INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
SOUTHWEST ORTHOPAEDIC SPECIALISTS, PLLC

I. PREAMBLE

Southwest Orthopaedic Specialists, PLLC (SOS) hereby enters into this Integrity Agreement (IA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this IA, SOS is entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE IA

A. This IA shall have a term of five years from the Effective Date. The Effective Date shall be the date on which the final signatory signs this IA. 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) SOS's final annual report; or (2) any additional materials submitted by SOS pursuant to OIG's request, whichever is later.

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

1. "Arrangements" shall mean:

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

b. every financial relationship (as defined in 42 C.F.R. § 411.354(a)) that is between SOS 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 SOS for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

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

3. The term "recipient of health care business or referrals" shall mean any individual or entity (1) to whom SOS refers an individual for the furnishing or arranging for the furnishing of any item or service, or (2) from whom SOS purchases, leases or orders or arranges for or recommends the purchasing, leasing, or ordering of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program.

4. "Focus Arrangements" means every Arrangement that:

   a. is between SOS and any actual source of health care business or referrals and involves, directly or indirectly, the offer, payment, or provision of anything of value; or

   b. is between SOS 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 SOS for designated health services (as defined at 42 U.S.C. §1395nn(h))(6)).

Notwithstanding the foregoing provisions of Section II.C.4, 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), shall not be considered a Focus

Arrangement for purposes of this IA, provided that SOS maintains sufficient documentation to demonstrate compliance with the applicable exception to 42 U.S.C. § 1395nn (Stark Law). Such documentation shall be made available to OIG upon request.

5. "Covered Persons" includes:

a. all owners and employees of SOS; and

b. all contractors, agents, and other persons who furnish patient care items or services or who perform billing or coding functions on behalf of SOS excluding vendors whose sole connection with SOS is selling or otherwise providing medical supplies or equipment to SOS. The employees of any third party billing company that submits claims to the Federal health care programs on behalf of SOS shall not be considered Covered Persons, provided that SOS and the third party billing company provide the certifications required by Section III.K.

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

III. INTEGRITY OBLIGATIONS

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

A. Compliance Officer

Within 90 days after the Effective Date, SOS shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the IA. The Compliance Officer shall be an employee and a member of senior management of SOS, shall report directly to the Chief Executive Officer of SOS, 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 SOS. 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 IA and with Federal health care program requirements;

b. making periodic (at least quarterly) reports regarding compliance matters to the Chief Executive Officer of SOS and shall be authorized to report on such matters to the Chief Executive Officer at any time. Written documentation of the Compliance Officer's reports to the Chief Executive Officer shall be made available to OIG upon request; and

c. monitoring the day-to-day compliance activities engaged in by SOS as well as any reporting obligations created under this IA.

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 IA.

SOS 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 IA, within five business days after such a change.

B. Policies and Procedures

Within 90 days after the Effective Date, SOS shall develop and implement written policies and procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this IA and SOS's compliance with Federal health care program requirements (Policies and Procedures). The Policies and Procedures also shall address:

a. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute) and the 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 IA, SOS 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), SOS 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. Posting of Notice

Within 60 days after the Effective Date, SOS shall post in a prominent place accessible to all patients and Covered Persons a notice that provides the name and phone number of the Compliance Officer and the HHS OIG Fraud Hotline telephone number (1-800-HHS-TIPS) as a confidential means by which suspected fraud or abuse in the Federal health care programs may be reported.

D. Training and Education

1. *Covered Persons Training*. All Covered Persons shall receive at least three hours of training during the first Reporting Period. Any individuals who become Covered Persons after the Effective Date and during the term of this IA shall receive at least three hours of training within 90 days of becoming a Covered Person.

Training may be completed in-person or online. These training requirements may be satisfied only by the completion of courses provided by the Centers for Medicare & Medicaid Services (CMS) Medicare Learning Network (MLN), SOS's Medicare contractor, or other training courses that are submitted to OIG, prior to registration for the training course, for review and approval.

At a minimum, the required training sessions must include the following topics: SOS's IA requirements and Compliance Program and the applicable Federal health care program requirements, including the requirements of the Anti-Kickback Statute and the Stark Law.

2. *Arrangements Covered Persons Training.* In addition to the training required in Section D.1 above, all Arrangements Covered Persons must receive at least three hours of training during the first Reporting Period regarding: (i) Arrangements 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) SOS'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.E of the CIA; (iii) the personal obligation of each individual involved in the development, approval, management, or review of SOS's Arrangements to know the applicable legal requirements and the SOS'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 OIG may, in its discretion, require that Covered Persons and Arrangements Covered Persons complete additional hours of training regarding the topics identified above, or additional topics, in the second or third years of the IA. The OIG shall provide notice to SOS of such additional required training at least 180 days prior to the required completion date for such training.

3. *Training Records.* SOS shall maintain written documentation (e.g., written or electronic certificates of completion from the training provider) that all Covered Persons and Arrangements Covered Persons required to receive training have in fact completed such training. The documentation shall specify the type of training received, the individual who completed the training, and the date received.

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

1. *Focus Arrangements Procedures.* Within 90 days after the Effective Date, SOS 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 guidance related to these statutes (Focus Arrangements Procedures). These procedures shall include the following:

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

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

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

d. documenting all fair market value determination(s) for any Focus Arrangement, including the fair market value amount or range and corresponding time period(s), the date(s) of completion of the fair market valuation(s), the individuals or entities that determined the fair market value amount or range, and the names and positions of the Covered Person(s) who received and/or were otherwise involved with the fair market value determination(s);

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

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

g. establishing and implementing a written review and approval process for Focus Arrangements, the purpose of which is to ensure that all new and existing or renewed Focus Arrangements do not violate the Anti-Kickback Statute and Stark Law, and that includes at least the following: (i) a legal review of all Focus Arrangements by counsel with expertise in the Anti-Kickback Statute and 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;

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

i. requiring the Compliance Officer to review the Focus Arrangements Tracking System, internal review and approval

process, and other Focus Arrangements Procedures on at least an annual basis and to provide a report on the results of such review to the Chief Executive Officer; and

j. 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.I and III.J when appropriate.

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

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

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

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

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

F. Review Procedures

1. *General Description*.

a. *Engagement of Independent Review Organization*. Within 90 days after the Effective Date, SOS shall engage a law or consulting firm, or lawyer (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this Section III.F. The applicable requirements relating to the IRO are outlined in Appendix A to this IA, which is incorporated by reference.

b. *Retention of Records*. The IRO and SOS shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and SOS) related to the reviews.

c. *Responsibilities and Liabilities*. Nothing in this Section III.F affects SOS'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.

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

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

3. *Certification Regarding Prohibited Relationships*. The IRO shall include in its report(s) to SOS a certification that the IRO (a) does not currently represent or is not currently employed or engaged by SOS and (b) does not have a current or prior relationship to SOS or its owners that would cause a reasonable person to question the IRO's objectivity in performing the reviews required by Section III.F. The IRO's certification shall include a summary of any current and prior relationships between SOS or its owners, officers, or directors and the IRO.

G. Ineligible Persons

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

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) a criminal offense that is related to the delivery of an item or service under Medicare or any state health care program; (b) a criminal offense relating to neglect or abuse of patients; (c) a felony criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service or with respect to a government funded health care program (other than Medicare or a state health care program); or (d) a felony criminal offense relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance, but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

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

a. SOS 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. SOS shall screen all current Covered Persons against the Exclusion List within 30 days after the Effective Date and on a monthly basis thereafter.

c. SOS shall require all Covered Persons to immediately disclose immediately if they become an Ineligible Person.

SOS shall maintain documentation demonstrating that SOS: (1) has checked the Exclusion List (e.g., print screens from search results) and determined that its Covered Persons are not Ineligible Persons; and (2) has required its Covered Persons to disclose if they are an Ineligible Person.

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

3. *Removal Requirement*. If SOS has actual notice that a Covered Person has become an Ineligible Person, SOS shall remove such Covered Person from responsibility for, or involvement with, SOS'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 SOS 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, SOS shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary or the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceeding

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

I. Overpayments

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

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

J. Reportable Events

1. *Definition of Reportable Event*. For purposes of this IA, a "Reportable Event" means anything that involves:

a. a substantial Overpayment;

b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;

c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or

d. the filing of a bankruptcy petition by SOS.

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

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

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

a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of 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 SOS to identify and quantify any Overpayments; and

e. a description of SOS'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, SOS shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. §1320a-7k(d) and any applicable regulations and Centers for Medicare and Medicaid Services (CMS) guidance and provide OIG with a copy of the notification and repayment.

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

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

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

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

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

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

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

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

K. Third Party Billing

If, prior to the Effective Date or at any time during the term of this IA SOS contracts with a third party billing company to submit claims to the Federal health care programs on behalf of SOS, SOS must certify to OIG that it does not have an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in the third party billing company.

SOS also shall obtain a certification from any third party billing company that the company: (i) has a policy of not employing any person who is excluded from participation in any Federal health care program to perform any duties related directly or indirectly to the preparation or submission of claims to Federal health care programs; (ii) screens its prospective and current employees against the Exclusion List; and (iii) provides training in the applicable requirements of the Federal health care programs to

those employees involved in the preparation and submission of claims to Federal health care programs.

A copy of these certifications shall be included in SOS's Implementation Report and each Annual Report required by Section V below.

IV. SUCCESSOR LIABILITY; CHANGES TO LOCATIONS OR BUSINESS

In the event that, after the Effective Date, SOS proposes to (a) sell any or all of its locations or businesses that are subject to this IA (whether through a sale of assets, sale of stock, or other type of transaction), or (b) purchase or establish a new location or business related to the furnishing of items or services that may be reimbursed by any Federal health care program, the IA shall be binding on the purchaser of any such location or business and any new location or business (and all Covered Persons at each new location or business) shall be subject to the requirements of this IA, unless otherwise determined and agreed to in writing by OIG. SOS shall give notice of such sale or purchase to OIG within 30 days following the closing of the transaction.

If, in advance of a proposed sale or proposed purchase, SOS wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the IA, SOS 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 location or business 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 90 days after the Effective Date, SOS shall submit a written report to OIG summarizing the status of its implementation of the requirements of this IA (Implementation Report). The Implementation Report shall, at a minimum, include:

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

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

3. a copy of the notice required by Section III.C, a description of where the notice is posted, and the date the notice was posted;

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

5. the following information regarding the IRO: (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 IA; and (d) a certification from the IRO that it does not have a prohibited relationship with SOS as set forth in Section III.F.3 that includes a summary of any current and prior relationships between SOS or its owners, officers, or directors and the IRO;

6. a copy of the documentation demonstrating that SOS has screened all Covered Persons against the Exclusion List as required by Section III.G within 30 days of the Effective Date;

7. a copy of SOS's policies and procedures regarding the identification, quantification and repayment of Overpayments required by Section III.I;

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

9. a certification by the Compliance Officer each member of SOS's executive committee that: (a) the Compliance Officer has reviewed the IA in its entirety, understands the requirements described within, and maintains a copy for reference; (b) to the best of his or her knowledge, except as otherwise described in the Implementation Report, SOS is in compliance with all of the requirements of this IA; (c) he or she has reviewed the Implementation Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful; (d) R.J. Langerman, D.O. is not involved in the executive committee's operations or decisions, the management of SOS, nor the negotiation of any Focus Arrangements as defined in Section II.C.4. of the IA; and (e) he or she understands that this certification is being provided to and relied upon by the United States.

10. a certification by R.J. Langerman, D.O. that states: "I will not enter into any Focus Arrangements, as defined in Section II.C.4. of the IA, on behalf of myself

or SOS for the duration of this Integrity Agreement. I will not participate directly or indirectly in the negotiation of any such Focus Arrangements. I am not involved in the management of SOS nor any of its parent, subsidiary, or affiliate corporations or other entities. I understand that this certification is being provided to and relied upon by the United States."

11. a copy of the certification from the third party billing company required by Section III.K.

B. Annual Reports

SOS shall submit to OIG a written report on its compliance with the IA 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 described in Section III.A;

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

3. (in the first Annual Report) the following information regarding the training required by Section III.D: a copy of the training program registration for each Covered Person and Arrangements Covered Person who completed the training, the name of the training course, the name of the entity that provided the training, the location, date and length of the training; and a training program brochure or other materials from the training program or training program sponsor that describes the content of the training program. A copy of all training materials shall be made available to OIG upon request;

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

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

6. a certification from the IRO that it does not have a prohibited relationship with SOS as described in Section III.F.3 above, including a summary of any

current and prior relationships between SOS or its owners, officers, or directors and the IRO;

7. a copy of the documentation demonstrating that SOS screened all prospective and current Covered Persons against the Exclusion List, as required by Section III.G;

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

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

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

11. a description of all changes to the most recently provided list of SOS's locations (including addresses) as required by Section V.A.7; and

12. a certification signed by SOS's Compliance Officer and each member of SOS's executive committee that: (a) he or she has reviewed the IA in its entirety, understands the requirements described within, and maintains a copy for reference; (b) to the best of his or her knowledge, except as otherwise described in the Annual Report, SOS is in compliance with all of the requirements of this IA; (c) he or she has reviewed the Annual Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful; (d) R.J. Langerman, D.O. has not been involved in the executive committee's operations or decisions, the management of SOS, nor the negotiation of any Focus Arrangements as defined in Section II.C.4. of the IA; and (e) he or she understands that this certification is being provided to and relied upon by the United States.

13. a certification by R.J. Langerman, D.O. that states: "I have not entered into any Focus Arrangements, as defined in Section II.C.4. of the IA, on behalf of myself or SOS during this Reporting Period. I have not participated directly or indirectly in the negotiation of any such Focus Arrangements. I am not involved in the management of SOS nor any of its parent, subsidiary, or affiliate corporations or other entities. I understand that this certification is being provided to and relied upon by the United States."

14. a copy of the certification from the third party billing company required by Section III.K.

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

C. Designation of Information

SOS 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. SOS 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 IA 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, SW
Washington, DC 20201
Telephone: (202) 619-2078
Facsimile: (202) 205-0604

SOS:
James D. Moore, FACHE
Administrator/CEO
8100 S. Walker Ave. Bldg. A
Oklahoma City, OK 73139
405-632-4468, ext. 1805
jmoore@southwestortho.com

Unless otherwise specified, all notifications and reports required by this IA shall be made by electronic mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. Upon request by OIG, SOS may be required to provide OIG with an additional copy of each notification or report required by this IA, in OIG's requested format (electronic or paper).

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

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

VIII. DOCUMENT AND RECORD RETENTION

SOS shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this IA 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 SOS prior to any release by OIG of information submitted by SOS pursuant to its obligations under this IA and identified upon submission by SOS as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, SOS shall have the rights set forth at 45 C.F.R. § 5.42(a).

X. BREACH AND DEFAULT PROVISIONS

SOS is expected to fully and timely comply with all of its IA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, SOS and OIG hereby agree that failure to comply with certain obligations set forth in this IA 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 $1,000 (which shall begin to accrue on the day after the date the obligation became due) per obligation for each day SOS fails to establish, implement or comply with any of the following obligations as described in Section III:

   a. appoint a Compliance Officer as required by Section III.A;

   b. written Policies and Procedures required by Section III.B;

   c. post a notice in accordance with the requirements of Section III.C;

   d. complete the training and education required for Covered Persons and Arrangements Covered Persons and maintain training records, in accordance with the requirements of Section III.D;

   e. screen Covered Persons in accordance with the requirements of Section III.G or require Covered Persons to disclose if they are excluded in accordance with the requirements of Section III.G; and maintain documentation of screening and disclosure requirements in accordance with the requirements of Section III.G;

   f. notify OIG of a government investigation or legal proceeding, in accordance with the requirements of Section III.H;

   g. establish policies and procedures regarding the repayment of Overpayments;

h. report a Reportable Event in accordance with Section III.J; and

i. provide to OIG the certification required by Section III.K relating to any third-party biller engaged by SOS during the term of the IA.

2. A Stipulated Penalty of $1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day SOS fails to engage and use an IRO, as required by Section III.F, Appendix A, or Appendix B.

3. A Stipulated Penalty of $1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day SOS fails to timely submit (a) a complete Implementation Report or Annual Report, (b) a certification to OIG in accordance with the requirements of Section V, or (c) a complete response to any request for information from OIG.

4. A Stipulated Penalty of $1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day SOS fails to submit any Arrangements Review Report in accordance with the requirements of Section III.F and Appendix B.

5. A Stipulated Penalty of $1,000 for each day SOS fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date SOS fails to grant access.)

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

7. A Stipulated Penalty of $2,500 for each day SOS fails to grant the IRO access to all records and personnel necessary to complete the reviews listed in Section III.F, and for each day SOS fails to furnish to the IRO accurate and complete records, as required by Section III.F and Appendix A.

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

receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-7 of this Section.

B. Timely Written Requests for Extensions

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

C. Payment of Stipulated Penalties

1. *Demand Letter*. Upon a finding that SOS 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 SOS of: (a) SOS's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter*. Within 10 business days after the receipt of the Demand Letter, SOS 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 SOS elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until SOS 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 IA 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 SOS has materially breached this IA, 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 IA

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

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

b. repeated violations or a flagrant violation of any of the obligations under this IA, 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 IA by SOS constitutes an independent basis for SOS's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that SOS has materially breached this IA and that exclusion is the appropriate remedy, OIG shall notify SOS of: (a) SOS'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*. SOS 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) SOS has begun to take action to cure the

material breach; (ii) SOS is pursuing such action with due diligence; and (iii) SOS has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter*. If, at the conclusion of the 30 day period, SOS fails to satisfy the requirements of Section X.D.3, OIG may exclude SOS from participation in the Federal health care programs. OIG shall notify SOS in writing of its determination to exclude SOS. (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 SOS'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, SOS 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 SOS of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this IA, SOS 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 IA. 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 IA shall be: (a) whether SOS was in full and timely compliance with the obligations of this IA for which OIG demands payment; and (b) the period of noncompliance. SOS 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 IA and orders SOS to pay Stipulated Penalties, such Stipulated Penalties shall

become due and payable 20 days after the ALJ issues such a decision unless SOS 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 IA shall be whether SOS was in material breach of this IA and, if so, whether:

a. SOS 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 SOS's receipt of the Notice of Material Breach: (i) SOS had begun to take action to cure the material breach; (ii) SOS pursued such action with due diligence; and (iii) SOS 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 SOS, only after a DAB decision in favor of OIG. SOS's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude SOS 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 SOS 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. SOS 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 SOS, SOS 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 IA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this IA.

XI. EFFECTIVE AND BINDING AGREEMENT

SOS and OIG agree as follows:

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

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

C. OIG may agree to a suspension of SOS's obligations under this IA based on a certification by SOS 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 SOS is relieved of its IA obligations, SOS shall be required to notify OIG in writing at least 30 days in advance if SOS 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 IA will be reactivated or modified.

D. All requirements and remedies set forth in this IA are in addition to and do not affect (1) SOS'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 SOS signatories represent and warrant that they are authorized to execute this IA. The undersigned OIG signatories represent that they are signing this IA in their official capacity and that they are authorized to execute this IA.

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

ON BEHALF OF SOS

_____/Derek West/_____ ___6/30/2020_____
DEREK WEST, D.O. DATE
Chairman, Executive Committee

_____/M. Richard Mullins/_____ ____7/2/20_____
M. RICHARD MULLINS DATE
McAfee & Taft
Counsel for Southwest
Orthopaedic Specialists, PLLC

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

_____/Lisa M. Re/_____ _____07/07/2020_____
LISA M. RE DATE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

_____/Karen Glassman/_____ _____07/07/2020_____
KAREN S. GLASSMAN DATE
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. SOS 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 SOS, as set forth in Paragraph E. Within 30 days after OIG receives the information identified in Section V.A.5 of the IA or any additional information submitted by SOS in response to a request by OIG, whichever is later, OIG will notify SOS if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, SOS may continue to engage the IRO.

2. If SOS engages a new IRO during the term of the IA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, SOS shall submit the information identified in Section V.A.5 of the IA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by SOS at the request of OIG, whichever is later, OIG will notify SOS if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, SOS may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Arrangements Review who are knowledgeable in the requirements of the Anti-Kickback Statute and the 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 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 IA on a timely basis.

C. IRO Responsibilities

The IRO shall:

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

2. respond to all OIG inquires 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 IA.

D. SOS Responsibilities

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

E. IRO Relationship to SOS

The IRO shall not (1) currently represent or currently be employed or engaged by SOS or (2) have a current or prior relationship to SOS or its owners that would cause a reasonable person to question the IRO's objectivity in performing the reviews required by Appendix B to this IA.

F. Assertions of Privilege

SOS 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. SOS'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.

G. IRO Removal/Termination

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

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

APPENDIX B

ARRANGEMENTS REVIEW

The Arrangements Review shall consist of two components: a systems review and a transactions review. The IRO shall perform all components of each Arrangements Review. If there are no material changes to SOS's systems, processes, policies, and procedures relating to Arrangements, the Arrangements Systems Review shall be performed for the first and fourth Reporting Periods. If SOS 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 SOS's systems, processes, policies, and procedures relating to the initiation, review, approval, and tracking of Arrangements. Specifically, the IRO shall review the following:

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

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

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

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

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

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

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

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

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

10. SOS'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; and

11. SOS'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.E.2 of the IA.

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 SOS's systems, policies, processes, and procedures relating to the items identified in Section A.1-11 above;

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

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

C. Arrangements Transactions Review. The Arrangements Transactions Review shall consist of a review by the IRO of each Focus Arrangement that was entered into or renewed by SOS during the Reporting Period. The IRO shall assess whether SOS has complied with the Focus Arrangements Procedures and the Focus Arrangements Requirements described in Sections III.E.1 and III.E.2 of the IA, with respect to the selected Focus Arrangements.

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

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

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

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

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

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

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

g. verifying that the Focus Arrangement satisfies the Focus Arrangements Requirements of Section III.E.2 of the IA.

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

D. Arrangements Transactions 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 Transactions Review.

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

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

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