

**CORPORATE INTEGRITY
AGREEMENT BETWEEN THE
OFFICE OF INSPECTOR
GENERAL OF THE
DEPARTMENT OF HEALTH AND HUMAN
SERVICES AND
TEXAS GENERAL SURGEONS**

I. PREAMBLE

Texas General Surgeons (TGS) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, TGS 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 TGS 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. 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 TGS and any actual or potential source of health care business or referrals to TGS or any actual or potential recipient of health care business or referrals from TGS.

- 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 (1) to whom TGS refers an individual for the furnishing or arranging for the furnishing of any item or service, or (2) from whom TGS 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.
 - b. is between TGS 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 TGS for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).
2. “Focus Arrangements” shall include:
- a. every Arrangement that:
 - i. is between TGS and any actual source or recipient of health care business or referrals to TGS and involves, directly or indirectly, the offer, payment, or provision of anything of value; or
 - ii. is between TGS 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 TGS for designated health services (as defined at 42 U.S.C. §1395nn(h))(6)).
3. “Covered Persons” includes:

- a. all owners of TGS who are natural persons, officers, directors, and employees of TGS;
- b. all contractors, subcontractors, agents, and other persons who furnish patient care items or services or who perform billing or coding functions on behalf of TGS excluding vendors whose sole connection with TGS is selling or otherwise providing medical supplies or equipment to TGS; and
- c. physicians who are members and employees of TGS or any of its directly or indirectly owned subsidiaries or affiliates.

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

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Officers

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

- a. Maintaining, 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; and
- b. monitoring the day-to-day compliance activities engaged in by TGS as well as for any reporting obligations created under this CIA.

B. Written Standards

Within 90 days after the Effective Date, TGS 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 TGS'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, TGS 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), TGS 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. Within 90 days after the Effective Date, TGS shall develop a written plan (Training Plan) that outlines the steps TGS will take to ensure that all Covered Persons receive at least annual training regarding TGS'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 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) TGS'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 TGS's Arrangements to know the applicable legal requirements and the TGS'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.

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

1. *Focus Arrangements Procedures.* Within 90 days after the Effective Date, TGS 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, directives, 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 (Focus Arrangements Tracking System);
- b. tracking remuneration to and from all parties to Focus Arrangements;
- c. 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);
- d. 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);
- e. 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 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 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;

- f. 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
- g. 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

2. *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, TGS shall comply with the following requirements (Focus Arrangements Requirements):

- a. Ensure that each Focus Arrangement is set forth in writing and signed by TGS 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, TGS 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.

E. Risk Assessment and Internal Review Process

Within 90 days after the Effective Date, TGS shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with Arrangements (as defined in Section II.C.1 above) and TGS's participation in the Federal health care programs, including but not limited to the risks associated with the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries. The risk assessment and internal review process shall require compliance, legal and department leaders, at least annually, to: (1) identify and prioritize risks, (2) develop internal audit work plans related to the identified risk areas, (3) implement the internal audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. TGS shall maintain the risk assessment and internal review process for the term of the CIA.

F. Disclosure Program

Within 90 days after the Effective Date, TGS 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 TGS'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. TGS 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 Compliance Officer (or designee) shall maintain a disclosure log and shall record each disclosure in the disclosure log within two business days of receipt of the disclosure. The disclosure log shall include a summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews.

G. Ineligible Persons

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

- a. an “Ineligible Person” shall include an individual or entity who:
 - i. is currently excluded from participation in any Federal health care program; or
 - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded.
- b. “Exclusion List” means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at <http://www.oig.hhs.gov>).

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

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

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

H. Overpayments

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

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

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

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

IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, TGS 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, TGS 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, TGS 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. BREACH AND DEFAULT PROVISIONS

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

- a. a Chief Compliance Officer;
- b. written Policies and Procedures;

- c. training and education of Covered Persons, and Arrangements Covered Persons;
- d. the Focus Arrangements Procedures and/or Focus Arrangements Requirements;
- e. a risk assessment and internal review process;
- f. a Disclosure Program;
- g. Ineligible Persons screening and removal requirements;
- h. notification of Government investigations or legal proceedings;
- i. policies and procedures regarding the repayment of Overpayments; and
- j. reporting of Reportable Events

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

VI. EFFECTIVE AND BINDING AGREEMENT

TGS 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.

ON BEHALF OF TEXAS GENERAL SURGEONS

2/1/2017

Richard Cutten, President

DATE

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

/Lisa M. Re/

2/1/2017

DATE

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