CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ALLIANCE PARENT, INC.

I. PREAMBLE

Alliance Parent, Inc. and its subsidiaries attached as Exhibit A (Provider) 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, Provider is entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Provider 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) Provider's final annual report; or (2) any additional materials submitted by Provider pursuant to OIG's request, whichever is later.

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

1. "Arrangements" shall mean every arrangement or transaction that involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between Provider and any actual or potential source of health care business or referrals to Provider or any actual or potential recipient of health care business or referrals from Provider.

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

3. The term "recipient of health care business or referrals" shall mean any individual or entity (1) to whom Provider refers an individual for the furnishing or arranging for the furnishing of any item or service, or (2) from whom Provider 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.

4. "Focus Arrangements" means every Arrangement that is between Provider and any actual source or recipient of health care business or referrals and involves, directly or indirectly, the offer, payment, or provision of anything of value.

5. "Covered Persons" includes:

   a. all owners, officers, directors, and employees of Provider; and

   b. all contractors, subcontractors, agents, and other persons who furnish patient care items or services or who perform billing or coding functions on behalf of Provider excluding vendors whose sole connection with Provider is selling or otherwise providing medical supplies or equipment to Provider.

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

III. CORPORATE INTEGRITY OBLIGATIONS

Provider 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, Provider 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 Provider, shall report directly to the Chief Executive Officer of Provider, 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 Provider. 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 in person to the Board of Directors of Provider (Board) and shall be authorized to report on such matters to the Board at any time. Written documentation of the Compliance Officer's reports to the Board shall be made available to OIG upon request; and

c. monitoring the day-to-day compliance activities engaged in by Provider 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.

Provider 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 businessdays after such a change.

2. *Compliance Committee*. Within 90 days after the Effective Date, Provider 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 Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of Provider'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.

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

3. *Board Compliance Obligations.* The Board of Provider 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-employee and non-executive) members.

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

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

b. submitting to the 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 Provider's compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

> "The Board has made a reasonable inquiry into the operations of Provider'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, Provider 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 Provider.

Provider 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 business days after such a change.

4. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Provider employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Provider department is in compliance with applicable Federal health care program requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Chief Executive Officer, Chief Financial Officer, Chief Legal Officer, and the Compliance 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 Provider policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] of Provider 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 90 days after the Effective Date, Provider 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 90 days after the Effective Date, Provider 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 Provider's compliance with Federal health care program requirements (Policies and Procedures). The Policies and Procedures also shall address:

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

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

The Policies and Procedures shall be made available to all Covered Persons. Throughout the term of this CIA, Provider shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all employees.

At least annually (and more frequently, if appropriate), Provider shall assess and update, as necessary, the Policies and Procedures. Any revised or new 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, Provider shall develop a written plan (Training Plan) that outlines the steps Provider will take to ensure that all Covered Persons receive at least annual training regarding Provider's CIA requirements and Compliance Program and the applicable Federal health care program requirements, including the requirements of the Anti-Kickback Statute; and that all Arrangements Covered Persons receive at least annual training regarding: (i) Arrangements that potentially implicate the Anti-Kickback Statute, as well as the regulations and other guidance documents related to these statutes; (ii) Provider's policies, procedures, and other requirements relating to Arrangements and Focus Arrangements, including but not limited to the Focus Arrangements Tracking System, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals required by Section III.D of the CIA; (iii) the personal obligation of each individual involved in the development, approval, management, or review of Provider's Arrangements to know the applicable legal requirements and the Provider's policies and procedures; (iv) the legal sanctions under the Anti-Kickback Statute and (v) examples of violations of the Anti-Kickback Statute.

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

2. *Board Training*. In addition to the training described in Section III.C.1, within 90 days after the Effective Date, each member of the Board shall receive training regarding 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 shall receive the Board training described above within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later.

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

D. Compliance with the Anti-Kickback Statute

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

a. creating and maintaining a centralized tracking system for all existing and new or renewed Focus Arrangements and the information specified in Sections III.D.1.b-f below for each existing and new or renewed Focus Arrangement (Focus Arrangements Tracking System);

b. documenting the names and positions of the Arrangements Covered Person(s) involved in the negotiation, review, and approval of all Focus Arrangements;

c. tracking all remuneration to and from all parties to Focus Arrangements, to ensure that the parties are complying with the financial terms of the Focus Arrangements and that the Focus Arrangements are commercially reasonable;

d. documenting all fair market value determination(s) for any Focus Arrangement, including the fair market value amount or range and corresponding time period(s), the date(s) of completion of the fair market valuation(s), the individuals or entities that determined the fair market value amount or

range, and the names and positions of the Covered Person(s) who received and/or were otherwise involved with the fair market value determination(s);

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

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

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

h. ensuring that all existing Focus Arrangements are subject to the review and approval process described in Section III.D.1.g above;

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

j. implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events and quantifying and repaying

Overpayments pursuant to Sections III.J and III.K when appropriate.

2. *New or Renewed Focus Arrangements*. No later than 90 days after the Effective Date, and prior to entering into new Focus Arrangements or renewing existing Focus Arrangements, in addition to complying with the Focus Arrangements Procedures set forth above, Provider shall comply with the following requirements (Focus Arrangements Requirements):

a. Ensure that all written Focus Arrangements are signed by Provider and the other party(ies) to the Focus Arrangement prior to the payment or receipt of any remuneration pursuant to the Focus Arrangement;

b. Ensure that all Focus Arrangements have been subject to the written review and approval process described in Section III.D.1.g prior to the payment or receipt of any remunerations pursuant to the Focus Arrangement, and that Provider maintains appropriate documentation of the review and approval of such Focus Arrangement; and

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

3. *Records Retention and Access*. Provider shall retain and make available to OIG, upon request, the Focus Arrangements Tracking System and all supporting documentation of the Focus Arrangements subject to this Section and, to the extent available, all non-privileged communications related to the Focus Arrangements and the actual performance of the duties under the Focus Arrangements.

E. Review Procedures

1. *General Description*.

a. *Engagement of Independent Review Organization*. Within 90 days after the Effective Date, Provider shall engage a law or consulting firm or a lawyer to perform the arrangements

review described in Section III.E.2. The entity (or entities) engaged to perform the arrangements review are referred to hereinafter as the "Independent Review Organization" or "IRO." 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 Provider shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Provider) related to the reviews.

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

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

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

3. *Certifications*. The IRO for the Arrangements Review shall include in its report(s) to Provider a certification that the IRO does not have a current or prior relationship to Provider or its owners, officers, or directors that would cause a reasonable person to question the IRO's objectivity in performing the reviews required by Section III.E. The IRO's certification shall include a summary of any current and prior relationships between Provider or its owners, officers, or directors and the IRO.

F. Risk Assessment and Internal Review Process

Within 90 days after the Effective Date, Provider shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with Arrangements (as defined in Section II.C.1 above) and Provider's

participation in the Federal health care programs, including but not limited to the risks associated with the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries. 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 Provider 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. Provider shall maintain the risk assessment and internal review process for the term of the CIA.

G. Disclosure Program

Within 90 days after the Effective Date, Provider 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 Provider'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. Provider 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 Provider'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 Provider. 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, Provider 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 all disclosures, whether or not related to a potential violation of criminal, civil, or administrative law related to the Federal health care programs, 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 individual or department responsible for reviewing the disclosure. the status of the review, and any corrective action taken in response to the review.

H. 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.* Provider shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

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

c. Provider shall implement a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

Nothing in this Section III.H affects Provider'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. Provider understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that Provider may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Provider meets the requirements of Section III.H.

3. *Removal Requirement.* If Provider has actual notice that a Covered Person has become an Ineligible Person, Provider shall remove such Covered Person from responsibility for, or involvement with, Provider'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 Provider 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 or during the term of a physician's or other practitioner's medical staff privileges, Provider 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.

I. Notification of Government Investigation or Legal Proceeding

Within 30 days after discovery, Provider shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Provider conducted or brought by a

governmental entity or its agents involving an allegation that Provider 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. Provider shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceeding, if any.

J. Overpayments

1. *Definition of Overpayments*. An "Overpayment" means any funds that Provider receives or retains under any Federal health care program to which Provider, after applicable reconciliation, is not entitled to under such Federal health care program.

2. *Overpayment Policies and Procedures.* Within 90 days after the Effective Date, Provider shall develop and implement written policies and procedures regarding the identification, quantification and repayment of Overpayments received from any Federal health care program.

K. 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.H.1.a; or

d. the filing of a bankruptcy petition by Provider.

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

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

3. *Reportable Events under Section III.K.1.a.and III.K.1.b.* For Reportable Events under Section III.K.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 entities and individuals 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 Provider to identify and quantify any Overpayments; and

e. a description of Provider'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, Provider 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 (CMS) guidance and provide OIG with a copy of the notification and repayment.

4. *Reportable Events under Section III.K.1.c.* For Reportable Events under Section III.K.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 Provider completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the Ineligible Persons 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.K.1.d*. For Reportable Events under Section III.K.1.d, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, Provider 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. Provider shall give notice of such sale or purchase to OIG within 30 days following the closing of the transaction.

If, in advance of a proposed sale or proposed purchase, Provider 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, Provider 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, Provider 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, business address, business 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 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 the written process for Certifying Employees to follow in order to complete the certification required by Section III.A.4;

5. a list of all 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. a description of (a) the Focus Arrangements Tracking System required by Section III.D.1.a, (b) the internal review and approval process required by Section III.D.1.g; and (c) the tracking and monitoring procedures and other Focus Arrangements Procedures required by Section III.D.1;

8. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to

demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; and (d) a certification from the IRO that it does not have a prohibited relationship with Provider as set forth in Section III.E.3, that includes a summary of any current and prior engagements or relationships between Provider or its owners, officers, or directors and the IRO;

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

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

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

12. a copy of Provider's policies and procedures regarding the identification, quantification and repayment of Overpayments required by Section III.J;

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

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

15. the certifications required by Section V.C.

B. Annual Reports

Provider 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 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, and Certifying Employees;

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

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 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;

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

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

7. a description of (a) any changes to the Focus Arrangements Tracking System required by Section III.D.1.a; (b) any changes to the internal review and approval process required by Section III.D.1.g; and (c) any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1;

8. a complete copy of all reports prepared pursuant to Section III.E and Provider's response to the reports, along with corrective action plan(s) related to any issues raised by the reports, including Provider's determination of whether the CMS overpayment rule requires the repayment of an extrapolated Overpayment (as defined in Appendix B);

9. a certification from the IRO regarding its professional independence and objectivity with respect to Provider or that the IRO does not have a prohibited relationship with Provider, as described in Section III.E.4, including a summary of all current and prior engagements or relationships between Provider and the IRO, as applicable;

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

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

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

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

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

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

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

17. a description of all changes to the most recently provided list of Provider's locations (including addresses) as required by Section V.A.14;

18. a description of any changes to Provider's corporate structure, including any parent and sister companies, individual owners, subsidiaries, and their respective lines of business; and

19. the certifications required by Section V.C.

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

C. Certifications

1. *Certifying Employees.* In each Annual Report, Provider shall include the certifications of Certifying Employees as 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, Provider is in compliance with all of the requirements of this CIA;

b. to the best of his or her knowledge, Provider has implemented procedures reasonably designed to ensure that all Focus Arrangements do not violate the Anti-Kickback Statute, including the Focus Arrangements Procedures required in Section III.D of the CIA;

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

d. 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

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

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, Provider 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); (c) to identify and adjust any past charges or claims for unallowable costs; and (d) he or she understands that the certification is being provided to and relied upon by the United States.

D. Designation of Information

Provider 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. Provider 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

Provider:

David Hruda
Chief Legal Officer
4545 Fuller Drive, Suite 100
Irving, TX 75038
Telephone: 301.752.5700

Facsimile: 888.982.8442
David@stratusneuro.com

Unless otherwise specified, all notifications and reports required by this CIA may be made by overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, Provider may be required to provide OIG with an additional copy of each notification or report required by this CIA, in OIG's requested format (electronic or paper).

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 Provider's books, records, and other documents and supporting materials, and conduct on-site reviews of any of Provider's locations for the purpose of verifying and evaluating: (a) Provider's compliance with the terms of this CIA; and (b) Provider's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Provider 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 Provider'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. Provider shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Provider's owners, employees, contractors, and directors may elect to be interviewed with or without a representative of Provider present.

VIII. DOCUMENT AND RECORD RETENTION

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

X. BREACH AND DEFAULT PROVISIONS

Provider 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, Provider 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) per obligation for each day Provider fails to establish, implement or comply with any of the following obligations as described in Sections III:

   a. a Compliance Officer;

   b. a Compliance Committee;

   c. the Board compliance obligations;

   d. the management certification obligations and the development and implementation of a written process for Certifying Employees, as required by Section III.A.4;

   e. written Policies and Procedures;

f. the development of a written training plan and the training and education of Covered Persons, Arrangements Covered Persons, and Board members;

g. the Focus Arrangements Procedures and/or Focus Arrangements Requirements;

h. a risk assessment and internal review process;

i. a Disclosure Program;

j. Ineligible Persons screening and removal requirements;

k. notification of Government investigations or legal proceedings;

l. policies and procedures regarding the repayment of Overpayments; and

m. 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 Provider fails to engage and use an IRO, as required by Section III.E, Appendix A or Appendix B.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Provider fails to timely submit (a) a complete Implementation Report or Annual Report, (b) a certification to OIG in accordance with the requirements of Section V, or (c) a complete response to any request for information from OIG.

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 Provider fails to submit any Arrangements Review Report in accordance with the requirements of Section III.E and Appendix B.

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

6. A Stipulated Penalty of $50,000 for each false certification submitted by or on behalf of Provider 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 $2,500 for each day Provider fails to grant the IRO access to all records and personnel necessary to complete the reviews listed in Section III.E., and for each day Provider fails to furnish accurate and complete records to the IRO, as required by Section III.E and Appendix A.

8. A Stipulated Penalty of $1,000 for each day Provider fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Provider stating the specific grounds for its determination that Provider has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Provider shall take to comply with the CIA. This Stipulated Penalty shall begin to accrue 10 business days after the date Provider 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 1-7 of this Section.

B. Timely Written Requests for Extensions

Provider 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 Provider fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Provider 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 Provider 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 Provider of: (a) Provider'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 business days after the receipt of the Demand Letter, Provider 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 Provider elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Provider 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 Provider has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA

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

a. a failure by Provider to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.K;

b. 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;

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

d. a failure to engage and use an IRO in accordance with Section III.E, Appendix A or Appendix B.

2. *Notice of Material Breach and Intent to Exclude*. The parties agree that a material breach of this CIA by Provider constitutes an independent basis for Provider'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 Provider has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Provider of: (a) Provider'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*. Provider 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) Provider has begun to take action to cure the material breach; (ii) Provider is pursuing such action with due diligence; and (iii) Provider has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter*. If, at the conclusion of the 30-day period, Provider fails to satisfy the requirements of Section X.D.3, OIG may exclude Provider from participation in the Federal health care programs. OIG shall notify Provider in writing of its determination to exclude Provider. (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 Provider'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, Provider 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 Provider 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, Provider 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 Provider was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Provider 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 Provider to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Provider 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 Provider was in material breach of this CIA and, if so, whether:

a. Provider 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 Provider's receipt of the Notice of Material Breach: (i) Provider had begun to take action to cure the material breach; (ii) Provider pursued such action with due diligence; and (iii) Provider 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 Provider, only after a DAB decision in favor of OIG. Provider's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Provider 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 Provider 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. Provider 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 Provider, Provider 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

Provider 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 Provider's obligations under this CIA based on a certification by Provider 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 Provider is relieved of its CIA obligations, Provider shall be required to notify OIG in writing at least 30 days in advance if Provider 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) Provider'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 Provider 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 Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF PROVIDER

/Charlie Alvarez/

7.7.2021

Charlie Alvarez
Chief Executive Officer

Date

/David N. Hruda/

7/7/2021

David Hruda
Chief Legal Officer

Date

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

/Lisa M. Re/

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

7/08/2021
DATE

/Nancy W. Brown/

NANCY W. BROWN
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services

7/8/2021
DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. Provider shall engage an IRO to perform the Arrangements Review that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall not have a prohibited relationship to Provider as set forth in Paragraph F.

2. Within 30 days after OIG receives the information identified in Section V.A.8 of the CIA or any additional information submitted by Provider in response to a request by OIG, whichever is later, OIG will notify Provider if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Provider may continue to engage the IRO.

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

B. IRO Qualifications

The IRO shall:

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

2. possess expertise in fair market valuation issues or have the ability to associate a valuation firm to assist in conducting the transactions review component of the Arrangements Review; and

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

C. IRO Responsibilities

The IRO shall:

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

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

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

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

D. Provider Responsibilities

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

E. IRO Relationship to Provider

The IRO engaged to perform the Arrangements Review shall not have a current or prior relationship to Provider or its owners, officers, or directors that would cause a reasonable person to question the IRO's objectivity in performing the Arrangements Review.

G. Assertions of Privilege

Provider shall not assert claims of attorney-client privilege in order to avoid disclosing to OIG information related to or resulting from the IRO's engagement to perform the Arrangements Review. Provider's engagement letter with the IRO shall include a provision stating that the IRO agrees not to assert claims of work product privilege in order to avoid disclosing to OIG information related to or resulting from its engagement.

H. IRO Removal/Termination

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

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

Exhibit A

Alliance Parent, Inc. Subsidiaries

AFC Buyer, Inc.
Alliance Family of Companies, Inc.
Alliance Family of Companies, LLC
Alliance Kvikna US Blocker, Inc.
Stratus Software Solutions, LLC
Kvikna Medical, ehf
MERLN, LLC
Alabama Neurodiagnostics, LLC
Alliance Neurodiagnostics, LLC
Alliance Physician Management, LLC
Alliance Sleep Medicine, LLC
Anci-Pro Healthcare Solutions, LLC
California Neurodiagnostics, LLC
Coastal Diagnostics Group, LLC
Colorado Neurodiagnostics, LLC
Connecticut Neurodiagnostics, LLC
DC Neurodiagnostics, LLC
Delaware Neurodiagnostics, LLC
Florida Neurodiagnostics, LLC
Georgia Neurodiagnostics, LLC
Houston Neurodiagnostics, LLC
Illinois Neurodiagnostics, LLC
Indiana Neurodiagnostics, LLC
Kansas Neurodiagnostics, LLC
Kentucky Neurodiagnostics, LLC
Louisiana Neurodiagnostics, LLC
Maryland Neurodiagnostics, LLC
Massachusetts Neurodiagnostics, LLC
Michigan Neurodiagnostics, LLC
Minnesota Neurodiagnostics, LLC
Mississippi Neurodiagnostics, LLC
Missouri Neurodiagnostics, LLC
Nevada Neurodiagnostics, LLC
New Hampshire Neurodiagnostics, LLC
New Jersey Neurodiagnostics, LLC
New Mexico Neurodiagnostics, LLC
North Carolina Neurodiagnostics, LLC
Ohio Neurodiagnostics, LLC
Oklahoma Neurodiagnostics, LLC
Oregon Neurodiagnostics, LLC
Pennsylvania Neurodiagnostics, LLC
Phoenix Neurodiagnostics, LLC
Respiratory Sleep Solutions, Inc.
Respiratory Sleep Solutions, LLC

Rhode Island Neurodiagnostics, LLC
Sleep Solutions LLC dba PC Processing Services
Sleep Source, LLC
South Carolina Neurodiagnostics, LLC
Tennessee Neurodiagnostics, LLC
TelemedX, LLC
Terces, LLC
Utah Neurodiagnostics, LLC
Virginia Neurodiagnostics, LLC
Washington Neurodiagnostics, LLC
West Virginia Neurodiagnostics, LLC

APPENDIX B

ARRANGEMENTS REVIEW

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

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

1. Provider's systems, policies, processes, and procedures with respect to creating and maintaining a centralized tracking system for all existing and new and renewed Focus Arrangements (Focus Arrangements Tracking System), including a detailed description of the information captured in the Focus Arrangements Tracking System;

2. Provider's systems, policies, processes, and procedures for documenting the names and positions of the Arrangements Covered Person(s) involved in the negotiation, review, and approval of all Focus Arrangements;

3. Provider's systems, policies, processes, and procedures for tracking all remuneration to and from all parties to Focus Arrangements to ensure that the parties are complying with the financial terms of the Focus Arrangements and that the Focus Arrangements are commercially reasonable;

4. Provider's systems, policies, processes and procedures for documenting all fair market value determination(s) for any Focus Arrangement, including the fair market value amount or range and corresponding time period(s), the date(s) of completion of the fair market valuation(s), the individuals or entities that determined the fair market value amount or range, and the names and positions of the Arrangements Covered Person(s) involved with the fair market value determination(s);

5. Provider's systems, policies, processes, and procedures for tracking service and activity logs to ensure that parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangement(s) (if applicable);

6. Provider's systems, policies, processes, and procedures for monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Focus Arrangement(s) (if applicable);

7. Provider's systems, policies, processes, and procedures for initiating Arrangements, including those policies that identify the individuals with authority to initiate an Arrangement and that specify the business need or business rationale required to initiate an Arrangement;

8. Provider's systems, policies, processes, and procedures for the internal review and approval of existing, new and renewed Focus Arrangements, including those policies that identify the individuals required to approve each type or category of Focus Arrangement entered into by Provider, the internal controls designed to ensure that all required approvals are obtained, the processes for determining and documenting the business need or business rationale for all Focus Arrangements, the processes for determining and documenting the fair market value of the remuneration specified in the Focus Arrangement, and the processes for ensuring that all Focus Arrangements are subject to a legal review by counsel with expertise in the Anti-Kickback Statute;

9. the Compliance Officer's annual review of and reporting to the Compliance Committee on the Focus Arrangements Tracking System, Provider's internal review and approval process, and other Focus Arrangements systems, process, policies, and procedures;

10. Provider's systems, policies, processes, and procedures for implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments when appropriate; and

11. Provider's systems, policies, processes, and procedures for ensuring that all new and renewed Focus Arrangements comply with the Focus Arrangements Requirements set forth in Section III.D.2 of the CIA.

B. Arrangements Systems Review Report. The IRO shall prepare a report based upon each Arrangements Systems Review performed. The Arrangements Systems Review Report shall include the following information:

1. a description of the documentation (including policies) reviewed and personnel interviewed;

2. a detailed description of Provider's systems, policies, processes, and procedures relating to the items identified in Section A.1-11 above;

3. findings and supporting rationale regarding weaknesses in Provider's systems, processes, policies, and procedures relating to Arrangements described in Section A.1-11 above; and

4. recommendations to improve Provider's systems, policies, processes, or procedures relating to Arrangements described in Section A.1-11 above.

C. Arrangements Transactions Review. The Arrangements Transactions Review shall consist of a review by the IRO of 50 randomly selected Focus Arrangements that were entered into or renewed by Provider during the Reporting Period. The IRO shall assess whether Provider has complied with the Focus Arrangements Procedures and the Focus Arrangements Requirements described in Sections III.D.1 and III.D.2 of the CIA, with respect to the selected Focus Arrangements.

1. The IRO's assessment with respect to each Focus Arrangement that is subject to review shall include:

a. verifying that the Focus Arrangement is maintained in Provider's centralized tracking system in a manner that permits the IRO to identify: (i) the parties to the Focus Arrangement, (ii) the name(s) and position(s) of the Arrangements Covered Person(s) involved in the negotiation, review, and approval of the Focus Arrangement; (iii) the relevant terms of the Focus Arrangement (i.e., the items, services, equipment, or space to be provided, the amount of compensation, the effective date, the expiration date, etc.); and (iv) the parties' performance under the Focus Arrangement (i.e., items or services actually provided, equipment or space actually provided or leased, amount of payments, dates of payment, etc.);

b. verifying that the Focus Arrangement was subject to the internal review and approval process (including both a legal and business review) and obtained the necessary approvals and that such review and approval is appropriately documented;

c. verifying that the remuneration related to the Focus Arrangement has been determined in accordance with Provider's policies and procedures for determining and documenting the fair market value of the remuneration, that the remuneration is properly tracked, and that the parties to the Focus Arrangement are complying with the financial terms of the Focus Arrangement;

d. verifying that the business need or business rationale for the Focus Arrangement is specified and is consistent with Provider's policies and procedures;

e. verifying that the service and activity logs are properly completed and reviewed (if applicable);

f. verifying that leased space, medical supplies, medical devices, and equipment, and other patient care items are properly monitored (if applicable); and

g. verifying that the Focus Arrangement satisfies the Focus Arrangements Requirements of Section III.D.2 of the CIA.

2. For any Focus Arrangement for which the IRO cannot verify compliance with each of the applicable requirements specified in Section C.1 above, the IRO shall identify and review the system(s) and process(es) that resulted in the identified non-compliance and recommend improvements to such system(s) and process(es). The IRO may need to review additional documentation and/or interview personnel to identify the system(s) and process(es) that resulted in the identified non-compliance.

3. If the IRO cannot verify compliance with each of the applicable requirements specified in Section C.1 above with respect to at least 90% of the Focus Arrangements subject to the Arrangements Transactions Review, then, at its discretion, within 60 days of receipt of the Arrangements Transactions Review Report, the OIG may require the IRO shall be required to select an additional sample of Focus Arrangements, not to exceed the number of Focus Arrangements initially reviewed by the IRO, that will be subject to the Arrangements Transactions Review (Additional Transactions Review) and complete and submit to Provider and OIG an Additional Transactions Review Report that includes the information specified in Section D below, within 60 days of the date the OIG notifies Provider and its IRO that an Additional Transactions Review will be required.

D. Arrangements Transactions Review Report. The IRO shall prepare a report based on each Arrangements Transactions Review performed. The Arrangements Transactions Review Report shall include the following information:

1. *Review Methodology*.

a. Review Protocol. A description of the process used by the IRO to identify the Focus Arrangements subject to review in the Arrangements Transactions Review.

b. Sources of Data. A full description of the documentation and other information relied upon by the IRO in performing the Arrangements Transactions Review.

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

2. *Review Findings*. The IRO's findings with respect to whether Provider has complied with the Focus Arrangements Procedures and Focus Arrangements Requirements with respect to each of the randomly selected Focus Arrangements reviewed by the IRO, including findings for each item listed in Sections C.1.a-g above. In addition, as applicable, the Arrangements Transactions Review Report shall include the IRO's recommendations as required by Section C.2 above.

3. *Names and Credentials*. The names and credentials of the individuals who conducted the Arrangements Systems Review and the Arrangements Transactions Review.