CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
KINEX MEDICAL COMPANY, LLC

I. PREAMBLE

Kinex Medical Company (Kinex), and all subsidiaries and any additional affiliated entities owned, controlled, or operated by Kinex, including those that may be created during the term of this CIA (collectively, Entity) 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, Entity is entering into a Settlement Agreement with the United States.

II. EFFECTIVE DATE, TERM, AND DEFINITIONS

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

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

C. Definitions.

1. "Arrangements" means:

a. every arrangement or transaction that involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value and is between Entity and (i) any actual or potential source of health care business or referrals to Entity or (ii) any actual or potential recipient of health care business or referrals from Entity,

i. "Source of health care business or referrals" means any individual or entity that refers, recommends, arranges for, orders, leases, or purchases any good, facility, item, or

service for which payment may be made in whole or in part by a Federal health care program.

ii. "Recipient of health care business or referrals" means any individual or entity (a) to whom Entity refers an individual for the furnishing or arranging for the furnishing of any item or service, or (b) from whom Entity 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.

and

b. every financial relationship (as defined at 42 C.F.R. § 411.354(a)) that is between Entity and a physician (or a physician's immediate family member (as defined at 42 C.F.R. § 411.351)) who makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to Entity for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

2. "Arrangements Covered Persons" means each Covered Person who is involved with the development, approval, management, or review of Entity's Arrangements.

3. "Certifying Covered Persons" means the following: Chief Executive Officer/President, Chief Financial Officer, Regional Director of Special Accounts, V.P. of Revenue Cycle, V.P. of Human Resources, V.P. of Internal Operations, V.P. of Contracting and Government Services, V.P. of Sales, Vice President of Information Technology, Software Engineer, and other Covered Persons that the OIG determines shall be Certifying Covered Persons.

4. "Covered Persons" means: (a) all owners who are natural persons, officers, board members, and employees of Entity, and (b) all contractors who furnish patient care items or services or perform billing or coding functions on behalf of Entity.

5. "Disclosure Program" means a program that enables individuals to disclose through one of several independent reporting paths any potential violations of criminal, civil, or administrative law related to the Federal health care programs, or any issues or questions associated with Entity's policies, conduct, practices, or procedures.

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

7. "Excluded Person" means an individual or entity who is currently excluded from participation in one or more Federal health care programs.

8. "Focus Arrangements" means every Arrangement that:

   a. is between Entity 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, or

   b. is between Entity and any physician (or a physician's immediate family member) (as defined at 42 C.F.R. § 411.351)) who makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to Entity for designated health services (as defined at 42 U.S.C. §1395nn(h)(6)).

   Any Arrangement that satisfies the requirements of 42 C.F.R. § 411.356 (ownership or investment interests), 42 C.F.R. § 411.357(g) (remuneration unrelated to the provision of designated health services), 42 C.F.R. § 411.357(i) (payments by a physician for items and services), 42 C.F.R. § 411.357(k) (non-monetary compensation), 42 C.F.R. § 411.357(m) (medical staff incidental benefits), 42 C.F.R. § 411.357(o) (compliance training), 42 C.F.R. § 411.357(q) (referral services), 42 C.F.R. § 411.357(s) (professional courtesy), or 42 C.F.R. § 357(u) (community-wide health information systems), shall not be considered a Focus Arrangement for purposes of this CIA, provided that Entity maintains sufficient documentation to demonstrate compliance with the applicable exceptions to 42 U.S.C. § 1395nn (Physician Self-Referral Law). This documentation shall be made available to OIG upon request.

9. "GAI" means Generative Artificial Intelligence.

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

11. "Renewed Focus Arrangement" means a Focus Arrangement that the parties agree to renew or that automatically renews at the end of the Focus Arrangement period.

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

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

14. "Training Plan" means a plan that meets the requirements of Section III.C.1.

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

16. "Timely Written Request" is defined as a request in writing received by OIG at least one day prior to the date on which any act is due to be performed or any notification or report is due to be filed.

III. COMPLIANCE PROGRAM REQUIREMENTS

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

A. Compliance Program Structure and Oversight.

1. *Compliance Officer*.

a. Within 90 days after the Effective Date, Entity shall appoint a Compliance Officer who shall be an employee and who shall report directly either to the Chief Executive Officer of Entity or to the Board of Entity. The Compliance Officer shall have direct and independent access to the Board at any time. The Compliance Officer shall have sufficient stature within the Entity to interact as an equal of all other leaders who report to the CEO or directly to the Board.

b. The Compliance Officer shall not lead or report to Entity's legal or financial functions and shall not provide Entity with legal or financial advice. The Compliance Officer also shall not be responsible, either directly or indirectly, for the delivery of health care items and services, billing and coding, claims submission, medical review, administrative appeals, or contracting.

c. The Compliance Officer shall be responsible for:

i. Overseeing and monitoring the implementation and operation of the compliance program,

ii. Advising the CEO, Board, and other executive and senior leaders on compliance risks facing Entity, compliance risks related to strategic and operational decisions of Entity, and the operation of Entity's compliance program,

iii. Chairing the Compliance Committee,

iv. Reporting to the Board at least quarterly on the implementation, operation, and needs of the compliance program, the compliance risks Entity faces, the methods through which Entity is addressing or can address those risks, and all the reporting requirements of this CIA,

v. Developing and implementing policies, procedures, processes, and programs designed to ensure compliance with the requirements set forth in this CIA,

vi. Revising the compliance program periodically in light of changes in the needs of the organization, applicable law, and policies and procedures of third-party payors,

vii. Coordinating with Human Resources to ensure that all directors, owners, employees, and contractors, are screened before appointment or engagement and monthly thereafter against the Exclusion Lists,

viii. Coordinating with other relevant Entity components (e.g., Internal Audit, Risk, Quality) to develop work plans for reviewing, monitoring, and auditing compliance risks,

ix. Monitoring the day-to-day compliance activities engaged in by Entity, and

x. Performing other duties related to the Entity's compliance program.

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

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

2. *Compliance Committee*.

a. Within 90 days after the Effective Date, Entity shall appoint a Compliance Committee to aid and support the Compliance Officer in implementing, operating, and monitoring the Compliance Program.

b. The Compliance Committee shall be chaired by the Compliance Officer.

c. The Compliance Committee shall include, at minimum, relevant leaders of both operational and supporting departments such as billing and coding, clinical and medical, finance, internal audit, information technology, health information management, artificial intelligence, human resources, legal, quality, risk management, sales and marketing, and other operational leaders. All members shall have the authority and ability to speak for the department they represent.

d. The Compliance Committee shall be responsible for, among other things,

i. Analyzing the legal and regulatory requirements applicable to the Entity,

ii. Analyzing, developing, and annually reviewing the policies and procedures required by Section III.B,

iii. Monitoring and recommending internal systems and controls,

iv. Assessing education and training needs and effectiveness, including reviewing the training required by Section III.C at least annually,

v. Implementing and overseeing the risk assessment process required by Section III.F,

vi. Developing the disclosure program required by Section III.G and promoting compliance reporting, and

vii. Developing and implementing the Transition Plan required by Section III.K.

e. The Compliance Committee shall meet at least quarterly.

3. *Board Oversight*.

a. The Board shall be responsible for the review and oversight of Entity's compliance with Federal health care program requirements, and the requirements of this CIA.

b. The Board must include at least one independent (e.g., non-owner, non-employee, and non-executive) member.

c. The Board shall, at minimum, ensure that:

i. the Compliance Officer and the Compliance Committee have sufficient authority, independence, and resources to perform the requirements of Sections III.A.1 and III.A.2,

ii. the Board has sufficient oversight to ensure the effectiveness of Entity's compliance program, including the performance of the Compliance Officer and the Compliance Committee,

iii. the Board periodically evaluates the effectiveness of the Compliance Committee's risk assessment process,

iv. the Board meets at least quarterly to review and oversee the Compliance Program and the performance of the Compliance Officer and the Compliance Committee, (e.g., meeting with the Compliance Officer and meeting in executive session with the Compliance Officer without Entity leaders, counsel, or employees present), and

v. adopt a resolution after the end of each Reporting Period, signed by each member of the Board, regarding its review and oversight of Entity's compliance with Federal health care program requirements and the requirements of this CIA.

The resolution shall include at minimum the following language:

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

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

Information relied upon by the Board to sign the Resolution

shall be made available to OIG upon request.

4. *Board Compliance Expert*.

   a. Within 90 days after the Effective Date, 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 Entity's compliance program for the Second and Fourth Reporting Periods of the CIA.

   b. *Independence.* The Compliance Expert must not be employed or engaged by Entity and must not have a current or prior relationship to Entity that would cause a reasonable person to question the Compliance Expert's objectivity in performing the review.

   c. *Written Report*. The Compliance Expert shall prepare a written report (Compliance Expert Report) that includes a description of the review and any recommendations with respect to Entity's compliance program.

   d. *Board Response.* The Board shall review the Compliance Expert Report as part of its review and oversight of Entity's compliance program. The Board shall prepare a written response to the Compliance Expert Report, with corrective action plan(s) related to any report recommendations.

   e. *Certification of Independence*. Each Compliance Expert Report must be accompanied by a certification from the Compliance Expert that it does not have a prohibited relationship with Entity as described in Section III.A.4.b. The certification must include a summary of any current or prior relationship between the Compliance Expert and Entity.

   f. *Records*. 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.

5. *Management Certifications.*

   a. Certifying Covered Persons shall monitor compliance within the divisions or departments for which they are responsible and annually certify that the applicable Entity division or department is in compliance with applicable Federal health care program requirements and the requirements of this CIA. Certifying Covered Persons shall draw from sources within their area of responsibility (e.g., departmental metrics, interactions with department

employees, knowledge gained from exercise of responsibility) to complete their certification.

b. For each Reporting Period, each Certifying Covered Person shall certify as follows:

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

Any exceptions that would otherwise prevent the Certifying Covered Person from providing this certification shall be noted in writing below the certification. If, despite this, any Certifying Covered Person is unable to provide this certification, the Certifying Covered Person shall provide a written explanation of the reasons why he or she is unable to provide the certification.

B. Written Standards. Within 90 days after the Effective Date, Entity shall develop and implement written policies and procedures (Policies and Procedures) that address the following:

1. Entity's compliance program,

2. the requirements of any Federal health care program in which Entity participates or through which it receives payment, directly or indirectly,

3. the requirements of 42 U.S.C. § 1320a-7b(b) (the Anti-Kickback Statute) and 42 U.S.C. § 1395nn (the Physician Self-Referral Law),

4. the requirements set forth in Section III.D, and

5. the identification, quantification, and repayment of Overpayments.

Entity shall make available all Policies and Procedures to Covered Persons, shall enforce its Policies and Procedures, and shall make compliance with its Policies and Procedures an element of evaluating the performance of all Covered Persons. All Policies and Procedures shall be made available to OIG upon request.

C. Training and Education.

1. *Training Plan.* Within 90 days after the Effective Date, Entity shall develop a Training Plan that includes the following information: (a) training topics, (b) categories of personnel required to attend each training session, (c) length of the training session(s), (d) schedule for training, and (e) format of the training. The Training Plan shall be a written plan developed based on the needs and risks of Entity. The Training Plan shall outline the steps Entity will take to ensure that Entity's personnel receive training on a periodic basis during the term of the CIA.

2. *Covered Persons Training.* Covered Persons shall be trained regarding (a) Entity's CIA requirements, (b) Entity's compliance program, (c) the requirements of any Federal health care program in which Entity participates or through which it receives payment, directly or indirectly, and (d) the requirements of 42 U.S.C. § 1320a-7b(b) (the Anti-Kickback Statute) and 42 U.S.C. § 1395nn (the Physician Self-Referral Law).

3. *Arrangements Covered Persons Training.* Arrangements Covered Persons shall be trained regarding (a) Arrangements that potentially implicate the Anti-Kickback Statute or the Physician Self-Referral Law, as well as the regulations and other guidance documents related to these statutes, (b) Entity'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, (c) the personal obligation of each individual involved in the development, approval, management, or review of Entity's Arrangements to know the applicable legal requirements and Entity's policies and procedures, (d) the legal sanctions under the Anti-Kickback Statute and the Physician Self-Referral Law, and (e) examples of violations of the Anti-Kickback Statute and the Physician Self-Referral Law.

4. *Compliance Committee Training.* Within 90 days after the Effective Date, the Compliance Committee shall receive training regarding the Compliance Committee's duties and responsibilities and Entity's expectation of them in their role as a Compliance Committee member. New Compliance Committee members shall receive this training within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later.

5. *Board Training*. Within 90 days after the Effective Date, Board members shall receive training regarding their responsibilities for corporate governance and review and oversight of the compliance program. The training shall address the specific responsibilities of health care board members, including the risks, oversight areas, and approaches to

conducting effective oversight of a health care entity, and shall include a discussion of the OIG's guidance on board member responsibilities. Each Board member shall also receive the training described in Section III.C.1.

New Board members shall receive the training described in this Section III.C.5 within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later. The Compliance Committee shall review the Board training at least annually and update the Board training as necessary.

6. *Training Records*. Entity shall make available to OIG, upon request, training materials and records verifying that the training described in this Section III.C has been provided.

D. Compliance with the Anti-Kickback Statute and Physician Self-Referral Law.

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

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

b. the parties to the Focus Arrangement,

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

d. 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,

e. 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),

f. 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),

g. 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),

h. establishing and implementing a written review and approval process for Focus Arrangements, the purpose of which is to ensure that all existing, new, or renewed Focus Arrangements do not violate the Anti-Kickback Statute and Physician Self-Referral Law and that includes at least the following:

i. a legal review of all Focus Arrangements by counsel with expertise in the Anti-Kickback Statute and Physician Self-Referral Law,

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 before the Focus Arrangement is executed or renewed, and during the pendency of the Focus Arrangement as may be appropriate,

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

j. requiring Entity to conduct an audit of Entity's compliance with Sections III.D.1.a-h and III.D.2 on at least an annual basis and to provide a report on the results of such review to the Compliance Committee (a copy of which shall be made available to OIG upon request), and

k. implementing effective corrective actions when suspected violations of the Anti-Kickback Statute and Physician Self-Referral Law are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments 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, Entity shall comply with the following requirements (Focus Arrangements Requirements):

a. ensure that all written Focus Arrangements are signed, if required by law, by Entity 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 remuneration pursuant to the Focus Arrangement, and that Entity 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 comply with applicable laws and regulations including, but not limited to, the Federal Anti-Kickback Statute and the Physician Self-Referral Law.

3. *Records Retention and Access*. Entity 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. *Engagement of Independent Review Organization*. Within 90 days after the Effective Date, Entity shall engage an entity (the "Independent Review Organization" or "IRO") that meets the qualifications outlined in Appendix A to perform the reviews specified in Appendix B.

2. *OIG Review of IRO*. Entity must submit 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, and

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

Within 30 days of OIG receiving the information required by this

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

3. *Access to Records and Personnel.* Entity shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in Appendix B and that all records furnished to the IRO are accurate and complete.

4. *Retention of Records*. Entity shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports exchanged between the IRO and Entity related to the reviews described in Appendix B.

5. *Responsibilities and Limitations*. Nothing in this Section III.E affects Entity'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 False Claims Act, the Anti-Kickback Statute, and/or the Physician Self-Referral Law.

6. *IRO Removal or Termination*.

   a. *By Entity or IRO*. If Entity terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Entity must submit a notice to OIG explaining (a) its reasons for termination of the IRO or (b) the IRO's reasons for its withdrawal, no later than 30 days after termination or withdrawal. Within 60 days of termination or withdrawal of the IRO, Entity must engage a new IRO that meets the requirements of Appendix A and must seek OIG approval of the new IRO in accordance with Section III.E.2.

   b. *By OIG*. If OIG believes the IRO does not possess the qualifications specified in Appendix A, is not independent or objective as described in Appendix A, or has failed to carry out the responsibilities enumerated in Appendix A, OIG shall notify Entity in writing regarding OIG's basis for determining that the IRO has not met the requirements of Appendix A. Entity 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 to resolve the concerns identified. If, following OIG's review of information provided by Entity, OIG determines that the IRO has not met the requirements of Appendix A, OIG shall notify Entity in writing that Entity shall be required to engage a new IRO. Entity must engage a new IRO within 60 days of its receipt of OIG's written notice and follow the

procedures in Section III.E.2. The final determination as to whether Entity must engage a new IRO shall be decided by OIG.

7. *Repayment of Overpayments*. Within 60 days of receiving the report detailed by Appendix B from the Independent Review Organization (IRO), Entity shall repay all identified Overpayments as specified in Appendix B.

F. Risk Assessment Process. Within 90 days after the Effective Date, Entity shall develop and implement a centralized annual risk assessment process to identify and address risks associated with Entity'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 and the entering of Arrangements. The risk assessment process shall be conducted at least annually and shall require Entity to:

1. identify potential risks,

2. assess the severity of the identified risks,

3. evaluate and prioritize the risks,

4. develop and implement work plans or audit plans (as appropriate) related to the identified risk areas, and

5. monitor the effectiveness of the work plans or audit plans in mitigating the risks.

The Compliance Committee shall be responsible for implementation and oversight of the risk assessment process.

G. Disclosure Program. Within 90 days after the Effective Date, Entity shall establish a Disclosure Program.

1. *Reporting Options*. The Disclosure Program's independent reporting paths shall include, at minimum, the option to disclose at any time (a) directly to the Compliance Officer or (b) through a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained, and which shall be operated under the direction and control of the Compliance Officer. Entity shall not require Covered Persons to communicate with a manager or other person before using the Disclosure Program.

2. *Nonretaliation*. The Disclosure Program shall prohibit retaliation against individuals for use of the Disclosure Program and Entity shall not retaliate against individuals for use of the Disclosure Program.

3. *Publication*. Entity shall publicize the existence of the Disclosure Program (e.g., via periodic e-mails, by posting the information on a website or in prominent common areas).

4. *Disclosure Log*. The Compliance Officer (or designee) shall record all disclosures (whether or not related to a potential violation of criminal, civil, or administrative law related to the Federal health care programs and regardless of the independent reporting path used) in a Disclosure Log within three days of receipt by the Compliance Program. The Disclosure Log shall include the following information: (a) a factual summary of each disclosure received (whether anonymous or not), (b) the date the disclosure was received, (c) the individual or department responsible for reviewing the disclosure, (d) the status of the review, (e) a description of the investigation's findings, (f) any corrective action taken in response to the review, (g) any policy, process, or other remedial changes made as a result of the investigation, (h) the date the disclosure was resolved, and (i) any resulting referral or disclosure to Federal or State authorities.

5. *Review of Disclosures*. The Compliance Officer (or designee) shall conduct a review of each disclosure received through the Disclosure Program, including gathering relevant information from the disclosing individual, and shall ensure that appropriate follow-up is conducted.

6. *Disclosure Oversight*. The Compliance Officer shall regularly share information about reports received through the Disclosure Program and investigations conducted with the Compliance Committee, the CEO, and the Board.

H. Excluded Persons.

1. *Screening Requirements*. Entity shall:

   a. Screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Excluded Persons, and

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

2. *Removal Requirement*. If Entity has actual notice that a Covered Person has become an Excluded Person, Entity shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid for in whole or part, directly or indirectly, by any Federal health care program(s) from which the Covered Person has been excluded, at least until such time as the Covered Person is reinstated into participation

in such Federal health care program(s). Items or services furnished, ordered, or prescribed by Excluded Persons are not payable by Federal health care programs and Entity may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an Excluded Person regardless of whether Entity meets the requirements of Section III.H.

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

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

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

a. a complete description of all details relevant to the Reportable Event, including, at minimum:

i. the types of claims, transactions, or other conduct giving rise to the Reportable Event,

ii. the period during which the conduct occurred,

iii. the Entity's investigation of the conduct,

iv. the root cause or causes of the conduct, and

v. the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event,

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

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

d. a description of the steps taken by Entity to identify and quantify any Overpayments, and

e. a description of Entity's actions taken to correct the Reportable Event, address the root cause(s) to prevent it from recurring, and strengthen any identified areas of vulnerability.

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

Any Reportable Event that involves solely a probable violation of the Physician Self-Referral Law should be submitted by Entity to CMS through the self-referral disclosure protocol (SRDP) with a copy to OIG. However, if Entity identifies a probable violation of the Physician Self-Referral Law and repays the applicable Overpayment directly to the CMS contractor, then Entity is not required by this Section III.J to submit the Reportable Event to CMS through the SRDP, but shall provide OIG with a copy of the repayment documentation.

2. *Excluded Person.* The report to OIG shall include:

a. the identity of the Excluded Person and the job duties performed by the Excluded Person,

b. the dates of the Excluded Person's employment or contractual relationship,

c. the Overpayment amount, which for a Covered Person who provided items or services that are not billed separately to Federal health care programs shall be based on the Federal payor mix; if using the Federal payor mix, the Reportable Event must include a separate calculation for each Federal health care program,

d. a description of the Exclusion Lists screening that Entity completed before and/or during the Excluded Person's employment or contract and any flaw or breakdown in the screening process that led to the hiring or contracting with the Excluded Person,

e. a description of how the Excluded Person was identified, and

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

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

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

IV. SUCCESSOR LIABILITY

A. Sales and Purchases.

1. *Sales*. If, after the Effective Date, Entity proposes to 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, then the CIA shall be binding on the purchaser.

2. *Purchases*. If, after the Effective Date, Entity proposes to 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 new business, business unit, or location (and all Covered Persons at each new business, business unit, or location).

B. Notification Requirements. Entity shall notify OIG in writing of any such sale, purchase, or establishment within 30 days following the closing of the transaction.

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

V. IMPLEMENTATION REPORT AND ANNUAL REPORTS

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

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

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

3. the names of the Board members who are responsible for satisfying the Board compliance requirements described in Section III.A.3, and identities of the Board member(s) who are independent,

4. For the Compliance Expert required by Section III.A.4 : (a) identity, address, and phone number, (b) information to demonstrate the individual's or entity's expertise in compliance with Federal health care program requirements, and (c) a certification from the Compliance Expert that they do not have a current or prior relationship to Entity that would cause a reasonable person to question the Compliance Expert's objectivity in performing the review,

5. the names and positions of the Certifying Covered Persons required by Section III.A.5,

6. a list of the Policies and Procedures required by Section III.B,

7. the Training Plan required by Section III.C.1 and descriptions of the Compliance Committee training required by Section III.C.4 and the Board training required by Section III.C.5 (including a summary of the topics covered, the length of the training, and when the training was provided),

8. 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.h, (c) the tracking and monitoring procedures and other Focus Arrangements Procedures required by Section III.D.1 and (d) the process for complying with Section III.D.2,

9. the IRO information required by Section III.E.2,

10. a description of the risk assessment process required by Section III.F,

11. a description of the Disclosure Program required by Section III.G,

12. a description of the Excluded Persons screening and removal process required by Section III.H,

13. a list of all arrangements entered into for the purpose of complying with the CIA, including the identity of the other party(ies) and the functions they will perform,

14. a description of Entity's corporate structure, including identification of any individual owners, any parent and sister companies, and their respective lines of business,

15. a list of all of Entity's locations and the corresponding name under which each location is doing business, and

16. certifications 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, Entity has implemented and is in compliance with all of the requirements of this CIA,

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

    c. to the best of his or her knowledge, Entity has fulfilled the requirements for new or 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.

B. Annual Reports. Entity shall submit to OIG a written report (Annual Report) for each of the five Reporting Periods. Annual Reports must be received by OIG no later than 60 days after the end of the applicable Reporting Period. Each Annual Report shall include, at minimum, the following information:

1. any change in the identity, position description, or noncompliance job responsibilities of the Compliance Officer required by Section III.A.1,

2. a current list of the Certifying Covered Persons required by Section III.A.5 and any changes made during the Reporting Period to the Certifying Covered Persons,

3. a current list of the members of the Compliance Committee required by Section III.A.2 and any changes made during the Reporting Period to the Compliance Committee members,

4. the dates of each meeting of the Compliance Committee required by Section III.A.2 (copies of the meeting minutes shall be made available to OIG upon request),

5. a current list of the Board members who are responsible for satisfying the Board compliance requirements required by Section III.A.3 and any changes made during the Reporting Period to the Board members,

6. the dates of each report made by the Compliance Officer to the Board required by Section III.A.1 (written documentation of such reports shall be made available to OIG upon request),

7. the Board resolution required by Section III.A.3,

8. a copy of the Compliance Expert's Report required by Section III.A.4.c and the certification from the Compliance Expert required by Section III.A.4.e,

9. the Board's response to the Compliance Expert Report required by Section III.A.4.d, with corrective action plan(s) related to any report recommendations (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),

10. the certifications of Certifying Covered Persons required by Section III.A.5,

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

12. a description of any changes to the Training Plan required by Section III.C.1, and a summary of all training furnished to Covered Persons and Board members during the Reporting Period, including the details required by Section III.C.1,

13. a description of any changes to (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.h, (c) the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1 and (d) the process for complying with Section III.D.2,

14. a complete copy of all reports prepared pursuant to Section III.E and a certification of independence from the IRO as specified in Appendix B,

15. Entity's response to the reports prepared pursuant to Section III.D, along with corrective action plan(s) related to any issues raised by the reports, and confirmation of Entity's commitment to timely provide information required by Section IV of Appendix B,

16. a description of any changes to the risk assessment process required by Section III.F, including the reason(s) for such changes,

17. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) risk areas identified, (b) work plans and internal audit plans developed, (c) internal

audits performed, (d) corrective action plans developed in response to internal audits, and (e) steps taken to track the implementation of the work plans and corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request,

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

19. a description of any changes to the Excluded Persons screening and removal process required by Section III.H, including the reason(s) for such changes,

20. a summary of any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.I that includes a description of the allegation(s), the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding,

21. a summary of all Reportable Events required to have been reported pursuant to Section III.J during the Reporting Period,

22. in the fourth Annual Report, a copy of the Transition Plan required by Section III.K,

23. a summary of all audits conducted during the applicable Reporting Period, including but not limited to those conducted by Entity (using either internal or external auditors), Medicare or state Medicaid program contractors, Part C Plans, Medicaid Managed Care Organizations, or government entities or contractors, involving a review of Federal health care program claims. The summary shall include a description of the audit's findings and the Entity's response and corrective action plan (including information regarding any Federal health care program refunds) relating to the audit findings,

24. a summary of all other overpayments refunded to the Federal Health Care Programs during the Reporting Period,

25. a description of all changes to the most recently provided list of Entity's locations (including addresses) as required by Section V.A.15,

26. a description of any changes to Entity's corporate structure, any parent and sister companies, and their respective lines of business,

27. A statement indicating whether the Entity used (or did not use) GAI in connection with its compliance program or the preparation of the Annual Report. If the Entity used GAI, the Entity should explain how GAI was used and verify that it checked the accuracy of any portion of the Annual Report drafted or assisted by GAI, and

28. certifications by the Compliance Officer, Chief Executive Officer, and any individual owner that:

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

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

    c. to the best of his or her knowledge, Entity has fulfilled the requirements for new or renewed Focus Arrangements under Section III.D.2 of the CIA,

    d. to the best of his or her knowledge, Entity provided complete and accurate documentation to the IRO,

    e. he or she has reviewed the report, has made reasonable inquiry regarding its content, and believes that the information in the report is accurate and truthful, and

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

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Telephone: 202.619.2078
Email Address: officeofcounsel@oig.hhs.gov

Entity:

Ann Ford
Interim Chief Compliance Officer
Telephone: 312.493.7815
Email Address: compliance@kinexmedical.com and
Ann_Ford@kinexmedical.com

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

VII. OIG 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 Entity's books, records, and other documents and supporting materials, and conduct announced or unannounced on-site reviews of any of Entity's locations, for the purpose of evaluating: (a) Entity's compliance with the requirements of this CIA and (b) Entity's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Entity to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction.

For purposes of this provision, OIG or its duly authorized representative(s) may interview any of Entity's Covered Persons 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. Entity shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Entity's Covered Persons may elect to be interviewed with or without a representative of Entity present.

VIII. DOCUMENT RETENTION AND DISCLOSURES

A. Document and Record Retention. Entity 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.

B. Disclosures. Entity 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. Entity shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Entity prior to any release by OIG of information submitted by Entity pursuant to this CIA and identified upon submission by Entity as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Entity shall have the rights set forth at 45 C.F.R. § 5.42(a).

IX. EXTENSIONS

Entity may submit a Timely Written Request for an extension of time to perform any act or file any notification or report required by this CIA.

X. BREACH PROVISIONS

A. Stipulated Penalties. OIG may assess:

1. A Stipulated Penalty of up to $2,500 for each day Entity fails to comply with any of the following CIA Sections:

III.A Compliance Program Structure and Oversight,

III.B Written Standards,

III.C Training and Education,

III.D Compliance with the Anti-Kickback Statute and Physician Self-Referral Law,

III.E Review Procedures,

III.F Risk Assessment Process,

III.G Disclosure Program,

III.H Excluded Persons,

III.I Notification of Government Investigation or Legal Proceeding,

III.J Reportable Events,

III.K Transition Plan,

IV Successor Liability,

V Implementation Report and Annual Reports,

VII OIG Rights,

VIII Document and Record Retention,

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

B. Stipulated Penalties and Timely Extension Requests. If OIG grants a 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 Entity fails to meet the revised deadline set by OIG. If OIG denies 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 Entity receives OIG's written denial of such request or the original due date, whichever is later.

C. Payment of Stipulated Penalties.

1. *Demand Letter*. If OIG determines that a basis for Stipulated Penalties under Section X.A exists, OIG shall notify Entity of: (a) Entity's failure to comply and (b) OIG's demand for payment of Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Payment*. Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter within 20 days after the date of the Demand Letter.

3. *Disputing Stipulated Penalties.* Entity may request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance within 20 days of the Demand Letter, pursuant to the agreed upon provisions set forth below in Section X.E.

D. Exclusion for Material Breach.

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

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

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

c. failure to comply with Section III.D,

d. failure to comply with Section III.E,

e. failure to comply with Section III.J,

f. failure to comply with Section V,

g. failure to respond to a Demand Letter in accordance with Section X.C,

h. a false statement or false certification made to OIG by or on behalf of Entity under this CIA,

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

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

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

3. *Response to Notice*. Entity shall have 20 days from the date of the Notice of Material Breach and Intent to Exclude to submit any information and documentation for OIG to consider before it makes a final determination regarding exclusion.

4. *Exclusion Letter*. If OIG determines that exclusion is warranted, OIG shall notify Entity in writing of its determination to exclude Entity. (This letter shall be referred to as the "Exclusion Letter.") Subject to the Dispute Resolution provisions in Section X.E, the exclusion shall go into effect 20 days after the date of the Exclusion Letter. The effect of the exclusion shall be that no Federal health care program payment may be made for any items or services furnished, ordered, or prescribed by Entity, including administrative and management services, except as stated in regulations found at 42 C.F.R. § 1001.1901(c). The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Entity may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution.

1. *Review Rights*. Upon OIG's issuing a Demand Letter or Exclusion Letter to Entity, and as an agreed-upon remedy for the resolution of disputes arising under this CIA, Entity shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the DAB, in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21, but only to the extent this CIA does not provide otherwise. Notwithstanding the language in 42 C.F.R. § 1005: (a) the request for a hearing shall be made within 20 days after the date of the Demand Letter or Exclusion Letter and (b) no discovery shall be available to the parties. The standard of proof will be judged by a preponderance of the evidence, as provided in 42 C.F.R. § 1005.15(d). Subject to the burdens allocated below in Section X.E.2 and X.E.3, Entity shall bear the burden of proof with respect to any affirmative defenses and OIG shall bear the burden of proof with respect to all other issues.

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 Entity was in full and timely compliance with the requirements of this CIA for which OIG demands payment and (b) the period of noncompliance. Entity shall have the burden of proving its full and timely compliance. If the ALJ upholds the OIG's determination that Entity has breached this CIA and orders Entity to pay Stipulated Penalties, Entity must (a) come into compliance with the requirement(s) that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 20 days after the ALJ issues a decision, unless Entity properly and timely requests review of the ALJ decision by the DAB. If the ALJ decision is properly and timely appealed to the DAB and the DAB upholds the determination of OIG, Entity must (a) come into compliance with the requirement(s) that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 20 days after the DAB issues its decision.

3. *Exclusion Review*. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be whether Entity was in material breach of this CIA. Entity shall have the burden of proving its full and timely compliance. If the ALJ sustains the OIG's determination of material breach, the exclusion shall take effect 20 days after the ALJ issues the decision. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Entity 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 Entity, Entity shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. The parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA and Entity agrees not to seek additional review of the DAB's decision (or the ALJ's decision if not appealed) in any judicial forum.

XI. GENERAL TERMS AND CONDITIONS

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

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

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

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

ON BEHALF OF KINEX MEDICAL COMPANY, LLC

/Michael A. Buckholdt/ 2/24/2026
MICHAEL BUCKHOLDT DATE
President
Kinex Medical Company, LLC

/Mark Kasten/ 2/25/2026
MARK A. KASTEN DATE
Counsel for Kinex Medical Company, LLC

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

/Susan Gillin/ 2026.02.27
SUSAN E. GILLIN DATE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

/Tamar Terzian/ March 2, 2026
TAMAR V. TERZIAN DATE
Senior Counsel
Office of Inspector General
U.S. Department of Health and Human Services

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION REQUIREMENTS

I. Independence and Objectivity. The Independent Review Organization (IRO) must be able to perform the reviews specified in Appendix B in a professionally independent and objective fashion as defined in the most recent Generally Accepted Government Auditing Standards (Yellow Book) issued by the U.S. Government Accountability Office.

II. Qualifications. The IRO shall assign:

A. individuals to conduct the Arrangements Review who are knowledgeable in the requirements of the Anti-Kickback Statute and the Physician Self-Referral Law and the regulations and other guidance documents related to these statutes,

B. individuals who possess expertise in fair market valuation issues or shall have the ability to associate a valuation expert to assist in conducting the transactions review component of the Arrangements Review,

C. sufficient staff and resources to conduct the Arrangements Review in a timely manner.

III. Responsibilities. The IRO shall:

A. perform each Arrangements Review in accordance with the requirements of the CIA and Appendix B,

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

C. prepare timely, clear, well-written reports that include all the information required by Appendix B, and

D. retain and make available to OIG, upon request, all Work Papers (as defined in Appendix B), supporting documents, correspondence, and draft reports exchanged between the IRO and Entity.

IV. Assertions of Privilege. Entity shall not assert claims of attorney-client privilege to avoid disclosing to OIG information related to or resulting from the IRO's engagement. Entity's engagement letter with the IRO shall include a provision stating that the IRO agrees not to assert claims of work product privilege to avoid disclosing to OIG information related to or resulting from its engagement.

APPENDIX B

ARRANGEMENTS REVIEW REQUIREMENTS

I. Arrangements Review. For each Reporting Period the IRO shall review Entity's Arrangements and shall prepare an Arrangements Review Report to describe its findings as detailed in Section II of this Appendix.

A. *Definitions*.

1. "Work Papers" means the information, worksheets, and other pertinent material compiled or created by the IRO while conducting the Arrangements Review. Work Papers encompasses all documents and other media containing the evidence used as a basis for the IRO's conclusions. Work Papers should document the procedures applied, the information obtained, the tests performed, and the conclusions reached sufficient to allow verification by any reviewing third-party.

B. *Description of Review.* The Arrangements Review shall consist of a review Entity's systems, processes, policies, and procedures relating to the initiation, review, approval, and tracking of Arrangements (Systems Review) as well as a review of Entity's Arrangements transactions (Transactions Review).

C. *Transactions Review Sample.* The IRO shall select a random sample of 50 Focus Arrangements that were entered into or renewed by Entity during the Reporting Period.

D. *Other Requirements*.

1. Supplemental Materials. The IRO shall request all documentation required for its Arrangements Review and Entity shall furnish such documentation to the IRO prior to the IRO initiating its review. If the IRO receives any supplemental documentation from Entity after the IRO has completed its initial review (Supplemental Materials), the IRO shall include the following in the Arrangements Review Report:

a. a description of the Supplemental Materials,

b. the date the Supplemental Materials were received,

c. the IRO's reason(s) for accepting or rejecting the Supplemental Materials, and

d. the relative weight the IRO gave to the Supplemental Materials in its review.

2. Retention of Work Papers. The IRO shall maintain in its possession and control all Work Papers associated with any Arrangements Review performed for a

period of six years from the Effective Date of this Agreement or until Entity is notified of the termination of this Agreement by OIG, whichever occurs first.

II. Arrangements Review Report. The IRO shall prepare an Arrangements Review Report that includes the following information:

A. *Systems Review*. A Systems Review shall be performed for the first and fourth Reporting Periods. If there are material changes to Entity's Arrangements systems, processes, policies, and procedures, then a Systems Review shall be performed for the Reporting Period in which such changes were made in addition to the Systems Review for the first and fourth Reporting Periods. For each Systems Review conducted, the IRO shall prepare a Systems Review Report as described in Section III.

B. *Transactions Review*. A Transactions Review shall be performed for each Reporting Period. For each Transactions Review conducted, the IRO shall prepare a Transactions Review Report as described in Section IV.

C. *Use of Artificial Intelligence*. The Arrangements Review Report should indicate whether the IRO used GAI in connection with its review or drafting of the report. If the IRO used GAI, the Arrangements Review should explain how GAI was used and include a certification that the IRO verified the accuracy of the review and any portion of the report drafted or assisted by GAI.

D. *Credentials*. The names and credentials of the individuals who conducted the Systems Review and the Transactions Review.

E. *Certification of Independence*. Each Arrangements Review Report must be accompanied by a current certification of independence. The certification must indicate that the IRO has (a) evaluated its professional independence and objectivity as defined in the most recent Generally Accepted Government Auditing Standards (Yellow Book) issued by the U.S. Government Accountability Office, and (b) concluded that it is, in fact, independent and objective. The certification must also include a summary of all current and prior engagements between Entity and the IRO.

III. Systems Review Report. Each Systems Review Report shall include the following information:

A. *Systems Review Methodology*. A description of the documentation (including policies) reviewed and personnel interviewed.

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

2. Sources of Data. A full description of the documentation and other information relied upon by the IRO in performing the Systems Review.

3. Review Protocol. A narrative description of how the Systems Review was conducted and what was evaluated.

4. Supplemental Materials. The information regarding any Supplemental Materials required by Section I.D.1.

B. *Description of Entity's Arrangements Systems, Policies, Processes, and Procedures*. A detailed description of Entity's systems, policies, processes, and procedures for:

1. creating and maintaining a centralized tracking system for all existing, new and renewed Focus Arrangements (Focus Arrangements Tracking System), including a detailed description of the information captured in the Focus Arrangements Tracking System,

2. identifying the parties to the Focus Arrangement,

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

4. 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,

5. 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 or were otherwise involved with the fair market value determination(s),

6. 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),

7. 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),

8. 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,

9. 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 Entity, 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 and Physician Self-Referral Law,

10. implementing effective responses when suspected violations of the Anti-Kickback Statute and Physician Self-Referral Law are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments when appropriate, and

11. ensuring that all new and renewed Focus Arrangements comply with the Focus Arrangements Requirements set forth in Section III.D.2 of the CIA.

C. Findings. Findings and supporting rationale regarding weaknesses in Entity's systems, processes, policies, and procedures relating to Arrangements described in Section III.B.

D. Recommendations. Recommendations to improve Entity's systems, policies, processes, or procedures relating to Arrangements described in Section III.B.

IV. Transactions Review Report. Each Transactions Review Report shall include the following information:

A. *Transactions Review Methodology*.

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

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

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

4. Supplemental Materials. The information regarding any Supplemental Materials required by Section I.D.1.

B. *Statistical Sampling Documentation*. A description or identification of the statistical sampling software package used by the IRO.

C. *Transactions Review Findings*.

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

a. that the Focus Arrangement is maintained in Entity's centralized tracking system in a manner that permits the IRO to identify (i) the items

described in Sections III.D.1.b-h of the CIA, (ii) 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 (iii) 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. 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. that the remuneration related to the Focus Arrangement has been determined in accordance with Entity'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. that the business need or business rationale for the Focus Arrangement is specified and is consistent with Entity's policies and procedures,

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

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

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

2. Failure Analysis. For every Focus Arrangement for which the IRO cannot verify compliance with each of the requirements specified in Section IV.C.1, the IRO shall identify and review:

a. *System or Process Failures*. 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.

b. *Administration Failures*. The documents and communications implementing and administering the Focus Arrangement that was non-compliant. This review will evaluate whether the non-compliance led to a potential violation of the Federal Anti-Kickback Statute or Physician Self-Referral Law.

3. Remediation. If the IRO cannot verify compliance with each of the applicable requirements specified in Section IV.C.1 with respect to at least 90% of the Focus Arrangements subject to the Transactions Review, then the IRO shall perform a review focused on the identification and remediation of any processes that led to the non-compliance.