (4) the average star rating; and (5) the total payment received from CMS. At least 150 days prior to the end of each Reporting Period, OIG shall select the Subject Plan and provide the name and address of the Subject Plan to the IRO.

3. *Record Review.* The IRO shall select the "Record Review Sample." For each sampled Risk Adjustment Member, IHA will provide the medical records that it believes supports the diagnoses that map to the HCCs for these individuals. The IRO shall review these medical records to determine whether CMS paid appropriately for HCCs of Risk Adjustment Members in the Record Review Sample. The IRO shall also review the controls that IHA has in place to ensure that HCCs for the Population Subset result from Risk Adjustment Data that is accurate and otherwise complies with CMS's Criteria for Risk Adjustment Eligible Diagnoses.

4. *Other Requirements.*

a. Supplemental Materials. The IRO shall request all medical record documentation required for its review of the diagnosis data in the Record Review Sample and IHA shall furnish such documentation to the IRO prior to the IRO initiating its review of the Record Review Sample. If the IRO accepts any supplemental documentation from IHA after the IRO has completed its initial review of the Record Review Sample (Supplemental Materials), the IRO shall include the following in the Record Review Report: (i) a description of the Supplemental Materials, (ii) the date the Supplemental Materials were accepted, and (iii) the IRO's reason(s) for accepting the Supplemental Materials.

b. HCCs without Supporting Documentation. Any HCCs for which IHA cannot produce medical record documentation that meets CMS's Criteria for Risk Adjustment Eligible Diagnoses shall be considered an error and the total payment received by IHA for that HCC shall be deemed an Overpayment. Replacement sampling for Risk Adjustment Members for whom IHA could not produce medical record documentation that meets CMS's Criteria for Risk Adjustment Eligible Diagnoses is not permitted.

c. Use of First Sample Drawn. The first set of Risk Adjustment Members selected for the Record Review Sample shall be used for that Record Review Sample (i.e., it is not permissible to generate more than one list of random samples and then select one for use).

5. *Repayment of Estimated Overpayment.* The findings of each Record Review Sample shall be used by the IRO to estimate the actual Overpayment in the Population Subset for that Record Review Sample (Estimated Overpayment) for the Subject Plan. Within 60 days of receipt of the Record Review Report, IHA shall take appropriate corrective or remedial action, including reporting and/or returning of overpayments in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and 42 C.F.R. § 422.326 (and any applicable CMS guidance). Documentation of IHA's refund or reporting of the Estimated Overpayment to CMS shall be submitted to OIG with IHA's Annual Report. OIG, in its sole discretion, may refer the findings of any Record Review Sample to CMS for appropriate follow up.

B. Record Review Report. The IRO shall prepare a Record Review Report for each Record Review that includes the following information:

1. *Record Review Methodology.*

   a. Record Review Objective. A statement of the objective intended to be achieved by the Record Review.

   b. Record Review Population. A description of the Population Subset subject to the Record Review.

   c. Source of Data. A description of (1) the process used to identify Risk Adjusted Members in the Population Subset and (2) the specific documentation and other information sources relied on by the IRO when performing the Record Review. Examples of sources include medical records, CMS guidance and program memoranda, Medicare administrative contractor manual or bulletins (including issue and date), other policies, regulations, or directives.

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

   e. Supplemental Materials. The information regarding any Supplemental Materials required by A.4.a., above.

2. *Statistical Sampling Documentation.*

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

   b. A description or identification of the statistical sampling software package used by the IRO.

3. *Record Review Findings.*

   a. Narrative Results.

i. A description of IHA's risk adjustment data collection and submission system(s), including the identification, by position description, of the personnel involved in the system.

ii. A description of controls that IHA has in place to ensure that all Risk Adjustment Data for Risk Adjustment Members comply with CMS's Criteria for Risk Adjustment Eligible Diagnoses.

iii. A narrative explanation of the results of the IRO's review of the Record Review Sample, including an explanation of all errors identified by the IRO. For each HCC found to be not supported, the IRO should indicate the following: "The IRO did not find support in any of the medical records that IHA provided that mapped to any of the diagnosis codes included in HCC [#]."

b. Quantitative Results.

i. A spreadsheet of the Record Review results that includes the following information for each sampled Risk Adjustment Member:

1. beneficiary health insurance claim number or Medicare Beneficiary Identifier (MBI);
2. Number of HCCs reviewed;
3. Number of HCCs that the IRO found as supported by Mapped Diagnoses;
4. Number of HCCs that the IRO found to be unsupported by Mapped Diagnoses;
5. Total dollar amount that CMS paid IHA;
6. Total dollar amount that CMS should have paid IHA; and
7. Total Overpayment (or underpayment)

For items 2 – 7, the IRO should calculate the totals for all of the sampled Risk Adjustment Members

ii. Based on the spreadsheet described in b.i above, the report also should include the following information:

1. Total number and percentage of instances in which the IRO determined that an HCC was not supported by Mapped Diagnoses.

2. Total dollar amount that CMS should have paid for Risk Adjustment Members in the Record Review Sample.

3. Error Rate for the Record Review Sample.

iii. An estimate of the total overpayments that CMS made to IHA for the Population Subset. This estimation should include the point estimate and the lower and upper limits of a two-sided 90% confidence interval.

iv. An additional spreadsheet of the Record Review results that includes the following information for each Risk Adjustment Member:

1. beneficiary health insurance claim number or Medicare Beneficiary Identifier (MBI);
2. each HCC;
3. Mapped Diagnoses for each HCC;
4. Whether the HCC was supported by Mapped Diagnoses;
5. Whether the HCC was supported only by Mapped Diagnoses Resulting From Chart Reviews; and
6. Whether the HCC was supported only by Mapped Diagnoses resulting from an hHRA

c. Recommendations. The Record Review Report shall include any recommendations for improvements to IHA's controls for ensuring that (i) all Mapped Diagnoses Resulting From Chart Reviews comply with CMS's Criteria for Risk Adjustment Eligible Diagnoses, as applicable; (ii) any Mapped Diagnoses Resulting from hHRAs comply with CMS's Criteria for Risk Adjustment Eligible Diagnoses as applicable; (iii) all Mapped Diagnoses otherwise comply with CMS's Criteria for Risk Adjustment Eligible Diagnoses; and (iv) Risk Adjustment Data are accurate, complete and truthful based on the findings of the Record Review.

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