

**CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
INTEGRATED ONCOLOGY NETWORK HOLDINGS, LLC;  
INTEGRATED ONCOLOGY NETWORK, LLC;  
ION SIGHTLINE HOLDINGS, LLC; SIGHTLINE HEALTH, LLC;  
SIGHTLINE DEVELOPMENT COMPANY, LLC;  
SIGHTLINE ONCOLOGY SERVICES, LLC; SL MED CENTER IMRT, LLC;  
SIGHTLINE MEDICAL CENTER IMRT HOLDINGS, LLC;  
SL LUBBOCK IMRT, LLC; SIGHTLINE LUBBOCK IMRT HOLDINGS, LLC;  
SL WEST HOUSTON IMRT, LLC; SIGHTLINE WEST HOUSTON IMRT  
HOLDINGS, LLC; SL WEST HILLS IMRT, LLC; SIGHTLINE WEST HILLS  
IMRT HOLDINGS, LLC; SL SANTA MONICA IMRT, LLC;  
SIGHTLINE SANTA MONICA IMRT HOLDINGS, LLC;  
SL SEATTLE IMRT, LLC; SIGHTLINE SEATTLE IMRT HOLDINGS, LLC;  
SL DENVER LEASING, LLC; SIGHTLINE DENVER LEASING HOLDINGS,  
LLC; SL COLORADO SPRINGS LEASING, LLC; SIGHTLINE COLORADO  
SPRINGS HOLDINGS, LLC; SL KANSAS CITY LEASING, LLC; SIGHTLINE  
KANSAS CITY HOLDINGS, LLC; SL NORTH TEXAS LEASING, LLC; AND  
SIGHTLINE NORTH TEXAS LEASING HOLDINGS, LLC**

**I. PREAMBLE**

Integrated Oncology Network Holdings, LLC; Integrated Oncology Network, LLC; ION SightLine Holdings, LLC; SightLine Health, LLC (“SightLine Health”); SightLine Development Company, LLC (“SightLine Development”); SightLine Oncology Services, LLC (SightLine Oncology”); SL Med Center IMRT, LLC; Sightline Medical Center IMRT Holdings, LLC; SL Lubbock IMRT, LLC; Sightline Lubbock IMRT Holdings, LLC; SL West Houston IMRT, LLC; Sightline West Houston IMRT Holdings, LLC; SL West Hills IMRT, LLC; Sightline West Hills IMRT Holdings, LLC; SL Santa Monica IMRT, LLC; Sightline Santa Monica IMRT Holdings, LLC; SL Seattle IMRT, LLC; Sightline Seattle IMRT Holdings, LLC; SL Denver Leasing, LLC; Sightline Denver Leasing Holdings, LLC; SL Colorado Springs Leasing, LLC; Sightline Colorado Springs Holdings, LLC; SL Kansas City Leasing, LLC; Sightline Kansas City Holdings, LLC; SL North Texas Leasing, LLC; and Sightline North Texas Leasing Holdings, LLC hereby enter into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare,

Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). SL Med Center IMRT, LLC; SL Lubbock IMRT, LLC; SL West Houston IMRT, LLC; SL West Hills IMRT, LLC; SL Santa Monica IMRT, LLC; SL Seattle IMRT, LLC; SL Denver Leasing, LLC; SL Colorado Springs Leasing, LLC; SL Kansas City Leasing, LLC; and SL North Texas Leasing, LLC shall hereafter collectively be referred to as the “SightLine Leasing Companies.” Integrated Oncology Network Holdings, LLC; Integrated Oncology Network, LLC; ION SightLine Holdings, LLC; SightLine Health; SightLine Development; SightLine Oncology; Sightline Medical Center IMRT Holdings, LLC; Sightline Lubbock IMRT Holdings, LLC; Sightline West Houston IMRT Holdings, LLC; Sightline West Hills IMRT Holdings, LLC; Sightline Santa Monica IMRT Holdings, LLC; Sightline Seattle IMRT Holdings, LLC; Sightline Denver Leasing Holdings, LLC; Sightline Colorado Springs Holdings, LLC; Sightline Kansas City Holdings, LLC; Sightline North Texas Leasing Holdings, LLC; and the SightLine Leasing Companies shall hereafter collectively be referred to as “ION.” Contemporaneously with this CIA, ION 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 ION 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) ION’s final annual report; or (2) any additional materials submitted by ION 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:
  - a. involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between: (1) ION and any actual or potential source of health care business or referrals to ION; (2) ION and any actual or potential recipient of health care business or referrals from ION; (3) ION and any actual or potential source of health care business or referrals to a Cancer Center or Health Care Provider that has a Leasing Arrangement or Management

Arrangement (as defined below) with ION; or (4) ION and any actual or potential recipient of health care business or referrals from a Cancer Center or Health Care Provider that has a Leasing Arrangement or Management Arrangement (as defined below) with ION.

- i. 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.
  - ii. The term “recipient of health care business or referrals” shall mean any individual or entity who:
    - (1) receives a referral for the furnishing or arranging for the furnishing of any item or service, or
    - (2) receives business in the form of: (a) a purchase, lease, or order, or (b) an arrangement for or recommendation for 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.
- b. is between ION 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 ION for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6));
  - c. is between ION and any Cancer Center (as defined below); or
  - d. is a Leasing Arrangement, Management Arrangement, Ownership Arrangement, or Other Arrangement (as defined below).
2. “Focus Arrangements” means every Arrangement that:
- a. involves, directly or indirectly, the offer, payment, or provision of anything of value and is between: (1) ION and any actual source or recipient of health care business or

referrals to or from ION or (2) ION and any actual source or recipient of health care business or referrals to or from a Cancer Center or Health Care Provider that has a Leasing Arrangement or Management Arrangement (as defined below) with ION.

- b. is between ION 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 ION for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)); or
- c. is between ION and any Cancer Center (as defined below); or
- d. is a Leasing Arrangement, Management Arrangement, Ownership Arrangement, or Other Arrangement (as defined below).

Notwithstanding the foregoing provisions of Section II.C.2, 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), 42 C.F.R. § 357(u) (community-wide health information systems), or any exception to the prohibitions of 42 U.S.C. § 1395nn enacted following the Effective Date that does not require a written agreement shall not be considered a Focus Arrangement for purposes of this CIA.

- 3. "Covered Persons" includes:
  - a. all owners (including all ION Physician-Investors), officers, directors, and employees of ION; and
  - b. all contractors, subcontractors, agents, and other persons who, for or on behalf of ION, furnish items or services in connection with patient care, or who perform billing, coding, or management functions on behalf of ION excluding vendors whose sole connection with ION is selling or otherwise providing medical supplies or equipment to ION.

4. “Arrangements Covered Persons” includes each Covered Person who is involved with the development, approval, management, review, or execution of ION’s Arrangements.

5. “Cancer Center” means any physician, physician practice, or other entity that leases space or equipment from ION for the treatment of cancer and the provision of related items or services to Federal health care program beneficiaries.

6. “Health Care Provider” means: (1) any individual physician or physician practice; (2) any entity that is a lessee of space or equipment from ION or has entered into a Letter of Intent with ION to become a lessee of space or equipment from ION; or (3) any joint venture in which ION owns an interest that provides cancer services, whether directly or indirectly owned by ION.

7. “ION Physician-Investor” means any Health Care Provider that has an ownership or investment interest in any ION entity, including the SightLine Leasing Companies.

8. “Leasing Arrangement” means any agreement between ION and any individual or entity for the lease of space or equipment for the treatment of cancer and the provision of related items or services to Federal health care program beneficiaries.

9. “Leasing Company” means an entity that leases space or equipment for the treatment of cancer to another individual or entity.

10. “Management Arrangement” means any agreement between ION and any individual or entity for the provision of management services, billing services, collection services, supplies, or marketing related to the treatment of cancer and the provision of related items or services to Federal health care program beneficiaries.

11. “Other Arrangement” means any agreement between ION and any Health Care Provider where ION has actual knowledge that ION Physician-Investors refer to the Health Care Provider.

12. “Ownership Arrangement” means any agreement between ION and any Health Care Provider that owns any percentage, directly or indirectly, whether through shares, membership interests, or other ownership or investment means, of a Leasing Company or other ION entity.

### **III. CORPORATE INTEGRITY OBLIGATIONS**

ION 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, ION 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 ION, shall report directly to the Chief Executive Officer of ION, 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 ION. The Compliance Officer shall be responsible for, without limitation:

- a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements;
- b. making periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of ION, and shall be authorized to report on such matters to the Board of Directors at any time. Written documentation of the Compliance Officer's reports to the Board of Directors shall be made available to OIG upon request;
- c. monitoring the day-to-day compliance activities engaged in by ION as well as any reporting obligations created under this CIA;
- d. reviewing and addressing the implementation and status of the Fair Market Value Reviews and Oversight Process required by Section III.E;
- e. reviewing and addressing the findings made and internal audits conducted as part of the Risk Assessment and Internal Review Process required by Section III.G; and

- f. reviewing and addressing the Financial Tracking Report of Arrangements created as part of the Focus Arrangements Procedures required by Section III.D with the Arrangements Officer, Chief Financial Officer, and Accounts Receivable Department.

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.

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

2. *Arrangements Officer.* Within 90 days after the Effective Date, ION shall appoint an Arrangements Officer and shall maintain an Arrangements Officer for the term of the CIA. The Arrangements Officer shall be an individual who has experience in negotiating contracts, ensuring compliance with the terms of contracts, and ensuring compliance with the Federal health care program requirements in contractual relationships. The Arrangements Officer shall be an employee and shall report directly to the Compliance Officer. The Arrangements Officer shall be responsible for, without limitation:

- a. assisting the Compliance Officer in developing and implementing the policies, procedures, and practices designed to ensure compliance with the Federal health care program requirements in all Arrangements matters;
- b. developing and conducting training for Arrangements Covered Persons who are engaged in or have responsibilities relating to Arrangements;
- c. making periodic (at least monthly) reports regarding Arrangements to the Compliance Officer. Written documentation of the Arrangements Officer's reports to the Compliance Officer shall be made available to OIG upon request;
- d. monitoring the day-to-day Arrangements engaged in by ION;

- e. assisting the Compliance Officer with reviewing and addressing the implementation and status of the Fair Market Value Reviews and Oversight Process required by Section III.E;
- f. assisting the Compliance Officer with reviewing and addressing the findings made and internal audits conducted as part of the Risk Assessment and Internal Review Process required by Section III.G that relate to Arrangements; and
- g. assisting the Compliance Officer with reviewing and addressing the Financial Tracking Report of Arrangements created as part of the Focus Arrangements Procedures required by Section III.D.

3. *Compliance Committee.* Within 90 days after the Effective Date, ION shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer, the Arrangements Officer, and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of ION'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.

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

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

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

- a. meeting at least quarterly to review and oversee ION's compliance program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. submitting to OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period;
- c. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board summarizing its review and oversight of ION's compliance with Federal health care program requirements and the obligations of this CIA; and
- d. in Reporting Periods one, three, and five of the CIA, the Board shall retain an individual or entity with expertise in compliance with Federal health care program requirements (Compliance Expert) to perform a review of the effectiveness of ION's Compliance Program (Compliance Program Review). The Compliance Expert shall create a work plan for the Compliance Program Review and prepare a written report about the Compliance Program Review. The written report (Compliance Program Review Report) shall include a description of the Compliance Program Review and any recommendations with respect to ION's compliance program. The Board shall review the Compliance Program Review Report as part of its review and oversight of ION's compliance program. A copy of the Compliance Program Review report shall be provided to OIG in each Annual Report submitted by ION. In addition, copies of any materials provided to the Board by the Compliance Expert, along with minutes of any meetings between the Compliance Expert and the Board, shall be made available to OIG upon request.

At minimum, the resolution required by Section III.A.4.c shall include the following language:

“The Board of Directors has made a reasonable inquiry into the operations of ION’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, ION 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 ION.

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

5. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain ION employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable ION 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, President, Chief Operating Officer, Chief Development Officer, Chief Financial Officer, Director of Compliance, Arrangements Officer, Director of Operations, Director of Business Development, Vice President of Revenue Cycle, Billing and Collections Manager, and Controller. 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 ION policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] of ION 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.

Additionally, for each Reporting Period, the Chief Executive Officer, Chief Operating Officer, Director of Compliance, and Arrangements Officer shall include in his/her certification the following statements in addition to the above language for all Certifying Employees:

“My responsibilities include ensuring that ION’s Arrangements (as that term is defined in the Corporate Integrity Agreement), and the manner in which ION negotiates, implements, and enforces its Arrangements, and performs under its Arrangements, comply with all applicable Federal health care program requirements, including the Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)) and the Stark Law (42 U.S.C. § 1395nn). During the current Reporting Period, I have monitored the negotiation, implementation, and enforcement of, and performance under, ION’s Arrangements on behalf of ION. I have taken steps to ensure that ION’s Arrangements and the manner in which ION negotiates, implements, and enforces, and performs under its Arrangements comply with all applicable Federal health care program requirements.

During the current Reporting Period, I have taken steps and exercised due diligence to ensure that:

- (1) The terms of every ION Physician-Investor’s investment do not take into account the volume or value of that ION Physician-Investor’s referrals to ION, any Health Care Provider, any Cancer Center, or any individual or entity with which ION has a Leasing Arrangement, Management Arrangement, or Ownership Arrangement;
- (2) ION does not use any means to pressure or influence ION Physician-Investors to refer or influence referrals to ION, any Health Care Provider, any Cancer Center, or any individual or entity with which ION has a Leasing Arrangement, Management Arrangement, or Ownership Arrangement;

- (3) ION has no role in medical decision-making related to individual patients of ION Physician-Investors or individual patients of any Health Care Provider or Cancer Center, including, but not limited to, not recommending treatments, procedures, or other medical courses of action related to individual patients;
- (4) ION does not provide to any ION Physician-Investor information about the volume or value of any other ION Physician-Investor's referrals to ION or to any entity with which ION has a Leasing Arrangement, Management Arrangement, or Ownership Arrangement;
- (5) ION has implemented policies and procedures to ensure that ION does not engage in the conduct described in (1) through (4), above, and Covered Persons have been trained on their individual and collective obligation to comply with these policies and procedures;
- (6) All ION Leasing Arrangements: (a) have rates fixed in advance; (b) are at fair market value; (c) do not include "Additional Time Blocks" or additional payments or compensation that vary with the value or volume of referrals or the value or volume of any item or service for which payment may be made in whole or in part under a Federal health care program; and (d) do not function in a manner that takes into account the value or volume of items, services, or referrals generated by ION or ION Physician-Investors;
- (7) The rental amounts, fees, charges, compensation, or other payment amounts enumerated in all Leasing Arrangements and Management Arrangements are supported by and consistent with fair market valuation reports conducted by independent, objective, and qualified individuals or entities with fair market valuation expertise, in accordance with requirements of Section III.E, below;
- (8) All Ownership Agreements or other agreements between ION and ION Physician-Investors do not include, or were amended within 60 days of the Effective Date so that they do not include, any explicit or implicit provision that ties an ION Physician-Investor's qualification to be an investor to the ION Physician-Investor's ability to refer or induce referrals to any entity with which ION has a Leasing Arrangement or Management Arrangement, including, but not limited to, provisions that strip an ION Physician-Investor of ownership or reduce their ownership interest in the event that the ION Physician-

Investor moves out of the geographic area of the Leasing Company in which they are invested or no longer practices medicine;

- (9) ION has made reasonable efforts to diversify the ownership of each Leasing Company to decrease the percentage of investors who are Health Care Providers in a position to make referrals to a Cancer Center and to decrease the percentage of referrals or business generated by investors in the Leasing Company; and
- (10) T.J. Farnsworth is neither an employee or officer of ION and he did not participate in the management of ION in such capacities and, other than in his capacity as (i) a member of SightLine Health, LLC or (ii) a director of SightLine Health, LLC in which capacity T.J. Farnsworth does not exert affirmative control of SightLine Health, LLC, T.J. Farnsworth was not entitled to participate in an advisory, management, or decision-making role with ION.

I understand that ION has a duty to comply with the Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)), the Stark Law (42 U.S.C. § 1395nn), the regulations, and other guidance documents related to these statutes, and other Federal law independent of the obligations and responsibilities described in the above certification. I further understand that the above certification is not an exclusive list of actions that ION must undertake to comply with the Anti-Kickback Statute, Stark Law, and other Federal laws. To the best of my knowledge, I believe that ION has complied at all times during the Reporting Period with the Anti-Kickback Statute, Stark Law, and other Federal laws. Furthermore, I understand that this certification is being provided to and relied upon by the United States.”

If the Chief Executive Officer, Chief Operating Officer, Director of Compliance, or Arrangements Officer is unable to provide such a certification the Chief Executive Officer, Chief Operating Officer, Director of Compliance, or Arrangements Officer shall provide a written explanation of the reasons why he/she is unable to provide the certification outlined above.

Within 90 days after the Effective Date, ION shall develop and implement a written process for Certifying Employees to follow for the purpose of completing the certifications 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, ION 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 ION'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 42 U.S.C. § 1395nn (Stark Law), 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 or the Stark Law; and
- b. the requirements set forth in Section III.D (Compliance with the Anti-Kickback Statute and Stark Law).

The Policies and Procedures shall be made available to all Covered Persons. Throughout the term of this CIA, ION 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), ION 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, ION shall develop a written plan (Training Plan) that outlines the steps ION will take to ensure that all Covered Persons receive at least annual training regarding ION's CIA requirements and Compliance Program and the applicable Federal health care program requirements, including the requirements of the Anti-Kickback Statute and the Stark Law; and that all Arrangements Covered Persons receive at least annual training regarding: (i) Arrangements and practices (e.g., profit distributions, inaccurate fair market value determinations, discounts, write-offs, debt forgiveness, short-pays, accounts receivable, collection efforts, settlements, and aging of balances) that potentially implicate the Anti-Kickback Statute or the Stark Law, as well as the regulations and other

guidance documents related to these statutes; (ii) ION'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 ION's Arrangements to know the applicable legal requirements and ION's policies and procedures; (iv) the legal sanctions under the Anti-Kickback Statute and the Stark Law; and (v) examples of violations of the Anti-Kickback Statute and the Stark Law.

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. ION shall furnish training to its Covered Persons and Arrangements Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *ION Physician-Investor Training.* Within 120 days after the Effective Date, each ION Physician-Investor shall receive at least one hour of training in addition to the Covered Persons training. The ION Physician-Investor Training shall address the Anti-Kickback Statute, the Stark Law, compliance risk areas specific to physician ownership and investment interests in health care entities, and the information contained in the ION Physician-Investor Certification Statement, below. Each ION Physician-Investor shall be required to complete the Certification Statement immediately following the ION Physician-Investor Training. ION shall retain copies of each ION Physician-Investor's signed Certification Statements, and these copies shall be made available to OIG upon request.

The contents of the ION Physician-Investor Certification Statement shall include the following information, to the extent applicable to the particular recipient:

- a. I, [insert name of ION Physician-Investor], have been trained on the Anti-Kickback Statute, the Stark Law, and compliance risk areas specific to physician ownership and investment interests in health care entities.
- b. Under the Anti-Kickback Statute, I understand it is unlawful to knowingly and willfully solicit or receive any remuneration (including a kickback) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for the furnishing or arranging for the

furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program.

Therefore, I understand I may not solicit or receive any remuneration in exchange for referring a Federal health care program patient to any radiation oncologist, medical practice, cancer treatment facility, or other health care provider that has a contract with a leasing company in which I am an investor, including [insert name of Leasing Company or other ION entity in which physician is an investor].

In addition, I understand I should not be solicited, pressured, or induced to refer patients to any radiation oncologist, medical practice, cancer treatment facility, or other health care provider that has a contract with a leasing company in which I am an investor, including [insert name of Leasing Company or other ION entity in which physician is an investor].

- c. I understand that I am not, and my employees, colleagues, and contractors are not, required to refer patients to any radiation oncologist, medical practice, cancer treatment facility, or other health care provider that has a contract with ION or any leasing company in which I am an investor, including [insert name of Leasing Company or other ION entity in which physician is an investor].
- d. I understand that I am, and my employees, colleagues, and contractors are, free to refer patients to and treat patients at cancer treatment facilities and other health care providers that have no affiliation with ION or any leasing company in which I am an investor, including [insert name of Leasing Company or other ION entity in which physician is an investor].
- e. I understand that ION and its subsidiaries will not take any adverse action of any kind against any physician who is an investor in any ION-affiliated entity who chooses to refer patients to or treat patients at a cancer treatment facility or other health care provider that has no affiliation with ION or any entity with which ION is affiliated.

New ION Physician-Investors shall receive the ION Physician-Investor Training and complete the ION Physician-Investor Certification Statement described above within 30 days after becoming an ION Physician-Investor or within 120 days after the Effective Date, whichever is later.

3. *Board Member Training.* Within 90 days after the Effective Date, each member of the Board of Directors shall receive at least two hours of training. This training shall address the corporate governance responsibilities of board members, and the responsibilities of board members with respect to review and oversight of the Compliance Program and compliance risk areas specific to Arrangements. 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 shall include a discussion of OIG's guidance on Board member responsibilities.

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

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

D. Compliance with the Anti-Kickback Statute and Stark Law

ION is responsible for ensuring that the following obligations are met:

1. *Selection Process and Selection Criteria Procedures.*

- a. Within 90 days after the Effective Date, ION shall develop a process for documenting the selection of Health Care Providers and Cancer Centers with whom it enters into Focus Arrangements (Selection Process).

The Selection Process for each type of Focus Arrangement shall include:

- i. a mechanism by which ION identifies Health Care Providers and Cancer Centers for possible selection;

- ii. confirmation that each Health Care Provider and Cancer Center considered meets designated Selection Criteria, as defined in Section III.D.1.b, below, specific to the type of Focus Arrangement; and
  - iii. ION's rationale for choosing the Health Care Provider or Cancer Center ultimately selected for entry into a particular Focus Arrangement.
- b. Within 90 days after the Effective Date, ION shall develop written criteria to guide its selection of Health Care Providers and Cancer Centers with whom it enters into Focus Arrangements (Selection Criteria). ION shall develop Selection Criteria for each type of Focus Arrangement that it enters into with Health Care Providers and Cancer Centers. The Selection Criteria shall relate to a Health Care Provider's or Cancer Center's eligibility and ability to perform the functions required in connection with each type of Focus Arrangement. The Selection Criteria shall not include:
- i. an ION Physician-Investor's ability to refer patients or induce the referral of patients to the Health Care Provider, the Cancer Center, ION, or any individual or entity with which ION has a Leasing Arrangement, Management Arrangement, or Ownership Arrangement;
  - ii. the Health Care Provider's or Cancer Center's ability to refer patients to any ION Physician-Investor;
  - iii. ION's ability to induce the referral of patients from any ION Physician-Investor or other physician to the Health Care Provider or Cancer Center; or
  - iv. ION's ability to induce the referral of patients from the Health Care Provider or Cancer Center to any ION Physician-Investor or other physician.

- c. ION shall maintain and apply its Selection Process and Selection Criteria Procedures throughout the term of the CIA.
- d. ION shall report (at least quarterly) on the status of its Selection Process and Selection Criteria Procedures to the Compliance Committee and Arrangements Officer.

2. *Focus Arrangements Procedures.* Within 90 days after the Effective Date, ION shall create procedures reasonably designed to ensure that each existing and new or renewed Focus Arrangement does not violate the Anti-Kickback Statute and/or the Stark Law or the regulations and other guidance related to these statutes (Focus Arrangements Procedures). These procedures shall include, but are not limited to, the following:

- a. creating and maintaining a centralized tracking system for all existing and new or renewed Focus Arrangements and the information specified in Section III.D.2.b-k below for each existing and new or renewed Focus Arrangement (Focus Arrangements Tracking System). The Focus Arrangements Tracking System shall include a Financial Tracking Report of Arrangements that continually tracks account balances, debts, and profit distributions with Health Care Providers, Cancer Centers, and ION Physician-Investors;
- b. tracking the names and positions of the Arrangements Covered Person(s) involved in the original negotiations for all Focus Arrangements, tracking the Arrangements Covered Person(s) with oversight over the Focus Arrangement, tracking the names and positions of the Arrangements Covered Person(s) involved with financial aspects of the Focus Arrangement, and verifying that an attorney reviewed and approved the Focus Arrangement;
- 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 Arrangement;
- d. tracking all investments made by all parties to all Ownership Arrangements during the term of the CIA and tracking all actual rates of return received by all parties to all Ownership Arrangements during the term of the CIA;

- e. tracking all discounts (e.g., prompt pay discounts, electronic payment discounts), write-offs, debt forgiveness, short-pays, accounts receivable, collection efforts, settlements related to any Focus Arrangement, and aging of balances;
- f. tracking the fair market value determination of remuneration specified in the Focus Arrangement, including the fair market value amount or range, 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;
- g. 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);
- h. 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);
- i. establishing and implementing a written review and approval process for all 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, the Stark Law, or the regulations and other guidance documents related to these statutes, 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 Stark 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;
- j. requiring the Compliance Officer and Arrangements 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

- k. implementing effective responses when suspected violations of the Anti-Kickback Statute and Stark Law are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments pursuant to Sections III.K and III.L when appropriate.

3. *New or Renewed Focus Arrangements.* Prior to entering into new Focus Arrangements or renewing existing Focus Arrangements, in addition to complying with the Focus Arrangements Procedures set forth above, ION shall comply with the following requirements (Focus Arrangements Requirements):

- a. ensure that each Focus Arrangement is set forth in writing and signed by ION and the other parties to the Focus Arrangement;
- b. include in the written agreement a requirement that each party to a Focus Arrangement who meets the definition of a Covered Person shall complete at least one hour of training regarding the Anti-Kickback Statute and the Stark Law and examples of arrangements that potentially implicate the Anti-Kickback Statute or the Stark Law. Additionally, ION shall provide each party to the Focus Arrangement with a copy of its Stark Law and Anti-Kickback Statute Policies and Procedures;
- c. include in the written agreement a certification by the parties to the Focus Arrangement that the parties shall not violate the Anti-Kickback Statute and the Stark Law with respect to the performance of the Arrangement.

4. *Records Retention and Access.* ION shall retain and make available to OIG, upon request, the Focus Arrangements Tracking System, financial systems, 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. Fair Market Value Reviews and Oversight Process

Within 120 days after the Effective Date, ION shall create review and oversight procedures designed to ensure that the rental amounts, fees, charges, compensation, or other payment amounts enumerated in all Leasing Arrangements and Management

Arrangements are supported by and consistent with fair market valuation reports conducted by independent, objective, and qualified individuals or entities with fair market valuation expertise. These review and oversight procedures shall include, but are not limited to, the following:

1. tracking all Leasing Arrangements and Management Arrangements that require a fair market value determination;
2. engaging independent, objective, and qualified individuals or entities with fair market valuation expertise to conduct: (a) fair market valuations of all new SightLine Leasing Companies' Leasing Arrangements or Management Arrangements within 180 days of the engagement date; (b) new fair market value determinations for all existing Leasing Arrangements and Management Arrangements related to the SightLine Leasing Companies that have not had a fair market valuation for more than 24 months prior; and (c) fair market value determinations for all Leasing Arrangements and Management Arrangements related to the Sightline Leasing Companies no less than every 24 months. For all Leasing Arrangements and Management Arrangements, the independent, objective and qualified individuals or entities with fair market valuation expertise shall not have been retained by ION at any time prior to the effective date of this CIA, unless ION either directly or indirectly owns a minority, non-controlling interest in the hospital entity providing health care services under such Leasing Arrangement or Management Arrangement.
3. establishing and implementing a schedule and method of routine oversight of the fair market value determination process; and
4. reporting (at least quarterly) on the status of the fair market value reviews and oversight to the Compliance Committee, Chief Executive Officer, Chief Operating Officer, Compliance Officer, Arrangements Officer, and Chief Financial Officer.

ION shall maintain the Fair Market Value Reviews and Oversight Process for the term of the CIA.

F. Review Procedures

1. *General Description.*
  - a. *Engagement of Independent Review Organization.* Within 60 days after the Effective Date, ION shall select a law firm or lawyer (hereinafter "Independent Review Organization" or

“IRO”), to perform the reviews listed in this Section III.F and shall notify OIG of its selection. Within 30 days of OIG’s receipt of ION’s selection for the IRO, OIG will notify ION of any objections to ION’s selection of the IRO. Absent notification by the OIG that the IRO is unacceptable, ION shall engage the IRO within 120 days after the Effective Date. 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 ION shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and ION) related to the reviews.
- c. *Responsibilities and Liabilities.* Nothing in this Section III.F affects ION’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 and/or the Stark Law.

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. *Additional Items Review.* In addition to the Arrangements Review, during the five years of the CIA, the IRO may be asked by OIG to review up to a total of five additional areas or practices of ION identified by OIG in its discretion (“Additional Items Review”) and shall prepare an Additional Items Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

4. *Certification Regarding IRO’s Relationship to ION.* The IRO shall include in its report(s) to ION a certification that the IRO: (a) has not previously represented or been employed or engaged by ION and (b) does not have a relationship to ION or its employees, officers, or directors that would cause a reasonable person to question the IRO’s objectivity.

#### G. Risk Assessment and Internal Review Process

Within 90 days after the Effective Date, ION shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with ION's participation in the Federal health care programs and Arrangements (as defined in Section II.C.1 above), including but not limited to the risks specific to: (1) the Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)) and the regulations and other guidance documents related to this statute; (2) the Stark Law (42 U.S.C. § 1395nn) and the regulations and other guidance documents related to this statute; (3) the negotiation of new and renewed Arrangements with Health Care Providers and Cancer Centers; (4) the operations under, and monitoring of, all existing Leasing Arrangements, Management Arrangements, and Ownership Arrangements; (5) the monitoring of all existing Arrangements with ION Physician-Investors; (6) the use of referral potential or ability to induce referrals to ION or any Cancer Center as part of the recruiting and selection process for ION Physician-Investors; (7) the use of past and present referral patterns to ION or any Cancer Center for the purpose of inducing referrals from ION Physician-Investors or marketing the business to potential or prospective purchasers, investors, partners, or lessees; (8) the determination of fair market value of Leasing Arrangements and Management Arrangements; (9) collections pursuant to all Arrangements and the application or provision of profit distributions, discounts, write-offs, debt forgiveness, accounts receivable, collection efforts, settlements, and aging of balances; and (10) the submission of claims for items or services furnished to Medicare and Medicaid program beneficiaries. The risk assessment and internal review process shall require compliance, legal, finance, and department leaders, at least annually, to: (1) identify and prioritize risks, (2) develop internal audit work plans related to the identified risk areas, (3) implement the internal audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed and reviews conducted by the IRO, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. ION shall maintain the risk assessment and internal review process for the term of the CIA.

#### H. Disclosure Program

Within 90 days after the Effective Date, ION 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 ION'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. ION 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 ION'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 ION. 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, ION shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

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

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

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

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

3. *Removal Requirement.* If ION has actual notice that a Covered Person has become an Ineligible Person, ION shall remove such Covered Person from responsibility for, or involvement with, ION’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 ION 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, ION 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.

J. Notification of Government Investigation or Legal Proceeding

Within 30 days after discovery, ION shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to ION conducted or brought by a governmental entity or its agents involving an allegation that ION 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. ION 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.

K. Overpayments

1. *Definition of Overpayments.* An "Overpayment" means any funds that ION receives or retains under any Federal health care program to which ION, 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, ION shall develop, implement, and enforce written policies and procedures regarding the identification, quantification and repayment of Overpayments received from any Federal health care program.

L. 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.I.1.a; or
- d. the filing of a bankruptcy petition by ION.

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

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

3. *Reportable Events under Section III.L.1.a.and III.L.1.b.* For Reportable Events under Section III.L.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 ION to identify and quantify any Overpayments; and
- e. a description of ION'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, ION shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and 42 C.F.R. § 401.301-305 (and any applicable CMS guidance) and provide OIG with a copy of the notification and repayment.

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

6. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves solely a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by ION to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to OIG. If ION identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then ION is not required by this Section III.L to submit the Reportable Event to CMS through the SRDP.

#### **IV. SUCCESSOR LIABILITY**

In the event that, after the Effective Date, ION proposes to (a) sell any or all of its business, business units, or locations (whether through a sale of assets, sale of stock, or other type of transaction) relating to the furnishing of items or services that may be reimbursed by a Federal health care program, or (b) purchase or establish a new business, business unit, or location relating to the furnishing of items or services that may be reimbursed by a Federal health care program, the CIA shall be binding on the purchaser of any business, business unit, or location and any new business, business unit, or location (and all Covered Persons at each new business, business unit, or location) shall

be subject to the applicable requirements of this CIA, unless otherwise determined and agreed to in writing by OIG.

If, in advance of a proposed sale or proposed purchase, ION 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, ION 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, ION shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer and Arrangements Officer required by Sections III.A.1-2, and a summary of other noncompliance job responsibilities the Compliance Officer and Arrangements Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A.3;
3. the names of the Board members who are responsible for satisfying the Board of Directors compliance obligations described in Section III.A.4;
4. the names and positions of the Certifying Employees required by Section III.A.5;
5. the written process for Certifying Employees to follow for the purpose of completing the certifications required by Section III.A.5;
6. a list of all Policies and Procedures required by Section III.B;
7. the Training Plan required by Section III.C.1 and a description of the ION Physician-Investor Training and Board of Directors Training required by Sections

III.C.2-3 (including a summary of the topics covered, the length of the training, and when the training was provided);

8. a sample copy of the ION Physician-Investor Certification Statement required by Section III.C.2 and a list of the ION Physician-Investors who completed the Certification Statement;

9. a description of (a) the Selection Process and Selection Criteria Procedures required by Section III.D.1; (b) the Focus Arrangements Tracking System required by Section III.D.2, (c) the internal review and approval process required by Section III.D.2.i; and (d) the tracking and monitoring procedures and other Focus Arrangements Procedures required by Section III.D.2;

10. a description of the Fair Market Value Reviews and Oversight Process required by Section III.E;

11. 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 ION as set forth in Section III.F.4;

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

13. a description of the Disclosure Program required by Section III.H;

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

15. a copy of ION's policies and procedures regarding the identification, quantification and repayment of Overpayments required by Section III.K;

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

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

18. copies of all organizational and structure charts for ION;
19. a description of the structure(s) of ION's Leasing Arrangements; and
20. the certifications required by Section V.C.

B. Annual Reports

ION 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 and all reasons for the change; a current list of the Compliance Committee members, a current list of the Board members who are responsible for satisfying the Board of Directors' compliance obligations, and a current list of the Certifying Employees, along with the identification of and reasons for any changes made during the Reporting Period to the Compliance Committee, Board of Directors, and Certifying Employees;
2. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available to OIG upon request);
3. the Board resolution required by Section III.A.4 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;
4. the Compliance Program Review Report required by Section III.A.4;
5. any updates to the written process for Certifying Employees to follow for the purpose of completing the certifications as required by Section III.A.5;
6. a list of any new or revised Policies and Procedures developed during the Reporting Period;
7. a description of any changes to ION's Training Plan developed pursuant to Section III.C, and a summary of any ION Physician Investor Training and Board of Directors Training provided during the Reporting Period;

8. a sample copy of the ION Physician-Investor Certification Statement required by Section III.C.2 and a list of the ION Physician-Investors who completed the Certification Statement during the Reporting Period;
9. a copy of documents related to the Selection Process and Selection Criteria Procedures required by Section III.D.1 and an explanation of any modifications or change to, or deviations from, the Selection Process or Selection Criteria made during the Reporting Period;
10. a description of (a) any changes to the Focus Arrangements Tracking System required by Section III.D.2.a; (b) any changes to the internal review and approval process required by Section III.D.2.i; and (c) any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.2;
11. a description of any changes to the Fair Market Value Reviews and Oversight Process required by Section III.E;
12. a complete copy of all reports prepared pursuant to Section III.F;
13. a description of ION's response to all reports prepared pursuant to Section III.F and corrective action plan(s) related to issues raised by the Arrangements Review Report or Additional Items Review Report; ION's written responses to the IRO's observations, findings, and recommendations in the Arrangements Review Report or Additional Items Review Report, stating what action ION took in response to each observation, finding, and recommendation or why ION has elected not to take action based on the observation, finding or recommendation; and a description of when ION implemented the corrective action plan(s);
14. a certification from the IRO that it does not have a prohibited relationship with ION, as described in Section III.F.4 above;
15. a description of any changes to the risk assessment and internal review process required by Section III.G, including the reasons for such changes;
16. a copy of the annual findings and the Financial Tracking Report of Arrangements required by Section III.D.2;
17. a summary of the following components of the risk assessment and internal review process during the Reporting Period: work plans developed, internal audits performed, corrective action plans developed in response to internal audits, and steps taken to track the implementation of the corrective action plans. Copies of any

work plans, internal audit reports, and corrective actions plans shall be made available to OIG upon request;

18. a summary of the disclosures in the disclosure log required by Section III.H 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 or Stark law (the complete disclosure log shall be made available to OIG upon request);

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

20. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.J. 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;

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

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

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

24. copies of all organizational and structure charts for ION;

25. a description of any changes to the structure of ION's Leasing Arrangements; and

26. 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, ION shall include the certifications of Certifying Employees as required by Section III.A.5;

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, ION is in compliance with all of the requirements of this CIA;
- b. to the best of his or her knowledge, ION has implemented procedures reasonably designed to ensure that all Focus Arrangements do not violate the Anti-Kickback Statute and Stark Law, including the Focus Arrangements Procedures required in Section III.D of the CIA;
- c. to the best of his or her knowledge, ION has fulfilled the requirements for New and Renewed Focus Arrangements under Section III.D.3 of the CIA; and
- 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.

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

D. Designation of Information

ION 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. ION 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

### ION:

Nicki McKnight, Compliance Director  
Integrated Oncology Network  
2865 E. Coast Highway, Suite 210  
Corona del Mar, CA 92625  
Telephone: (949) 207-3111

Unless otherwise specified, all notifications and reports required by this CIA shall 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, ION may be required to provide OIG with an electronic copy of each notification or report required by this CIA, in addition to a paper copy.

## **VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS**

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may conduct interviews, examine and/or request copies of ION's books, records, and other documents and supporting materials,

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

## **VIII. DOCUMENT AND RECORD RETENTION**

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

## **X. BREACH AND DEFAULT PROVISIONS**

ION 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, ION and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day ION fails to establish, implement or comply with any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. an Arrangements Officer;
- d. the Board of Directors compliance obligations;
- e. the engagement of a Compliance Expert, the performance of a Compliance Program Review, and the preparation of a Compliance Program Review Report;
- f. the management certification obligations;
- g. written Policies and Procedures;
- h. training and education of Covered Persons, Arrangements Covered Persons, ION Physician-Investors, and Board Members;
- i. the ION Physician-Investor Certification Statements;
- j. the Selection Process and Selection Criteria Procedures, the Focus Arrangements Procedures and/or Focus Arrangements Requirements;
- k. the Fair Market Value Reviews and Oversight Process;
- l. a risk assessment and internal review process;
- m. annual findings and the Financial Tracking Report of Arrangements;
- n. a Disclosure Program;
- o. Ineligible Persons screening and removal requirements;

- p. notification of Government investigations or legal proceedings;
- q. policies and procedures regarding the repayment of Overpayments; and
- r. 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 ION fails to engage and use an IRO, as required by Section III.F, 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 ION fails to submit a complete Implementation Report, Annual Report, or any certification to OIG in accordance with the requirements of Section V by the deadlines for submission.

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

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

6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of ION as part of its Implementation Report, any Annual Report, additional documentation to a report (as requested by OIG), or otherwise required by this CIA.

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

## B. Timely Written Requests for Extensions

ION 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 ION fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three days after ION 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 ION 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 ION of: (a) ION's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, ION 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 ION elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until ION 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 ION 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 ION to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.L;
- 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.F, 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 ION constitutes an independent basis for ION's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that ION has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify ION of: (a) ION'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.* ION 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) ION has begun to take action to cure the material breach; (ii) ION is pursuing such action with due diligence; and (iii) ION has provided to OIG a reasonable timetable for curing the material breach.

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

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

ION 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 ION's obligations under this CIA based on a certification by ION 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 ION is relieved of its CIA obligations, ION shall be required to notify OIG in writing at least 30 days in advance if ION 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) ION'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 ION 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.

/Jeffrey Goffman/

ON BEHALF OF ION

3/13/18

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JEFFREY GOFFMAN  
*Chief Executive Officer of*  
Integrated Oncology Network Holdings, LLC;  
Integrated Oncology Network, LLC;  
ION SightLine Holdings, LLC;  
SightLine Health, LLC;  
SightLine Development Company, LLC; and  
SightLine Oncology Services, LLC

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DATE

*Manager of*  
SL Med Center IMRT, LLC;  
SL Lubbock IMRT, LLC;  
SL West Houston IMRT, LLC;  
SL West Hills IMRT, LLC;  
SL Santa Monica IMRT, LLC;  
SL Seattle IMRT, LLC;  
SL Denver Leasing, LLC;  
SL Colorado Springs Leasing, LLC;  
SL Kansas City Leasing, LLC; and  
SL North Texas Leasing, LLC

*On Behalf of*  
Sightline Medical Center IMRT Holdings, LLC;  
Sightline Lubbock IMRT Holdings, LLC;  
Sightline West Houston IMRT Holdings, LLC;  
Sightline West Hills IMRT Holdings, LLC;  
Sightline Santa Monica IMRT Holdings, LLC;  
Sightline Seattle IMRT Holdings, LLC;  
Sightline Denver Leasing Holdings, LLC;  
Sightline Colorado Springs Holdings, LLC;  
Sightline Kansas City Holdings, LLC; and  
Sightline North Texas Leasing Holdings, LLC  
/David E. Matyas/

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DAVID E. MATYAS  
Epstein Becker & Green, PC  
Counsel for ION

3/13/18

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DATE

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

/Lisa M. Re/

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

3/16/2018  
DATE

/Katie R. Fink/

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KATIE R. FINK, Senior Counsel  
Office of Inspector General  
U.S. Department of Health and Human Services

3/19/2018  
DATE

/Joan Matlack/

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JOAN MATLACK, Senior Counsel  
Office of Inspector General  
U.S. Department of Health and Human Services

3/19/2018  
DATE

/Michael R. Torrisi/

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MICHAEL R. TORRISI, Senior Counsel  
Office of Inspector General  
U.S. Department of Health and Human Services

3/19/2018  
DATE

## **APPENDIX A INDEPENDENT REVIEW ORGANIZATION**

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

### **A. IRO Engagement**

1. ION shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall not have a prohibited relationship to ION, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.11 of the CIA or any additional information submitted by ION in response to a request by OIG, whichever is later, OIG will notify ION if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, ION may continue to engage the IRO.

2. If ION engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix A. If a new IRO is engaged, ION shall submit the information identified in Section V.A.11 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 ION at the request of OIG, whichever is later, OIG will notify ION if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, ION may continue to engage the IRO.

### **B. IRO Qualifications**

The IRO shall:

1. assign individuals to conduct the Arrangements Review and Additional Items Review who are knowledgeable in the requirements of the Anti-Kickback Statute and the Stark Law 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 with 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 and Additional Items Review in accordance with the specific requirements of the CIA;
2. respond to all OIG inquiries in a prompt, objective, and factual manner; and
3. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Relationship to ION

The IRO shall not (1) have previously represented or been employed or engaged by ION or (2) have a relationship to ION or its employees, officers, or directors that would cause a reasonable person to question the IRO's objectivity.

E. Assertions of Privilege

ION 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. ION'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.

F. IRO Removal/Termination

1. *ION and IRO.* If ION terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, ION 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. ION must engage a new IRO in accordance with Paragraph A of this Appendix A 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 D, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify ION in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix A. ION shall

have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by ION regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix A, OIG shall notify ION in writing that ION shall be required to engage a new IRO in accordance with Paragraph A of this Appendix A. ION 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 ION to engage a new IRO shall be made at the sole discretion of OIG.

## **APPENDIX B ARRANGEMENTS REVIEW AND ADDITIONAL ITEMS REVIEW**

This Appendix B contains the requirements relating to the Arrangements Review and Additional Items Review required under Section III.F of the CIA.

### **I. 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 ION's systems, processes, policies, and procedures relating to Arrangements, the Arrangements Systems Review shall be performed for the first and fourth Reporting Periods. If ION 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 ION's systems, processes, policies, and procedures relating to the initiation, review, approval, and tracking of Arrangements. Specifically, the IRO shall review the following:

1. ION's systems, policies, processes, and procedures with respect to creating and maintaining the Selection Process and Selection Criteria Procedures required by Section III.D.1 of the CIA;

2. ION'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;

3. ION's systems, policies, processes, and procedures for tracking the names and positions of the Arrangements Covered Person(s) involved in the original negotiations for all Focus Arrangements, the Arrangements Covered Person(s) with oversight over the Focus Arrangement, the lawyer who reviewed and approved the Focus Arrangements, and the names and positions of the Arrangements Covered Person(s) involved with financial aspects of the Focus Arrangement;

4. ION'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 Arrangement;

5. ION's systems, policies, processes, and procedures for tracking all investments made by and estimated rates of return received during the term of the CIA by all parties to all Ownership Arrangements;

6. ION's systems, policies, processes, and procedures for tracking all discounts (e.g., prompt pay discounts, electronic payment discounts), write-offs, debt forgiveness, short-pays, accounts receivable, collection efforts, settlements related to any Focus Arrangement, and aging of balances;

7. ION's systems, policies, processes, and procedures for tracking the fair market value determination of remuneration specified in the Focus Arrangement, including the fair market value amount or range, 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;

8. ION'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);

9. ION'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);

10. ION'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;

11. ION's systems, policies, processes, and procedures for the internal review and approval of all Arrangements, including those policies that identify the individuals required to approve each type or category of Arrangement entered into by ION, the internal controls designed to ensure that all required approvals are obtained, the process for documenting the business need or business rationale for all Focus Arrangements, 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 Stark Law;

12. ION's systems, policies, processes, and procedures for determining and documenting the fair market value of the remuneration specified in all Focus Arrangements;

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

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

15. ION'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; and

16. ION's systems, policies, processes, and procedures with respect to creating and maintaining the Fair Market Value Reviews and Oversight Process required by Section III.E 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 ION's systems, policies, processes, and procedures relating to the items identified in Section A.1-16 above;

3. findings and supporting rationale regarding weaknesses in ION's systems, processes, policies, and procedures relating to Arrangements described in Section A.1-16 above;

4. recommendations to improve ION's systems, policies, processes, or procedures relating to Arrangements described in Section A.1-16 above; and

5. the names and credentials of the individuals who conducted the Arrangements Systems Review.

C. Arrangements Transactions Review. The Arrangements Transactions Review shall consist of annual reviews by the IRO of three Cancer Center locations chosen by OIG. For each Cancer Center location, the IRO shall review the following categories of Focus Arrangements: (1) all Leasing Arrangements in effect as of the Effective Date of the CIA; (2) all Management Arrangements in effect as of the Effective Date of the CIA; (3) 10 randomly-selected Ownership Arrangements in effect as of the Effective Date of the CIA. Additionally, the Arrangements Transactions Review shall consist of a review of 10 randomly selected Focus Arrangements that were entered into or renewed by ION during the Reporting Period that were not previously selected for review pursuant to Section I.C.(1)-(3) of this Appendix B.

In choosing the Cancer Center locations to be reviewed in Section I.C.(1)-(3) of this Appendix B, OIG may consider: (a) proposals submitted by ION or the IRO; (b) internal risk assessment, audit, and monitoring work conducted by ION or the IRO; and (c) other information known to OIG. OIG retains sole discretion over the selection of the Cancer Center locations to be reviewed.

The IRO shall assess whether ION has complied with the Focus Arrangements Procedures and the Focus Arrangements Requirements described in Sections III.D.2 and III.D.3 of the CIA, with respect to the selected Focus Arrangements.

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

1. verifying that the Focus Arrangement is maintained in ION's centralized tracking system in a manner that permits the IRO to identify: (1) the parties to the Focus Arrangement; (2) the name(s) and position(s) of the Arrangements Covered Person(s) involved in the original negotiations and financial aspects of the Focus Arrangement; (3) the name(s) of the lawyer(s) who reviewed and approved the Focus Arrangement; (4) the relevant terms of the Focus Arrangement (*i.e.*, the items/services/equipment/space to be provided; the amount of compensation; the amount of compensation or distributions; any discounts, write-offs, debt forgiveness, short-pays, accounts receivable, collection efforts, settlements, and aging of balances; the effective date, the expiration date, etc.); and (5) 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, amounts owed, discounts, write-offs, debt forgiveness, short-pays, accounts receivable, collection efforts, settlements, aging of balances, etc.);

2. verifying that the Focus Arrangement was subject to the internal review and approval process (including legal, business, financial, and fair market value reviews) and obtained the necessary approvals and that such review and approval is appropriately documented;

3. verifying that the remuneration related to the Focus Arrangement is subject to ION's policies and procedures for determining and documenting the fair market value of the remuneration, that remuneration is properly tracked, and that parties to the Focus Arrangement are complying with the terms of the Focus Arrangement;

4. verifying that any investments made by and estimated rates of return received by all parties to all Ownership Arrangements are tracked, not improper, and provided in accordance with ION's written Policies and Procedures;

5. verifying that any discounts (e.g., prompt pay discounts, electronic payment discounts), write-offs, debt forgiveness, short-pays, accounts receivable, collection efforts, settlements related to the Focus Arrangement, and aging of balances are tracked, not improper, and provided in accordance with ION's written Policies and Procedures;

6. verifying that the business need or business rationale of entering into the Focus Arrangement is consistent with ION's written Policies and Procedures;

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

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

9. verifying that if ION discovered a suspected violation of the Anti-Kickback Statute involving the Focus Arrangement, it implemented an effective response, including disclosing Reportable Events and quantifying and repaying Overpayments when appropriate; and

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

D. Arrangements Transaction Review Report. The IRO shall prepare a report based on each Arrangements Transactions Review performed. The Arrangements Transaction 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 Transaction 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 Transaction Review and ION 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 ION after the IRO has completed its initial review of the Focus Arrangements (Supplemental Materials), the IRO shall identify in the Arrangements Transaction 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 Transaction 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 ION has complied with the Focus Arrangements Procedures and Focus Arrangements Requirements with respect to each of the Focus Arrangements reviewed by the IRO. In addition, the Arrangements Transactions Review Report shall include observations, findings and recommendations on possible improvements to ION's policies, procedures, and systems in place to ensure that all Focus Arrangements comply with the Focus Arrangements Procedures and Focus Arrangements Requirements.

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

## **II. Additional Items Review**

A. Additional Items Review. During the term of this CIA, the IRO may be asked by OIG to perform the Additional Items Review of up to a total of five additional reviews of other areas or practices (Additional Items) of ION identified by OIG in its sole discretion, with input from ION and the IRO as stated in Section II.A.1, below, during the five-year term of the CIA. OIG shall determine the appropriate review methodology. The IRO shall perform all components of each Additional Items Review.

1. For purposes of identifying the Additional Items to be included in the Additional Items Review for a particular Reporting Period, OIG may consider: (1) proposals submitted by ION or the IRO at least 120 days prior to the end of each Reporting Period; (2) internal risk assessment, audit, and monitoring work conducted by ION or the IRO; and (3) other information known to OIG.

2. ION may propose to OIG that their internal audit(s), reviews, and/or monitoring activities be partially substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO as part of the Additional Items Review. OIG retains sole discretion over whether, and in what manner, to allow ION's internal audit work, reviews, and monitoring activities to be substituted for a portion of the Additional Items Review conducted by the IRO.

In making its decision, the OIG agrees to consider, among other factors, the nature and scope of ION's planned internal audit work, reviews, and monitoring activities, the results of the Transactions Review(s) during prior Reporting Period(s), and ION's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies ION's request to permit its internal audit work, reviews, or monitoring activities to be substituted for a portion of the IRO's review of Additional Items in a given Reporting Period, ION shall engage the IRO to perform the Additional Items Review as determined by OIG. If the OIG agrees to permit certain of ION's internal audit work, reviews, or monitoring activities for a given Reporting Period to be substituted for a portion of Additional Items review, such internal work may be subject to verification by the IRO (Verification Review). In such an instance, the OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO.

3. OIG shall notify ION of the nature and scope of the IRO review for each of the Additional Items in the Additional Items Review as well as the information to be included in the Additional Items Review Report at least 120 days prior to the end of each Reporting Period. Prior to undertaking the review of the Additional Items, the IRO shall submit an audit work plan to OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by OIG.