

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
FREEDOM HEALTH INC. AND OPTIMUM HEALTHCARE, INC.**

I. PREAMBLE

Freedom Health, Inc. and Optimum Healthcare, Inc. (collectively or individually, “Freedom”) hereby enter into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, Freedom is entering into a Settlement Agreement with the United States.

Freedom represents that, prior to the execution of this CIA, Freedom established a Compliance Program that includes, among other things, a Compliance Officer, Compliance Committee, written standards of conduct, compliance education and training, a mechanism for individuals to report incidents of non-compliance, screening programs for ineligible persons, and removal requirements for ineligible persons.

II. TERM AND SCOPE OF THE CIA

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

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

C. For purposes of this CIA, the term “Covered Persons” means: (1) all owners who are natural persons and have an ownership interest of 5% or more, officers directors, and employees of Freedom; and (2) all contractors, subcontractors, agents, and

other persons who furnish patient care items or services or who perform billing, coding, or risk-adjustment data functions on behalf of Freedom. Covered Persons do not include active Medicare providers who are not employees of Freedom or Global TPA, LLC.

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Officer and Committee, Board of Directors, and Management Compliance Obligations

1. *Compliance Officer.* Within 90 days after the Effective Date, Freedom shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be an employee and a member of senior management of Freedom, shall report directly to the Chief Executive Officer of Freedom, 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 Freedom. The Compliance Officer shall be responsible for, without limitation:

- a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements;
- b. making periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Freedom and shall be authorized to report on such matters to the Board of Directors at any time. Written documentation of the Compliance Officer's reports to the Board of Directors shall be made available to OIG upon request; and
- c. monitoring the day-to-day compliance activities engaged in by Freedom as well as 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.

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

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

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

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

- a. meeting at least quarterly to review and oversee Freedom'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 documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period; and

- c. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board summarizing its review and oversight of Freedom's compliance with Federal health care program requirements and the obligations of this CIA.
- d. for each Reporting Period of the CIA, the Board shall retain an individual or entity with expertise in compliance with Federal health care program requirements (Compliance Expert) to perform a review of the effectiveness of Freedom's Compliance Program (Compliance Program Review). The Compliance Expert shall create a work plan for the Compliance Program Review and prepare a written report about the Compliance Program Review. The written report (Compliance Program Review Report) shall include a description of the Compliance Program Review and any recommendations with respect to Freedom's compliance program. The Board shall review the Compliance Program Review Report as part of its review and oversight of Freedom's compliance program. A copy of the Compliance Program Review report shall be provided to OIG in each Annual Report submitted by Freedom. In addition, copies of any materials provided to the Board by the Compliance Expert, along with minutes of any meetings between the Compliance Expert and the Board, shall be made available to OIG upon request.

At minimum, the resolution shall include the following language:

“The Board of Directors has made a reasonable inquiry into the operations of Freedom'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, Freedom 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 Freedom.

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

4. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Freedom employees (Certifying Employees) are expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Freedom department is in compliance with applicable Federal health care program requirements and the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Chief Executive Officer, Chief Financial Officer, Vice President of Claims, Vice President of Enrollment, Compliance Officer, Vice President of Medicare Revenue Management, Vice President of Network Operations and Business Development, Senior Vice President of Operations, Vice President of Sales, and Chief Medical Officer. For each Reporting Period, each Certifying Employee shall sign a certification that states:

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

If any Certifying Employee is unable to provide such a certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above.

Within 120 days after the Effective Date, Freedom shall develop and implement a written process for Certifying Employees 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 Employee making the required certification).

B. Written Standards

Within 120 days after the Effective Date, Freedom shall develop and implement written policies and procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA and Freedom's compliance with Federal health care program requirements (Policies and Procedures). Throughout the term of this CIA, Freedom shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all employees. The Policies and Procedures shall be made available to all Covered Persons.

At least annually (and more frequently, if appropriate), Freedom shall assess and update, as necessary, the Policies and Procedures. 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. *Training Plan.* Within 120 days after the Effective Date, Freedom shall develop a written plan (Training Plan) that outlines the steps Freedom will take to ensure that: (a) all Covered Persons receive at least annual training regarding Freedom's CIA requirements and Compliance Program and Federal health care program requirements including the requirements of the Anti-Kickback Statute and the Stark Law.

The Training Plan shall include information regarding the following: training topics, categories of Covered Persons required to attend each training session, length of the training session(s), schedule for training, and format of the training. Freedom shall furnish training to its Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Board Member Training.* Within 120 days after the Effective Date, each member of the Board of Directors shall receive at least two hours of training. This training shall address the corporate governance responsibilities of board members, and the responsibilities of board members with respect to review and oversight of the Compliance Program. Specifically, the training shall address the unique responsibilities of health care Board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the Board and should include a discussion of the OIG's guidance on Board member responsibilities.

New members of the Board of Directors shall receive the Board Member Training described above within 30 days after becoming a member or within 120 days after the Effective Date, whichever is later.

3. *Training Records.* Freedom shall make available to OIG, upon request, training materials and records verifying that Covered Persons and Board members have timely received the training required under this section.

D. Review Procedures

1. *General Description*

- a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, Freedom 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 Freedom shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Freedom) related to the reviews.

2. *Conditional Provider and Facility Network Review.* In the event that Freedom, during the term of this CIA, expands its service area under an existing Medicare Advantage contract or enters into a new Medicare Advantage contract with CMS, the IRO shall confirm the accuracy of the data submitted to CMS and shall prepare a Network Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Risk Adjustment Review.* The IRO shall conduct a Risk Adjustment Review and shall prepare a Risk Adjustment Review Report, as outlined in Appendix C to this CIA, which is incorporated by reference. The Risk Adjustment Review shall consist of a review of Freedom’s RAPS filtering logic and a chart review of a random sample of 100 risk adjusted members.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Freedom 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 Freedom and the IRO.

E. Risk Assessment and Internal Review Process

Within 120 days after the Effective Date, Freedom shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with Freedom's participation in the Federal health care programs, including, but not limited to, the risks associated with the development and maintenance of adequate provider networks and the submission of accurate risk adjustment and encounter data under the Part C program. The risk assessment and internal review process shall require compliance, legal, and department leaders, at least annually, to: (1) identify and prioritize risks, (2) develop internal audit work plans related to the identified risk areas, (3) implement the internal audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. Freedom shall maintain the risk assessment and internal review process for the term of the CIA.

F. Disclosure Program

Within 120 days after the Effective Date, Freedom 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 Freedom'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. Freedom 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. The Disclosure Program also shall include a requirement that all of Freedom's Covered Persons shall be expected to report suspected violations of any Federal health care program requirements to the Compliance

Officer or other appropriate individual designated by Freedom. 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, Freedom shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log and shall record each disclosure in the disclosure log within two business days of receipt of the disclosure. The disclosure log shall include a summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews.

G. Ineligible Persons

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

- a. an “Ineligible Person” shall include an individual or entity who:
 - i. is currently excluded from participation in any Federal health care program; 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.
- b. “Exclusion List” means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at <http://www.oig.hhs.gov>).

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

- a. Freedom shall screen all prospective Covered Persons against the Exclusion List 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. Freedom shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on a monthly basis thereafter.
- c. Freedom shall implement a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

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

3. *Removal Requirement.* If Freedom has actual notice that a Covered Person has become an Ineligible Person, Freedom shall remove such Covered Person from responsibility for, or involvement with, Freedom's business operations related to the Federal health care program(s) from which such Covered Person has been excluded 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 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).

4. *Pending Charges and Proposed Exclusions.* If Freedom 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, Freedom 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 or the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceeding

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

I. Overpayments

1. *Definition of Overpayment.* For purposes of this CIA, an “Overpayment” shall mean the amount of money Freedom receives or retains under any Federal health care program to which Freedom, after applicable reconciliation, is not entitled under such Federal health care program.

2. *Overpayment Policies and Procedures.* Within 120 days after the Effective Date, Freedom shall develop and implement written policies and procedures regarding the identification, quantification, and notifications and/or repayments to CMS of Overpayments received from any Federal health care program.

J. Reportable Events

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

- a. a substantial Overpayment;
- b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or
- d. the filing of a bankruptcy petition by Freedom.

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

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

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

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of 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, if any;
- c. the Federal health care programs affected by the Reportable Event;
- d. a description of the steps taken by Freedom to identify and quantify any Overpayments; and
- e. a description of Freedom's actions taken to correct the Reportable Event and prevent it from recurring.

If the Reportable Event involves an Overpayment, Freedom shall report and/or repay the Overpayment, 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) and provide OIG with a copy of the notification and repayment to CMS and any related information about reporting and/or repayment.

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

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

- b. the dates of the Ineligible Person's employment or contractual relationship;
- c. a description of the Exclusion List screening that Freedom 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.

5. *Reportable Events under Section III.J.1.d.* For Reportable Events under Section III.J.1.d, the report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program requirements implicated.

IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, Freedom 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 applicable requirements of this CIA, unless otherwise determined and agreed to in writing by OIG.

If, in advance of a proposed sale or a proposed purchase, Freedom wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the CIA, Freedom must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. 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 AND ANNUAL REPORTS

A. Implementation Report

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

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A;
3. the names of the Board members who are responsible for satisfying the Board of Directors compliance obligations described in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.4 and a copy of Freedom's written process for Certifying Employees to follow for the purpose of completing the certification;
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 of Directors training required by Section III.C.2 (including a summary of the topics covered, the length of the training, and when the training was provided);
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 Freedom;
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 copy of Freedom's policies and procedures regarding the identification, quantification and repayment of Overpayments required by Section III.I;

12. a list of all of Freedom's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, and the location's Medicare and state Medicaid program provider number and/or supplier number(s);

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

14. the certifications required by Section V.C.

B. Annual Reports

Freedom shall submit to OIG a report on its compliance with the CIA requirements for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum, the following information:

1. any change in the identity, position description, or other 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 of Directors compliance obligations, and a current list of the Certifying Employees, along with the identification of any changes made during the Reporting Period to the Compliance Committee, Board of Directors, and Certifying Employees;

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

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

4. a list of any new or revised Policies and Procedures developed during the Reporting Period;

5. a description of any changes to Freedom's Training Plan developed pursuant to Section III.C, and a summary of any Board of Directors training provided during the Reporting Period;

6. a complete copy of all reports prepared pursuant to Section III.D and Freedom's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;

7. a certification from the IRO(s), retained pursuant to Section III.D, regarding its professional independence and objectivity with respect to Freedom;

8. a description of any changes to the risk assessment and internal review process required by Section III.E, including the reasons for such changes;

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

10. 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 description of the disclosure, the date the disclosure was received, the resolution of the disclosure, and the date the disclosure was resolved (if applicable). The complete disclosure log shall be made available to OIG upon request;

11. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G, including the reasons for such changes;

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

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

14. a summary of Reportable Events (as defined in Section III.J) identified during the Reporting Period;

15. 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 Freedom's response/corrective action plan (including information regarding any Federal health care program refunds) relating to the audit findings;

16. a description of all changes to the most recently provided list of Freedom's locations as required by Section V.A.12; and

17. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 90 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report

C. Certifications

1. *Certifying Employees.* In each Annual Report, Freedom shall include the certifications of Certifying Employees required by Section III.A.4;

2. *Compliance Officer and Chief Executive Officer.* The Implementation Report and each Annual Report shall include a certification by the Compliance Officer and Chief Executive Officer that:

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

3. *Chief Financial Officer.* The first Annual Report shall include a certification by the Chief Financial Officer that, to the best of his or her knowledge, Freedom 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

Freedom 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. Freedom 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

Freedom:

Pawan V. Shah
Compliance Officer
Freedom Health, Inc. and Optimum Healthcare, Inc.
5600 Mariner St., Ste 101
Tampa FL 33609
pvshah@freedomh.com
Telephone: 813.506.6107
Facsimile: 813.506.6179

Unless otherwise specified, all notifications and reports required by this CIA shall be made by electronic mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. Upon request by OIG, Freedom may be required to provide OIG with an electronic copy of each notification or report required by this CIA 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 conduct interviews, examine and/or request copies of or copy Freedom's books, records, and other documents and supporting materials, and conduct on-site reviews of any of Freedom's locations, for the purpose of verifying and evaluating: (a) Freedom's compliance with the terms of this CIA and (b) Freedom's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Freedom to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Freedom's owners, employees, contractors, and directors 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. Freedom shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Freedom's owners, employees, contractors, and directors may elect to be interviewed with or without a representative of Freedom present.

VIII. DOCUMENT AND RECORD RETENTION

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

X. BREACH AND DEFAULT PROVISIONS

Freedom 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, Freedom 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 Freedom fails to establish, implement or comply with any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. the Board of Directors compliance obligations and the engagement of a Compliance Expert, the performance of a Compliance Program Review and the preparation of a Compliance Program Review Report, as required by Section III.A.3.;
- d. the management certification obligations;
- e. written Policies and Procedures;
- f. training and education of Covered Persons and Board Members;
- g. a risk assessment and internal review process;
- h. a Disclosure Program;
- i. Ineligible Persons screening and removal requirements;
- j. notification of Government investigations or legal proceedings;

- k. policies and procedures regarding the repayment of Overpayments; and
- l. reporting of Reportable Events.

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

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Freedom fails to submit a complete Implementation Report, Annual Report or any certification 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 Freedom fails to submit any Network Review Report or Risk Adjustment Data Review Report in accordance with the requirements of Section III.D, Appendix B and Appendix C or fails to report and/or repay any Overpayment identified by the IRO, as required by Appendix B or Appendix C.

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

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

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

C. Payment of Stipulated Penalties

1. *Demand Letter.* Upon a finding that Freedom 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 Freedom of: (a) Freedom'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, Freedom 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 Freedom elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Freedom 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 Freedom 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. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- b. a failure by Freedom to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.J;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to engage and use an IRO in accordance with Section III.D, Appendix A, Appendix B, or Appendix C.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Freedom constitutes an independent basis for Freedom's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that Freedom has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Freedom of: (a) Freedom'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.* Freedom shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate that:

- a. the alleged material breach has been cured; or
- b. the alleged material breach cannot be cured within the 30 day period, but that: (i) Freedom has begun to take action to cure the material breach; (ii) Freedom is pursuing such action with

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

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, Freedom fails to satisfy the requirements of Section X.D.3, OIG may exclude Freedom from participation in the Federal health care programs. OIG shall notify Freedom in writing of its determination to exclude Freedom. (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 Freedom’s receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Freedom 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 Freedom 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, Freedom shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG’s determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter. The procedures relating to the filing of a request for a hearing can be found at <http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html>

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Freedom was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Freedom 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 Freedom to pay Stipulated Penalties, such

Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Freedom requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

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

- a. Freedom cured such breach within 30 days of its receipt of the Notice of Material Breach; or
- b. the alleged material breach could not have been cured within the 30 day period, but that, during the 30 day period following Freedom's receipt of the Notice of Material Breach: (i) Freedom had begun to take action to cure the material breach; (ii) Freedom pursued such action with due diligence; and (iii) Freedom provided to OIG a reasonable timetable for curing the material breach.

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

Freedom and OIG agree as follows:

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

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

C. OIG may agree to a suspension of Freedom's obligations under this CIA based on a certification by Freedom that it is no longer providing health care items or services that will be billed to any Federal health care program and 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 Freedom is relieved of its CIA obligations, Freedom shall be required to notify OIG in writing at least 30 days in advance if Freedom plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.

D. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) Freedom'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.

E. The undersigned Freedom 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.

F. 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 FREEDOM

/Bijal Patel/

BIJAL PATEL
Corporate Counsel

5/11/2017
DATE

/Latour Lafferty/

LATOUR "LT" LAFFERTY
Holland & Knight, LLP
Counsel for Freedom

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EDUARDO SUAREZ
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5/11/2017
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/Rachel May Zysk/

RACHEL MAY ZYSK /
The Suarez Law Firm, PA
Counsel for Freedom

5/11/2017
DATE

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

/Lisa M. Re/

LISA RE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

5/11/17

DATE

/Sarah Kessler/

SARAH KESSLER
Senior Counsel
Office of Inspector General
U.S. Department of Health and Human Services

5/11/17

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. Freedom 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.7 of the CIA or any additional information submitted by Freedom in response to a request by OIG, whichever is later, OIG will notify Freedom if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Freedom may continue to engage the IRO.

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

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Provider and Facility Network Review and Risk Adjustment Review who have expertise in the Medicare program requirements applicable to the data or systems being reviewed;

2. assign individuals to design and select the Provider and Facility Network Review and/or Risk Adjustment Review samples who are knowledgeable about the appropriate statistical sampling techniques;

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

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

C. IRO Responsibilities

The IRO shall:

1. perform each Provider and Facility Network Review and/or Risk Adjustment Review in accordance with the specific requirements of the CIA;
2. follow all applicable Medicare program rules and reimbursement guidelines in making assessments in the Provider and Facility Network Review and Risk Adjustment Reviews;
3. request clarification from the appropriate authority if in doubt of the application of a particular Medicare program policy or regulation;
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 and Appendix C to the CIA.

D. IRO Independence and Objectivity

The IRO(s) must perform the Provider and Facility Network Review and Risk Adjustment Reviews in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

E. IRO Removal/Termination

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

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Freedom in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Freedom 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 Freedom regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Freedom in writing that Freedom shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Freedom 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 Freedom to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

PROVIDER AND FACILITY NETWORK REVIEW

A. Provider and Facility Network Review. In the event that Freedom either expands the service area of an existing¹ Medicare Advantage contract (“Service Area Expansion”) or enters into a new contract² with CMS for a Medicare Advantage plan (“New Contract”), an IRO shall perform all components of the Provider and Facility Network Review at the conclusion of the Reporting Period during which Freedom applied for the Service Area Expansion or New Contract. The Provider and Facility Network Review shall consist of confirmation of the accuracy of the data in Freedom’s Health Services Delivery (HSD) Tables, any exception request information data provided to CMS, and Provider and Facility Directories and shall include a review of whether the sample of providers and/or facilities are under contract with Freedom to provide services to Freedom’s Medicare Advantage enrollees.

1. *Definitions*. For the purposes of the Provider and Facility Network Review, the following definitions shall be used:

- a. Applicable Contract: As applicable, either (1) Freedom’s contract(s) for which it seeks a Service Area Expansion or (2) a New Contract.
- b. Health Services Delivery (HSD) Table: Identification and details of network providers and facilities within the full service area of a Medicare Advantage Contract ID.³
- c. Network Population: Providers and/or facilities for which Freedom identified as in-network for the Applicable Contract based upon the data in Freedom’s Health Services Delivery (HSD) Tables, any exception request information data provided to CMS, and Provider and Facility Directories.

2. *HSD Tables and Provider Directories*. The IRO shall obtain from Freedom HSD Tables, exception requests submitted to CMS, and Provider and/or Facility Directories for each Applicable Contract.

3. *Network Review Sample*. The IRO will identify a random sample of 100 providers/facilities from the Network Population (Network Review Sample(s)) and determine the accuracy of the provider/facility information contained in the sample and to

¹ “Existing” contract includes those held by Freedom at the Effective Date of the CIA.

² For purposes of this Appendix B, a renewal of an existing contract will not be considered a new contract.

³ For purposes of this Appendix B, HSD Tables submitted for IRO review may include any exception requests submitted to CMS and related material.

verify that each provider/facility was under contract with Freedom to provide services to enrollees in the plan with the Applicable Contract. Any provider/facility for which Freedom cannot produce documentation sufficient to support that the provider/facility was in Freedom's contracted network for the Applicable Contract and correctly identified in the HSD Table and Provider and/or Facility Directory shall be promptly corrected or removed from the HSD Table and Provider and/or Facility Directory.

- a. Use of First Samples Drawn. For the purposes of the Network Review Sample, the first set of providers/facilities selected shall be used (i.e., it is not permissible to generate more than one list of random samples and then select one for use with the Network Review Sample(s)).

4. *Other Requirements.*

- a. Supplemental Materials. The IRO shall request all documentation and materials required for its Provider and Facility Network Review and Freedom shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Provider and Facility Network. If the IRO accepts any supplemental documentation or materials from Freedom after the IRO has completed its initial review of the Provider and Facility Network (Supplemental Materials), the IRO shall identify in the Network Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Network Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

5. *Referral to CMS.* Freedom shall promptly notify its members of any material corrections regarding its network, if applicable, and shall promptly inform CMS of the Provider and Facility Network Review findings of its IRO. In addition, OIG, in its sole discretion, may refer any findings of the Provider and Facility Network Review (and any related work papers) received from Freedom to CMS for appropriate follow up.⁴

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

1. *Methodology.*

⁴ To the extent requested, Freedom shall submit any material reviewed by OIG directly to CMS in electronic form.

- a. Provider and Facility Network. A description of the Network Population subject to the Provider and Facility Network Review.
 - b. Network Review Objective. A clear statement of the objective intended to be achieved by the Provider and Facility Network Review.
 - c. Source of Data. A description of (1) the process used to identify providers/facilities in the Network Population and (2) the specific documentation relied upon by the IRO when performing the Provider and Facility Network Review (e.g., written agreements between Freedom and the provider/facility, telephone calls with the provider/facility contacts, printouts or screenshots of maps identifying providers/facilities, electronic communication or letters between Freedom and the provider/facility contact, exception requests information provided by Freedom to CMS), CMS program rules or memoranda (including title, date, and issuance number), Medicare Managed Care Manual or bulletins (including issue, section if relevant, and date), other policies, regulations, or directives).
 - d. Review Protocol. A narrative description of how the Provider and Facility Network Review was conducted and what was evaluated.
 - e. Supplemental Materials. A description of any Supplemental Materials as required by A.4.a., above.
2. *Statistical Sampling Documentation.*
- a. Documentation of the sample selection from the statistical sampling software package used (e.g., the input file, the output files, the log file of the program run).
 - b. A description or identification of the statistical sampling software package used by the IRO.
3. *Findings.*
- a. Narrative Results.
 - i. A description of Freedom’s provider/facility contracting system(s), including the identification, by position description, of the personnel involved in developing and maintaining Freedom’s provider and facility networks.

- ii. A description of controls in place at Freedom to ensure that (1) its members have sufficient access to providers/facilities identified in Freedom's Provider and/or Facility Directories; and (2) the data in Freedom's HSD Tables, Provider and/or Facility Directories, and exception requests are accurate and regularly updated consistent with CMS's requirements.
 - iii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Provider and Facility Network Review, including the results of the Provider and Facility Network Review.
- b. Quantitative Results.
- i. Total number and percentage of instances in which the IRO determined that Freedom's provider/facility data differed from the correct provider/facility data and in which such difference resulted in a correction and/or removal from the HSD Table and/or Provider and Facility Directory.
 - ii. Total number and percentage of instances in which the IRO determined that a provider or facility from the Network Review Sample was not under contract for the Applicable Contract and such determination resulted in either a correction and/or removal from the HSD Table and/or Provider and Facility Directory or creation/updating of a contract between Freedom and the provider or facility.
 - iii. Total number and percentage of instances in which the IRO determined that Freedom did not produce documentation sufficient to support the provider/supplier data was accurate and in which such difference resulted in a correction and/or removal from the HSD Table and/or Provider and Facility Directory.
 - iv. Total amount of providers and facilities in the Network Review Sample that resulted in (1) correction and/or removal from the HSD Table and/or Provider and Facility Directory; and (2) creation/updating of a contract between Freedom and the provider or facility.
 - v. Total amount of all providers/facilities in the Network Review Sample for the Applicable Contract.

- vi. Total amount of all providers/facilities in the Network Population.
 - vii. Error Rate in the Network Review Sample. The Error Rate shall be calculated by dividing the number of providers/facilities that were either not accurate (or were otherwise granted an exception request) or failed to be under contract with Freedom to provide services to enrollees in the plan with the Applicable Contract by the number of providers/facilities in the Network Population.
4. *Recommendations.* The Network Review Report shall include any recommendations for improvements to Freedom's network contracting system or to Freedom's controls for ensuring that providers/facilities listed in Freedom's Provider or Facility Directories are accurate and otherwise meet CMS's provider/facility access and contracting criteria, based on the findings of the Provider and Facility Network Review.
5. *Credentials.* The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Provider and Facility Network Review and (2) performed the Provider and Facility Network Review.

APPENDIX C

RISK ADJUSTMENT REVIEW

A. Risk Adjustment Review. The IRO shall perform a Risk Adjustment Review annually in conjunction with each of the five Reporting Periods. The purpose of the Risk Adjustment Review is to determine whether Freedom properly submitted risk adjustment eligible diagnoses to CMS in accordance with CMS's rules and criteria under the Medicare Advantage Program. The Risk Adjustment Review shall consist of two components: (1) a review of Freedom's Risk Adjustment Processing System (RAPS) filtering logic ("Filter Logic Review"); and (2) a chart review of a random sample of 100 risk adjusted members ("Chart Review"); the Risk Adjustment Review shall also include recommendations for improvement. The IRO shall perform all parts of the Risk Adjustment Review.

1. *Definitions*. For the purposes of the Risk Adjustment Review, the following definitions shall be used:
 - a. Data Submission Period: The period during which MA organizations may submit diagnoses for CMS to use to calculate a beneficiary's risk score for a particular Payment Year; all such data must typically be received by CMS in March of the Payment Year. The Data Submission Period for the first Reporting Period under the CIA began January 1, 2016.
 - b. Payment Year: 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 2016 Data Submission Period.
 - c. Risk Adjusted Member: A Medicare Advantage (MA) plan enrollee in a Freedom MA Plan who (1) was continuously enrolled in a Freedom MA Plan from January of the Data Submission Period through January of the Payment Year; (2) had at least one risk adjustment diagnosis during the Data Submission Period that mapped to at least one HCC during the Payment Year; (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.

- d. Population: The Population(s) shall be defined as all Risk Adjusted Members for a particular Payment Year.
- e. Filtering Logic: The algorithm (regardless of whether it is fixed or variable and regardless of whether it is computerized, otherwise mechanized, or applied by hand) applied to some or all diagnoses to determine whether a particular diagnosis should be used for Medicare Advantage risk adjustment purposes.
- f. CMS's Criteria for Risk Adjustment Eligible Diagnoses: As applicable for each Reporting Period, CMS's requirements for diagnoses submissions including, but not limited to, Chapter 7 of CMS's Medicare Managed Care Manual.
- g. Type of Bill Codes: Three digit codes located on a claim form that describe the type of bill a provider is submitting to a payer.
- h. Place of Service Codes: Two-digit codes placed on health care professional claims to indicate the setting in which a service was provided.
- i. Acceptable Physician Specialty Type Codes: Codes included on CMS's published lists of acceptable physician specialty types codes.

2. *Code-Based Data Review to Ensure Compliance with CMS's Criteria for Risk Adjustment Eligible Diagnoses.* For purposes of the Risk Adjustment Review, the following shall apply:

- a. Reviewing Professional Data and Code-Based Filtering of Professional Data:
 - i. The IRO will apply the rules in Chapter 7 of the Medicare Managed Care Manual and in CMS's Encounter Data guidance.
 - ii. The IRO may utilize CPT/HCPCS codes when reviewing whether Freedom's submissions were consistent with CMS's Criteria for Risk Adjustment Eligible Diagnoses.

- iii. The IRO will utilize CMS's published lists of Acceptable Physician Specialty Type Codes when reviewing whether Freedom's submissions were consistent with CMS's Criteria for Risk Adjustment Eligible Diagnoses.
 - iv. The IRO may utilize Place of Services Codes when reviewing whether Freedom's submissions were consistent with CMS's Criteria for Risk Adjustment Eligible Diagnoses.
 - b. Reviewing Institutional Inpatient Data and Code-Based Filtering of Institutional Inpatient Data: The IRO will apply the rules in Chapter 7 of the Medicare Managed Care Manual and CMS's Encounter Data guidance and may, accordingly, utilize the institutional Type of Bill Codes when reviewing whether Freedom's submissions were consistent with CMS's Criteria for Risk Adjustment Eligible Diagnoses.
 - c. Reviewing Institutional Outpatient Data and Code-Based Filtering of Institutional Outpatient Data:
 - i. The IRO will apply the rules in Chapter 7 of the Medicare Managed Care Manual and CMS's Encounter Data guidance and may, accordingly, utilize the institutional outpatient Type of Bill Codes when reviewing whether Freedom's submissions were consistent with CMS's Criteria for Risk Adjustment Eligible Diagnoses.
 - ii. The IRO may utilize CPT/HCPCS codes when reviewing Freedom's filtering of encounter data.
- 3. *Filter Logic Review.* For each Reporting Period, the IRO shall review the filters used by Freedom's RAPS submission system for the applicable Payment Year to ensure Freedom's compliance with CMS's Criteria for Risk Adjustment Eligible Diagnoses.
 - a. In the event that the IRO, through its review of Freedom's filtering logic, identifies a deficiency in the filtering logic, the IRO shall confirm that: (a) Freedom remediates the filter logic that generated the deficiency; and (b) Freedom 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).

- b. The IRO shall provide Freedom with its observations and recommendations on suggested improvements to the filtering logic consistent with section B, *infra*.

4. *Chart Review.* For each Reporting Period, the IRO shall randomly select and review a sample of at least 100 Risk Adjusted Members (Chart Review Samples) from the Population to ensure Freedom's compliance with CMS Criteria for Risk Adjustment Eligible Diagnoses. Through its Chart Review, the IRO should confirm, at a minimum, the following: acceptable risk adjustment provider type, source, and physician specialty were used; that dates of service are within the Data Submission Period; valid signatures and credentials; identification of the correct beneficiary; diagnoses were coded in accordance with ICD-9/10 coding guidelines; and the CMS-HCC used in payment is substantiated.

- a. In the event that the IRO, through its Chart Review, identifies submitted diagnoses that were not risk adjustment eligible in accordance with CMS Criteria for Risk Adjustment Eligible Diagnoses, Freedom 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).
- b. The IRO shall provide its observations and recommendations on suggested improvements to Freedom's policies, procedures, and/or filtering logic, as applicable, consistent with section B, *infra*.

5. *Documenting Correction of Previously Submitted Codes.* Freedom shall make available to OIG all documentation that reflects the reporting to CMS. OIG, in its sole discretion, may refer the findings of the Risk Adjustment Review (and any related work papers) received from Freedom to CMS or its contractor(s) for appropriate follow up.

- 6. *Other Requirements.*

- a. Supplemental Materials. The IRO shall request all documentation and materials required for its Risk Adjustment Review and Freedom shall furnish such documentation and materials to the IRO prior to the IRO initiating its review. If the IRO accepts any supplemental documentation or materials from Freedom after the IRO has completed its initial review (Supplemental Materials), the IRO shall identify in the Risk Adjustment Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Risk Adjustment Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.
- b. Exception for Uncontrollable Circumstances. In the event of circumstances beyond Freedom's control that prevent Freedom from accessing medical records for the IRO's review, Freedom may request that the OIG allow the IRO to replace the affected Risk Adjusted Member with a new randomly selected Risk Adjustment Member. Freedom's request must include an explanation of the uncontrollable circumstances and whether any alternative records for that Risk Adjusted Member are available. If the OIG grants Freedom's request, the IRO shall include any such replacement in its Risk Adjustment Data Review Report. The decision to grant or deny any request for an exception based on uncontrollable circumstances is in the discretion of OIG and not subject to review.
- c. Risk Adjusted Member's Diagnosis without Supporting Documentation. Subject to the exception for uncontrollable circumstances in Paragraph A.6.b., any diagnoses from a Risk Adjusted Member for which Freedom cannot produce supporting documentation shall be considered an error and Freedom shall delete such diagnosis per CMS's requirements. Replacement sampling for Risk Adjusted Members diagnoses with missing documentation is permitted only for uncontrollable circumstances.
- d. Use of First Samples Drawn. For the purposes of the Chart Review Sample discussed in this Appendix, and subject to the uncontrollable circumstances exception in Paragraph A.6.b., the first set of Risk Adjusted Members selected shall be used (i.e., it is not permissible to generate more than one list of random samples and then select one for use in the Chart Review Sample).

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

1. *Methodology*.
 - a. Risk Adjustment Review. A description of: (i) the filtering logic subject to the Filter Logic Review; and (ii) the Population subject to the Chart Review.
 - b. Risk Adjustment Review Objective. A clear statement of the objective intended to be achieved by each component of the Risk Adjustment Review.
 - c. Source of Data.
 - i. A description of (a) the process used to identify Freedom’s filtering logic; and (b) the process used to identify the Chart Review Sample.
 - ii. A description of the specific documentation relied upon by the IRO when performing each component of the Risk Adjustment Review, (e.g., program rules or memoranda (including title, date, and issuance number) issued by CMS or its contractors, Medicare Managed Care Manual or bulletins (including issue, section if relevant, and date), and other policies, regulations, or directives).
 - d. Review Protocol. A narrative description of how the Filter Logic Review and Chart Review were conducted and what was evaluated in each.
 - e. Supplemental Materials. A description of any Supplemental Materials as required by A.6.a above.
2. *Statistical Sampling Documentation – Chart Review*.
 - 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. *Findings.*

a. Narrative Results.

- i. A description of Freedom's filtering logic, including the identification, by position description, of the personnel involved in developing and maintaining Freedom's filtering logic.
- ii. A description of the external sources of risk adjustment eligible diagnoses (e.g., network primary care physician) and the identification, by position description, of Freedom personnel responsible for communicating with external sources of risk adjustment eligible diagnoses.
- iii. A description of the controls in place at Freedom to ensure the accuracy and integrity of risk adjustment data submissions to CMS.
- iv. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding each component of the Risk Adjustment Review.

b. Quantitative Results.

- i. Two spreadsheets of the results of the Chart Review that include the following information for each diagnosis submitted in the Chart Review Sample:
 - a) Spreadsheet 1: beneficiary health insurance claim number or Medicare Beneficiary Identifier (MBI), service from date, service through date, diagnosis codes submitted, type of provider (inpatient, outpatient, or physician), and any HCC (that resulted from the diagnosis code) for each diagnoses submitted for the applicable Reporting Period.
 - b) Spreadsheet 2: beneficiary health insurance claim number or Medicare Beneficiary Identifier (MBI), service from date, service through date, diagnosis codes submitted, type of provider (inpatient, outpatient, or physician), and any HCC (that resulted from the diagnosis code) for each submitted diagnoses that the IRO determined was not risk adjustment eligible in accordance with CMS Criteria for Risk Adjustment Eligible Diagnoses.

- ii. Error rate in the Chart Review Sample. The Error Rate shall be calculated by dividing the number of Risk Adjusted Members in the Chart Review Sample for whom Freedom submitted diagnoses that the IRO determined were not risk adjustment eligible by the number of Risk Adjusted Members in the Chart Review Sample.

4. *Recommendations.* The Risk Adjustment Review Report shall include any recommendations for improvements to Freedom's filtering logic and Freedom's controls for ensuring that risk adjustment data submitted to CMS are accurate, based on the findings of the Risk Adjustment Review.

5. *Credentials.* The names and credentials of the individuals who: (1) designed the review methodology utilized for each component of the Risk Adjustment Review and (2) performed each component of the Risk Adjustment Review.

6. *Independence and Objectivity Certification.* The IRO shall include in its report 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. The IRO's certification shall include a summary of all current and prior engagements between Freedom and the IRO.