



# **COMPLIANCE PLAN RELATING TO PHYSICIAN-OWNED ENTITIES**

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## **I. INTRODUCTION**

In connection with its activities relating to management of and investment in physician-owned entities (each a “Physician Entity” and collectively “Physician Entities”), HealthTronics, Inc., together with its wholly-owned subsidiaries (collectively “HealthTronics”), is committed to the highest quality of patient care and conducting its business activities in full compliance with all applicable laws and in accordance with the highest standards of honesty, integrity, ethics, and professionalism. HealthTronics has adopted this Compliance Plan effective March 30, 2011 (the “Effective Date”) to reinforce this commitment and to promote legal compliance and ethical conduct by and among all employees and officers of HealthTronics whose job responsibilities relate to Physician Entities (“Covered Persons”).

This Compliance Plan constitutes a critical part of HealthTronics’ overall compliance program and should be read in connection with, and is in addition to (and not in lieu of), all other HealthTronics policies and procedures.

This Compliance Plan cannot address every situation that Covered Persons may encounter. Therefore, HealthTronics expects Covered Persons to comply with all applicable laws and exercise personal integrity and good judgment in every situation, regardless of whether specifically addressed in this Compliance Plan.

Questions and inquiries regarding this Compliance Plan should be directed to HealthTronics’ Compliance Officer.

## **II. COMPLIANCE OFFICER**

HealthTronics has appointed a Compliance Officer to implement and monitor this Compliance Plan. The Compliance Officer's primary responsibilities include the following:

- develop and manage this Compliance Plan
- coordinate an annual review and update this Compliance Plan as necessary
- provide each new Covered Person with a copy of this Compliance Plan promptly after employment or affiliation with HealthTronics and require each new Covered Person to read this Compliance Plan and sign an acknowledgment that he or she has received, read, understands and supports this Compliance Plan
- distribute and post online any revisions to this Compliance Plan within thirty (30) days after any revisions are finalized
- provide quarterly reports to HealthTronics' Board of Directors and senior management regarding the results of any audits, the status of any investigations, and the existence of any non-compliance with the provisions of this Compliance Plan
- consistent with Part IV of this Compliance Plan, arrange for, conduct, and oversee periodic training programs regarding this Compliance Plan and to provide further education to Covered Persons regarding compliance with all applicable laws and regulations
- establish methods, such as periodic audits, to improve efficiency and quality of services, and to reduce HealthTronics' vulnerability to fraud and abuse
- coordinate internal compliance review and monitoring activities
- be familiar with all applicable laws, regulations, and standard operating procedures relevant to this Compliance Plan
- maintain records related to this Compliance Plan
- make Physician Entities and Physician Investors aware of the existence of this Compliance Plan and HealthTronics' commitment to the principles set forth herein
- ensure that all Covered Persons are screened before employment or affiliation with HealthTronics and annually thereafter to determine that they are not Ineligible Persons
- review reports of noncompliance and take appropriate action in response to such reports
- investigate any report or allegation concerning possible unlawful, unethical, or improper business practices, and monitor subsequent corrective action and compliance

- maintain a disclosure log that includes a record and summary of each report received, whether anonymous or not; the status of the respective internal reviews; and any corrective action taken in response to the internal reviews
- maintain records of compliance training programs, including an attendance log, copies of training materials, and certifications of attendance
- participate with counsel in appropriate reporting of any self-discovered violations of federal healthcare program requirements
- perform other activities as may be required to achieve a successful application of this Compliance Plan

### **III. POLICIES AND PROCEDURES**

HealthTronics has adopted these policies and procedures to reinforce its dedication to compliance with applicable laws and adherence to the highest standards of honesty, integrity, ethics, and professionalism. HealthTronics has identified certain financial arrangements and transactions, such as arrangements and transactions with referring physicians and healthcare facilities, that are subject to heightened scrutiny by regulatory authorities under the Stark Law and Anti-Kickback Statute. The purpose of these policies and procedures is to establish practical standards and procedures that facilitate compliant behaviors for Covered Persons engaging in such arrangements and transactions.

HealthTronics performs several different roles relating to Physician Entities; it may own an interest in a Physician Entity, act as the manager, management agent, general partner, or managing member for a Physician Entity, or have some other role in a Physician Entity's business. A Covered Person may participate on HealthTronics' behalf in the business, activities, and affairs of a Physician Entity, whether directly or indirectly through HealthTronics' role as partner, member, manager, management agent, general partner, managing member, or otherwise. All Covered Persons who so act shall comply with these policies and procedures to the extent they apply to the Covered Person's responsibilities on HealthTronics' behalf relating to any Physician Entity.

#### **A. SCREENING AND ELIGIBILITY**

The government monitors the eligibility of individuals to participate in federal healthcare programs. Therefore, it is HealthTronics' policy to require all Covered Persons to comply with the policies and procedures listed below.

##### **1. ELIGIBILITY**

Covered Persons who are involved in the arrangements and transactions described in Sections III.B, III.C, and III.D of this Compliance Plan or who are otherwise identified by the Compliance Officer must not be or become an Ineligible Person.

- “Ineligible Person” means any individual or entity who:
  - is currently excluded, debarred, suspended, or otherwise ineligible to participate in federal healthcare programs or in federal procurement or nonprocurement programs;
  - has been convicted of program-related crimes, patient abuse, or healthcare fraud or has been convicted of a criminal offense for which the individual or entity may be, but has not yet been, excluded, debarred, suspended, or otherwise declared ineligible to participate in federal healthcare programs or in federal procurement or nonprocurement programs;
  - is listed on the General Services Administration's System for Award Management (SAM) which includes information regarding entities debarred, suspended,

proposed for debarment, excluded or disqualified under the nonprocurement common rule, or otherwise declared ineligible from receiving federal contracts, certain subcontracts, and certain federal assistance and benefits;

- is listed on the Office of the Inspector General’s List of Excluded Individuals/Entities (“LEIE”), which is available at [http://oig.hhs.gov/fraud/exclusions/exclusions\\_list.asp](http://oig.hhs.gov/fraud/exclusions/exclusions_list.asp) and includes information regarding individuals and entities who are excluded from participating in federally funded healthcare programs due to violations of the Social Security Act, including convictions for program-related fraud and patient abuse, licensing board actions, and default on Health Education Assistance Loans;
- controls a Sanctioned Entity under the Social Security Act, whether through a direct or indirect ownership or control interest of five percent or more, or as an officer or managing employee. A “Sanctioned Entity” is an entity that has been convicted of program-related crimes, patient abuse, or healthcare fraud or that has been excluded from participation in a federal healthcare program;
- controls an entity, whether through a direct or indirect ownership or control interest of five percent or more, or as an officer or managing employee, that is itself an Ineligible Person under this Compliance Plan.

## 2. SCREENING FOR INELIGIBILITY

All Covered Persons who are involved in the arrangements and transactions described in Sections III.B, III.C, and III.D of this Compliance Plan or who are otherwise identified by the Compliance Officer must be screened to verify that they are not Ineligible Persons.

- Initial Screening. The Compliance Officer or someone designated by the Compliance Officer must screen all such Covered Persons prior to their becoming employed or affiliated with HealthTronics to verify that they are not Ineligible Persons.
- Monthly Screening. The Compliance Officer or someone designated by the Compliance Officer must screen all such Covered Persons monthly to verify that they are not and have not become Ineligible Persons.

Covered Persons shall also educate the appropriate principals of Physician Entities regarding screening of the Physician Investors in each Physician Entity to verify that they are not and have not become Ineligible Persons.

## 3. REPORTING INELIGIBILITY

All Covered Persons who are involved in the arrangements and transactions described in Sections III.B, III.C, and III.D of this Compliance Plan or who are otherwise identified by the Compliance Officer must immediately disclose to the Compliance Officer the occurrence of any debarment, exclusion, disqualification, suspension, criminal conviction, or other event that makes such Covered Person an Ineligible Person, and any government investigation or other event that might be reasonably expected to result in that Covered Person becoming an

Ineligible Person, including, without limitation, criminal charges against, and ongoing government investigations to exclude or sanction, that Covered Person.

#### 4. REMOVAL

If HealthTronics has actual notice that a Covered Person who is involved in the arrangements and transactions described in Sections III.B, III.C, and III.D of this Compliance Plan or who is otherwise identified by the Compliance Officer has become an Ineligible Person, HealthTronics shall remove such Covered Person from any position for which the Covered Person is responsible for, is involved in, or receives compensation from the HealthTronics' business operations related to the federal healthcare programs.

#### 5. PENDING CHARGES AND POTENTIAL EXCLUSIONS

If a Covered Person who is involved in the arrangements and transactions described in Sections III.B, III.C, and III.D of this Compliance Plan or who is otherwise identified by the Compliance Officer is being investigated for or is charged with a criminal offense that could make such Covered Person an Ineligible Person or is being investigated for exclusion or sanctions, HealthTronics shall have the right to 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 patient or any claim submitted to any federal healthcare program. Such Covered Person shall cooperate and perform all such other actions that may be deemed reasonably necessary or proper by HealthTronics to effectuate, confirm, perform, or carry out the actions taken by HealthTronics to ensure no adverse effects on quality of care or claim submissions.

### **B. ARRANGEMENTS WITH PHYSICIANS**

Certain arrangements and transactions between HealthTronics or Physician Entities, on the one hand, and physician owners of Physician Entities ("Physician Investors"), on the other hand, are subject to heightened regulatory scrutiny due to anti-kickback and patient self-referral concerns. Examples of these arrangements and transactions include the acquisition and redemption of investment interests, physician compensation arrangements, and loans and guaranties. Therefore, it is HealthTronics' policy to require all Covered Persons who, on behalf of HealthTronics, in any way facilitate, coordinate, organize, manage, administer, engage in, or otherwise participate in any way in the process of negotiating, evaluating, assessing, vetting, drafting, preparing, reviewing, revising, amending, executing, implementing, interpreting, or enforcing any contract, agreement, arrangement, or transaction between HealthTronics or Physician Entities, on the one hand, and any Physician Investor, on the other hand, to comply with the policies and procedures listed below.

#### 1. ACQUIRING INVESTMENT INTERESTS

These policies and procedures apply to arrangements and transactions that involve acquiring, holding, retaining, and redeeming Investment Interests.

- “Investment Interest” means any ownership or investment interest in a Physician Entity or any other entity, whether through equity, debt, or other means, and whether directly or indirectly through other business entities or through immediate family members. For example, Investment Interests include any of the following in, to, or with a Physician Entity or any other entity:
  - equity such as stock; stock options; partnership interests, shares, and units; limited liability membership interests, shares, and units; and other forms of equity ownership interests; and
  - debt such as loans, bonds, and other financial instruments and accommodations.
- Referral Neutrality. The actual or potential volume of patient referrals that a prospective or existing Physician Investor may make to HealthTronics, a Physician Entity or any other entity must not be used for any of the following purposes: (a) determining whether a prospective or existing Physician Investor may retain an Investment Interest; (b) determining the size or amount of any Investment Interest to be acquired; (c) determining or establishing the purchase price to be paid for the acquisition of an Investment Interest; or (d) any other purpose that may be construed as inducing patient referrals to HealthTronics, a Physician Entity or any other entity.
- Fair Market Value. A Physician Investor must pay Fair Market Value for any Investment Interest that such Physician Investor acquires. Fair Market Value must be determined in accordance with the policies and procedures contained in Section III.E of this Compliance Plan.

## 2. REDEEMING INVESTMENT INTERESTS

These policies and procedures apply to arrangements and transactions that involve redeeming Investment Interests from Physician Investors.

- Referral Neutrality. The actual or potential volume of patient referrals that a Physician Investor may make to HealthTronics, a Physician Entity or any other entity contracting with HealthTronics or a Physician Entity must not be used for any of the following purposes: (a) determining whether to redeem a Physician Investor’s Investment Interest; (b) determining the size or amount of any Investment Interest to be redeemed; (c) determining or establishing the purchase price to be paid for the redemption of an Investment Interest; or (d) any other purpose that may be construed as inducing patient referrals to HealthTronics, a Physician Entity or any other entity, or construed as punishment for not making patient referrals to HealthTronics, a Physician Entity or any other entity.
  - Active Practice of Medicine Redemptions. In order solely to enhance and preserve quality of patient care and to the extent required or permitted by a Physician Entity’s governing documents, a Physician Entity may redeem the Investment Interest of a Physician Investor who is not actively practicing medicine as defined in the Physician Entity’s governing documents (“APM”)

- Culpable Redemptions. Each Physician Entity has an interest in ensuring compliance and defending legitimate business interests that are referral neutral as defined herein, and may use redemptions as a tool to effect such goals. To the extent required or permitted by a Physician Entity’s governing documents, the Physician Entity may redeem the Investment Interest of a Physician Investor who violates or fails to perform his or her obligations under any governing documents or agreements with the Physician Entity, including noncompete and confidentiality obligations.
- Benign Redemptions. To the extent required or permitted by a Physician Entity’s governing documents, the Physician Entity may redeem the Investment Interest of a Physician Investor upon the occurrence of any of the following:
  - divorce
  - insolvency
  - death
  - mental incompetence
  - any other referral-neutral reason contained in the applicable governing documents
- Fair Market Value. A Physician Entity must pay a Physician Investor Fair Market Value for any Investment Interest redeemed for failure to satisfy any APM requirements in the Physician Entity’s governing documents. Fair Market Value must be determined in accordance with the policies and procedures contained in Section III.E of this Compliance Plan. The purchase price paid for Investment Interests for all other redemption-triggering events shall follow the terms of the Physician Entity’s governing documents.

### 3. PHYSICIAN COMPENSATION ARRANGEMENTS

These policies and procedures apply to any arrangement or transaction that involves any payment or other benefit received by a Physician Investor (or a member of a Physician Investor’s immediate family) from HealthTronics or a Physician Entity, whether directly or indirectly, overtly or covertly, in cash or in kind. Examples of such arrangements and transactions include gifts, stipends, medical director fees, and committee fees (“Physician Compensation Arrangements”).

- Referral Neutrality. The actual or potential volume of referrals that a Physician Investor may make to HealthTronics, a Physician Entity or any other entity contracting with HealthTronics or a Physician Entity must not be used for any of the following purposes: (a) establishing or determining a Physician Compensation Arrangement for a Physician Investor; (b) selecting or appointing a Physician Investor for a compensated position, such as a medical director; or (c) any other

purpose that may be construed as inducing referrals to HealthTronics, a Physician Entity or any other entity.

- Professional Medical Services. Neither HealthTronics nor any Physician Entity is itself a licensed healthcare professional and therefore neither HealthTronics nor any Physician Entity is permitted to engage in the practice of medicine or otherwise perform professional medical services. Except as otherwise permitted by law, Physician Investors must independently bill and collect for any professional medical services that may be related to the business of HealthTronics or a Physician Entity.
- Fair Market Value. All Physician Compensation Arrangements must reflect Fair Market Value. Fair Market Value must be determined in accordance with the policies and procedures contained in Section III.E of this Compliance Plan.

#### 4. LOANS AND GUARANTIES

These policies and procedures apply to loans and guaranties benefitting Physician Investors.

- Loans to Physician Investors. Neither HealthTronics nor any Physician Entity may make loans to Physician Investors.
- Guaranties of Physician Investor Obligations. Neither HealthTronics nor any Physician Entity may guaranty or co-guaranty any obligations of a Physician Investor.
- Guaranties of Physician Entity Obligations. To the extent permitted by law, HealthTronics may guaranty or co-guaranty obligations of a Physician Entity.

#### 5. PHYSICIAN DISTRIBUTIONS

A Physician Investor's share of profit distributions of a Physician Entity may only be determined by the Physician Investor's ownership percentage in the Physician Entity, and may not take into account the Investor's actual or potential referrals to HealthTronics or a Physician Entity or entities contracting with HealthTronics or a Physician Entity.

### **C. ARRANGEMENTS WITH HEALTHCARE FACILITIES**

Certain financial arrangements and transactions between HealthTronics or a Physician Entity, on the one hand, and facilities that provide medical care and treatment to patients, such as hospitals or ambulatory surgery centers ("Healthcare Facilities"), on the other hand, are subject to heightened regulatory scrutiny due to anti-kickback and patient self-referral concerns. Examples of such arrangements and transactions include any contract, agreement, arrangement, or financial transaction between HealthTronics or a Physician Entity and any Healthcare Facility that actually or potentially receives patient referrals from HealthTronics, a Physician Entity or a Physician Investor, and that involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value ("Healthcare Facility Contracts"). Therefore, it is HealthTronics' policy to require all Covered Persons who, on behalf of HealthTronics, in any way facilitate, coordinate, organize, manage, administer, engage in, or otherwise participate in any way in the process of

negotiating, evaluating, assessing, vetting, drafting, preparing, reviewing, revising, amending, executing, implementing, interpreting, or enforcing any Healthcare Facility Contract to comply with the policies and procedures listed below.

#### 1. REFERRAL NEUTRALITY

No Covered Person involved in the Healthcare Facility Contract process may threaten to change a Physician Investor's patient referral or practice patterns or otherwise discuss, refer to, or in any way use the actual or potential volume of referrals that a Physician Investor may make to a Healthcare Facility for any of the following purposes: (a) to obtain any advantage in acquiring, negotiating, vetting, preparing, revising, amending, or implementing any Healthcare Facility Contract, or (b) any other purpose that may be construed as inducing referrals to HealthTronics, a Physician Entity or any other entity.

#### 2. QUALITY OF CARE

Covered Persons involved in the Healthcare Facility Contract process may properly focus on the quality of patient care when acquiring, negotiating, vetting, preparing, revising, amending, or implementing any Healthcare Facility Contract. Communications involving quality of patient care may include the following topics:

- quality assurance and efficacy
- device benefits and differences
- technician qualifications and training
- frequency of service and patient convenience
- patient safety
- availability of backup equipment

#### 3. FAIR MARKET VALUE

The value offered, paid, solicited, or received by or from HealthTronics or a Physician Entity under any Healthcare Facility Contract must be Fair Market Value. Fair Market Value must be determined in accordance with the policies and procedures contained in Section III.E of this Compliance Plan.

#### 4. LEGAL REVIEW AND APPROVAL

All Healthcare Facility Contracts, and all amendments and renewals to such arrangements, must be reviewed and approved by HealthTronics' Legal Department to ensure they are compliant with this Compliance Plan and applicable federal and state requirements. In the case of any template agreement reviewed and approved by HealthTronics' Legal Department, any material modifications to such template agreement must be reviewed and approved by HealthTronics' Legal Department.

- Services. Each Healthcare Facility Contract must include within its scope all of the services provided by HealthTronics or the applicable Physician Entity to a Healthcare Facility under such contract. No services may be provided outside of the scope of a Healthcare Facility Contract.
  - The aggregate services contracted for in any Healthcare Facility Contract must not exceed those that are reasonable and necessary for the legitimate business purpose of the arrangement with the Healthcare Facility.
  - The services described in or provided under any Healthcare Facility Contracts must comply with all applicable federal and state laws.
- Amendment. All Healthcare Facility Contracts must be reviewed, updated, and amended from time to time as necessary or appropriate to maintain compliance with all applicable federal and state laws, including but not limited to compliance with the Anti-Kickback Statute and the Stark Law.

#### **D. ARRANGEMENTS WITH RELATED PARTIES**

Certain arrangements and transactions between a Physician Entity, on the one hand, and HealthTronics or any other affiliate of the Physician Entity (each a “Related Party” and collectively “Related Parties”), on the other hand, are subject to heightened regulatory scrutiny due to anti-kickback and patient self-referral concerns. An affiliate of a party is any entity that manages, has an ownership interest in, or a compensation arrangement with the party. Examples of these arrangements and transactions include any management contract, equipment maintenance contract, sales of equipment, disposables or other items, and the lease of medical technology, transport vehicles or other assets (“Equipment Leases”) between a Physician Entity and a Related Party (“Related Party Agreements”). Therefore, it is HealthTronics’ policy to require all Covered Persons who, on behalf of HealthTronics, in any way facilitate, coordinate, organize, manage, administer, engage in, or otherwise participate in any way in the process of negotiating, evaluating, assessing, vetting, drafting, preparing, reviewing, revising, amending, executing, implementing, interpreting, or enforcing any Related Party Agreement or arrangement to comply with the policies and procedures listed below.

##### **1. RELATED PARTY AGREEMENTS GENERALLY**

These policies and procedures apply to all Related Party Agreements.

- Referral Neutrality. The compensation to be paid over the term of any Related Party Agreement must not be determined in a manner that takes into account the volume or value of any patient referrals or other business generated between the parties.
- Fair Market Value. The aggregate value offered, paid, solicited, or received under any Related Party Agreement must reflect Fair Market Value. Fair Market Value must be determined in accordance with the policies and procedures contained in Section III.E of this Compliance Plan.

- Equipment Leases. In addition to the above requirements for Related Party Agreements generally, the rental charges over the term of an Equipment Lease must not be determined using a formula based on one of the following:
  - A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed on or business generated by the use of the equipment; or
  - Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred between the parties.
- Use of Historical Procedure Volume. When setting prospective annual lease charges, a time-based approach, taking into account the aggregate projected time the equipment will be utilized to perform the projected procedure volume during the year, is acceptable.
- Approval. All Related Party Agreements, and all amendments and renewals to such agreements, must be reviewed and approved by HealthTronics' Legal Department. In the case of any template agreement reviewed and approved by HealthTronics' Legal Department, any material modifications to such template agreement must be reviewed and approved by HealthTronics' Legal Department.
- Amendment. All Related Party Agreements must be reviewed, updated, and amended from time to time as necessary or appropriate to maintain compliance with all applicable federal and state laws, including but not limited to compliance with the Anti-Kickback Statute and the Stark Law.

## 2. SALES OF EQUIPMENT, DISPOSABLES, AND OTHER ITEMS

These policies and procedures apply to the sale of equipment, disposables, and other items between a Physician Entity and a Related Party.

- Fair Market Value. The price of any equipment, disposables, or other items sold between a Physician Entity and a Related Party must reflect Fair Market Value, and must be on terms that are commercially reasonable without taking into account the volume or value of referrals, or other business generated between the parties.

## 3. LOANS AND GUARANTIES

These policies and procedures apply to loans and guaranties between a Physician Entity and Related Parties.

- Loans between a Physician Entity and Related Parties. Loans between a Physician Entity and a Related Party must comply with all applicable laws, must reflect Fair Market Value, and must be on terms that are commercially reasonable without taking into account the volume or value of referrals, or other business generated between the parties. Notwithstanding the above, in no event may HealthTronics, a Physician Entity or a Related Party loan money to a Physician Investor.

- Guaranties from Related Parties to a Physician Entity. Any guaranties or co-guaranties by a Related Party of any obligation of a Physician Entity must comply with all applicable laws, must reflect Fair Market Value, and must be on terms that are commercially reasonable without taking into account the volume or value of referrals, or other business generated between the parties.

## **E. FAIR MARKET VALUE DETERMINATIONS**

The concept of Fair Market Value is critical to addressing anti-kickback and patient self-referral concerns. Therefore, it is HealthTronics' policy to require all Covered Persons to comply with the policies and procedures listed below in addressing Fair Market Value considerations.

### **1. FAIR MARKET VALUE DEFINED**

Fair Market Value means the value in arm's-length transactions, consistent with the general market value. "General market value" means the price that an asset would bring as the result of *bona fide* bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of *bona fide* bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement.

Usually, the fair market price is the price at which *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.

With respect to equipment leases, Fair Market Value means the value of rental property for general commercial purposes (not taking into account its intended use).

### **2. METHODS TO DETERMINE FAIR MARKET VALUE**

Covered Persons may determine Fair Market Value using any commercially reasonable methodology that is appropriate under the circumstances, including but not limited to the following methodologies:

- Independent Appraisers. A qualified independent appraiser may be engaged to determine the Fair Market Value for a particular arrangement or transaction or to provide appropriate valuation models and methodologies to be applied internally by designated qualified Covered Persons to determine Fair Market Value for particular arrangements or transactions where appropriate.
- Comparables. Comparable transactions or arrangements may be evaluated as a way of determining Fair Market Value for a particular arrangement or transaction, but the comparables may not include transactions or arrangements with parties in a position to make or influence patient referrals.

- Any Other Commercially Reasonable Method. Any other commercially reasonable method may be used to determine Fair Market Value. For example, IRS guidelines may be consulted for determining Fair Market Value, when appropriate, or the cost plus reasonable rate of return on investment on leases of comparable medical equipment from disinterested lessors may be utilized if appropriate.

### 3. INTERNAL CONSISTENCY

To the extent reasonably practicable, HealthTronics should utilize consistent methods for determining Fair Market Value for all similar pricing and valuation determinations.

## F. UTILIZATION INFORMATION

The use and sharing of information regarding the actual or potential volume of patient referrals from identified physicians is subject to heightened regulatory scrutiny due to anti-kickback and patient self-referral compliance concerns. Examples of such information include data, whether oral, written, or otherwise, and regardless of form or medium, regarding the actual or potential volume of patient referrals from any physician or physicians to a Physician Entity or any other entity contracting with or that may contract with a Physician Entity (“Utilization Information”). Therefore, it is HealthTronics’ policy to require all Covered Persons to comply with the policies and procedures listed below.

### 1. USING UTILIZATION INFORMATION

No Covered Person may use or consider Utilization Information for any of the following purposes: (a) determining whether a Physician Entity may redeem an Investment Interest; (b) determining the size or amount of any Investment Interest that may be owned by a Physician Investor or that may be redeemed by a Physician Entity; (c) determining or establishing the purchase price to be paid for an Investment Interest upon acquisition, disposition, redemption, or otherwise; or (d) any other purpose that may be construed as influencing patient referrals to HealthTronics, a Physician Entity or any other entity.

### 2. SHARING UTILIZATION INFORMATION

A Covered Person may not give, distribute, circulate, communicate, reference, provide, or otherwise make available Utilization Information to any Physician Investor. This restriction does not prohibit a Covered Person from providing to any Physician Investor aggregate patient volume data across an entire Physician Entity, or other affiliated entities, in a manner that does not identify or enable the identification of any referral volume from any particular physician or physicians, so long as such aggregated data is used for quality of patient care, or other legitimate business purpose.

### 3. PATIENT ACCEPTANCE AND REFERRAL

Physician Investors are not required to refer patients to HealthTronics or any Physician Entity, or to entities that contract with HealthTronics or any Physician Entity. Physician Investors must always act in the best interests of their patients in determining medical treatment.

- Medical Necessity. Physician Investors must determine where and how to treat patients based on medical necessity in accordance with customary medical community standards and the best interests of patients.
- Documentation. Physician Investors must document medical necessity in each patient's medical records when referring a patient for treatment at a facility contracting with HealthTronics or a Physician Entity. When required by law or by a Physician Entity's governing documents, Physician Investors must also disclose to patients their financial interest in any Physician Entity and its business relationship with contracting entities to which the patients may be referred.

## **G. BILLING POLICIES**

Patient and public and private insurance billing and coding practices are subject to heightened regulatory scrutiny. Therefore, it is HealthTronics' policy to require all Covered Persons involved with billing and coding practices to comply with the policies and procedures listed below.

### **1. BILLING ARRANGEMENTS**

These policies and procedures apply to the billing of claims for medical services to patients or to their public or private insurers.

- Compliance with Laws. HealthTronics shall comply with all laws governing the submission and review of its bills.
- Billing Inquiries. HealthTronics shall deal with any billing inquiries in a forthright manner. HealthTronics shall answer requests for information with complete and accurate information, and shall cooperate fully with payor requests.

### **2. BILLING AND CODING DOCUMENTATION**

These policies and procedures apply to documentation of claims for billing and coding purposes.

- Billings Generally. Covered Persons shall take great care to ensure that any billings to payors and patients are truthful, accurate, and complete.
- Under Arrangements Billing. HealthTronics shall truthfully, accurately, and completely submit information to hospitals that is sufficient to allow hospitals to bill for services provided under arrangement and to allow hospitals to comply with all laws governing the documentation and retention of medical records supporting billings and claims for payment.
- Compliance with Laws. Covered Persons shall comply with the current reimbursement principles set forth in applicable statutes, regulations, and federal, state, or payor healthcare program requirements. HealthTronics prohibits the following:

- billing for items or services not rendered or not provided as claimed
- submitting claims for equipment, medical supplies, and services that are not reasonable and necessary
- double billing resulting in duplicate payment
- billing for non-covered services as if covered
- knowing misuse of provider identification numbers, which results in improper billings
- failure to properly use coding modifiers
- clustering (the practice of coding/charging one or two middle levels of service codes exclusively, on the basis that some will be higher, some lower, and the charges will average out over an extended period)
- upcoding the level of service provided or compensating billing consultants in any way to improperly upcode claims

## **H. BUSINESS COURTESIES AND OTHER GRATUITIES**

Certain business courtesies and gratuities are subject to heightened regulatory scrutiny due to anti-kickback concerns. Therefore, it is HealthTronics' policy to require all Covered Persons to comply with the policies and procedures listed below.

### **1. BRIBERY PROHIBITED**

No Covered Person shall engage in any form of bribery, including the offer or acceptance of any improper payment, gratuity, or gift to obtain business, secure services, or influence governmental decisions.

### **2. EXTENDING BUSINESS COURTESIES TO PHYSICIAN INVESTORS AND OTHER POTENTIAL SOURCES OF BUSINESS REFERRALS**

Covered Persons may offer reasonable and appropriate meals and refreshments in conjunction with business events, provided that such events are in furtherance of HealthTronics' or a Physician Entity's legitimate business purposes and are unrelated to compensating parties for patient referrals or other business generated between the parties. Such expenses should be appropriately incurred by the party (i.e., either HealthTronics or a Physician Entity) whose business interest is being served.

- HealthTronics or a Physician Entity, as applicable, may reimburse reasonable transportation and lodging provided to physicians and other healthcare professionals who have a *bona fide* professional interest in the information being shared at such events. Such expenses should be appropriately incurred by the party (i.e., either HealthTronics or a Physician Entity) whose business interest is being served.

- Nothing may be provided to a customer in exchange for any explicit or implicit agreement or understanding to use, purchase, order, or recommend any HealthTronics, or Physician Entity service or product or for referral of services.

### 3. BUSINESS COURTESIES AND GOVERNMENT EMPLOYEES

Neither HealthTronics nor any Covered Person shall provide any gifts, entertainment, or anything else of value to any employee of the federal or state government.

- Modest meals and refreshments in connection with business discussions may be provided free of charge in those jurisdictions or with those agencies where government rules permit this practice.

### 4. ADVAMED CODE OF ETHICS

In addition to the requirements of this Compliance Plan, all Covered Persons whose job responsibilities relate to HealthTronics' cryoablation business must comply with the requirements of AdvaMed's *Code of Ethics on Interactions with Health Care Professionals*, as revised from time to time.

## I. RECORD RETENTION

The retention of proper documentation of business information, medical records, legal documents, and certain other types of documents is required by federal and state law. It is HealthTronics' policy to comply with all applicable legal requirements in connection with the retention and destruction of records. No Covered Person may falsify or wrongfully alter information on any record or document. HealthTronics follows the policies and procedures set forth in HealthTronics' *Records Retention Policy* as revised from time to time.

## J. HIPAA PRIVACY AND SECURITY

Ensuring the privacy and security of patients' protected health information is required by federal and state law. It is HealthTronics' policy to comply with all applicable legal requirements. HealthTronics follows the policies and procedures set forth in HealthTronics' *HIPAA Security Manual and HIPAA Privacy Policy and Procedure* as revised from time to time.

## **IV. EDUCATION AND TRAINING**

One of the most important components of this Compliance Plan and HealthTronics' overall compliance program is education.

### **A. TRAINING PROGRAM**

It is HealthTronics' policy that all Covered Persons complete compliance training regarding this Compliance Plan generally and, to the extent applicable to particular Covered Persons, specialized training in the risk areas covered by this Compliance Plan. Training will also address appropriate communications by Covered Persons to Physician Entities and Physician Investors regarding key elements of this Compliance Plan that are relevant to Physician Entity operations. Specialized training may also include, without limitation, the following topics if applicable to particular Covered Persons:

- applicable laws and regulations
- arrangements that potentially implicate the federal Anti-Kickback Statute and Stark Law, as well as the regulations and other guidance documents related to these laws
- the legal sanctions under the federal Anti-Kickback Statute and Stark Law
- relevant examples of violations of the federal Anti-Kickback Statute and Stark Law
- specific government and private payor reimbursement principles
- the personal obligation of each individual involved in the development, approval, management, or review of financial relationships to know the applicable legal requirements and HealthTronics' policies and procedures

Training shall be provided to Covered Persons upon employment or affiliation with HealthTronics and annually thereafter.

HealthTronics shall engage persons qualified and knowledgeable about the particular subject areas to train Covered Persons with respect to this Compliance Plan and such other policies and procedures for which HealthTronics deems training necessary from time to time.

HealthTronics shall review its training program annually and update it as necessary.

### **B. ATTENDANCE**

Failure to comply with these training requirements will be deemed a violation of this Compliance Plan and may result in disciplinary action as described in Section VIII. For Covered Persons who are employed by HealthTronics, attendance and participation at HealthTronics-sponsored training programs is a condition of continued employment and will be considered part of evaluations as applicable.

### **C. CERTIFICATION**

All training is tracked to ensure compliance. The Compliance Officer or the Compliance Officer's designee shall oversee the process for verifying that each Covered Person has received the required training.

## V. OPEN LINES OF COMMUNICATION AND COMPLIANCE HOTLINE

An open line of communication between Covered Persons and the Compliance Officer is essential for the success and effectiveness of the overall compliance program.

### A. DUTY TO REPORT

All Covered Persons are expected to report to the Compliance Officer, or other designated individual, suspected violations of any federal healthcare program requirement, any other applicable law, or this Compliance Plan.

Covered Persons should report any conduct that a reasonable person would believe to be erroneous, fraudulent, a violation of any applicable law, or a violation of this Compliance Plan. Further, Covered Persons should report any incidents in which they believe they may have been requested to engage in illegal or unethical conduct. When in doubt, Covered Persons should report.

If a Covered Person becomes aware of an actual or potential violation and does not report it, the failure to report will be deemed a violation of this Compliance Plan and may result in disciplinary action as described in Section VIII. A Covered Person's obligation to HealthTronics is not only to abide by this Compliance Plan with regards to his or her own actions, but also to help HealthTronics ensure that all of its operations are within the requirements of the law and this Compliance Plan.

No action will be taken against any Covered Person for reporting possible violations of applicable laws and this Compliance Plan. HealthTronics is committed to a policy of nonretribution and nonretaliation, and will maintain confidentiality and anonymity, as appropriate, with respect to reported violations.

### B. ETHICS AND COMPLIANCE HOTLINE

HealthTronics also has in place an Ethics and Compliance Hotline where reports can be made at any time by phone or online. If you use the Hotline, an external third party will ask for details about your question or report and provide a reference number. You can anonymously report an issue, concern or question in three ways:

1. Dial Toll-Free **1-844-TEL-HTRN (1-844-835-4876)** *24 hours a day 7 days per week.*
2. Sending an email to: [Tell-HealthTronics@GetInTouch.com](mailto:Tell-HealthTronics@GetInTouch.com)
3. Via the web: Visit [www.intouchwebsite.com/HealthTronics](http://www.intouchwebsite.com/HealthTronics)

The hotline may be used to anonymously report violations or suspected violations of the law or this Compliance Plan or report concerns regarding compliance issues. The hotline is intended to supplement, not replace, other channels for communicating questions and concerns within the organization. It should be used when you have exhausted other avenues of communication, are

uncomfortable with disclosing your identity when reporting a concern or if you feel that your complaint was not addressed when raised through another channel.

Covered Persons shall also communicate to Physician Entities and to Physician Investors the existence of the compliance hotline and its availability to be used by them to report any compliance concerns relating to a Physician Entity.

### **C. QUESTIONS AND INQUIRIES**

HealthTronics encourages open communication with Covered Persons. Covered Persons should direct any questions, comments, concerns, or other inquiries regarding this Compliance Plan or their duty to report to the Compliance Officer.

## **VI. INTERNAL MONITORING AND AUDITING**

Another important element of this Compliance Plan is the use of an ongoing evaluation process to determine the effectiveness of this Compliance Plan and to ensure that HealthTronics' policies and procedures remain current and accurate.

### **A. MONITORING**

The Compliance Officer shall implement a system of internal controls for monitoring the effectiveness of this Compliance Plan, including the use of risk evaluation techniques to monitor compliance and assist in the reduction of identified risk areas.

The periodic review and update of the Compliance Plan and all policies and procedures is important to ensuring continued legal compliance. The Compliance Officer shall conduct an annual review of this Compliance Plan to determine if it is current and complete and update this Compliance Plan as necessary.

### **B. AUDITING**

The Compliance Officer shall design and conduct or arrange for periodic internal or external audits to assess the success of this Compliance Plan and overall compliance program. These audits shall focus on high-risk areas identified by the OIG, federal healthcare programs, law enforcement agencies, internal reviews, and outside legal counsel. The Compliance Officer shall take corrective actions and make revisions to this Compliance Plan as appropriate to prevent the recurrence of problems identified by audits.

## **VII. APPROPRIATE RESPONSE TO DETECTED VIOLATIONS**

The Compliance Officer shall ensure that all reports of noncompliance are thoroughly investigated, documented, and resolved, and that indicated disciplinary actions are taken by appropriate management personnel.

### **A. INVESTIGATION**

Upon receipt of a report of suspected violation or a reasonable indication of suspected violation, the Compliance Officer shall assess whether a violation of this Compliance Plan or applicable laws and regulations has occurred. The Compliance Officer may engage the assistance of outside legal counsel if he/she deems it is warranted. The Compliance Officer shall make this assessment on a case-by-case basis on all reports of detected or suspected violations, and conduct a reasonable internal investigation to determine:

- whether a violation of this Compliance Plan or overall compliance program, applicable policies or procedures, or federal or state law occurred
- the severity of the misconduct

### **B. DUTY TO COOPERATE DURING PENDING INVESTIGATIONS**

Covered Persons who are the subject of an investigation have a duty to cooperate with the Compliance Officer while the investigation is pending. The Compliance Officer shall have the right to take all appropriate actions to ensure that the responsibilities of such Covered Persons have not and shall not adversely affect the quality of care rendered to any beneficiary or patient or any claim submitted to any federal healthcare program. Such Covered Persons shall cooperate and perform all such other actions that may be deemed reasonably necessary or proper by the Compliance Officer to effectuate, confirm, perform, or carry out the actions the Compliance Officer deems necessary to ensure no adverse effects on quality of care or claim submissions. Failure to cooperate with the Compliance Officer during a pending investigation will be deemed a violation of this Compliance Plan and may result in disciplinary action as described in Section VIII.

### **C. CORRECTIVE AND FOLLOW-UP ACTION**

The Compliance Officer shall take immediate steps to correct the violation, which may include, but is not limited to, the following actions:

- referral to the appropriate criminal and civil law enforcement authorities
- development and implementation of a corrective action plan
- report to the government
- submission of any overpayment

#### **D. DISCIPLINE**

HealthTronics will take appropriate disciplinary action as described in Section VIII against a Covered Person who has violated this Compliance Plan or applicable laws and regulations.

#### **E. DOCUMENTATION**

When a report results in a finding of noncompliant conduct, the Compliance Officer shall document in the compliance files the following information:

- date of incident
- name of the reporting individual
- name of the person responsible for taking action
- description of the investigative process
- copies of any relevant notes and documents, such as interview notes, a log of witnesses interviewed, and the documents reviewed
- results of the investigation, including any disciplinary or other follow-up action taken, and the corrective action implemented

## **VIII. DISCIPLINARY GUIDELINES**

This Compliance Plan is rendered ineffective if appropriate disciplinary actions related to acts of noncompliance or failure to detect and report noncompliance are not enforced consistently.

### **A. DISCIPLINARY GUIDELINES**

Strict compliance with this Compliance Plan and applicable laws and regulations is a condition of continued employment or affiliation with HealthTronics, since violation of this Compliance Plan, whether from carelessness or intentional action, puts both Covered Persons and HealthTronics at risk. Any violation of this Compliance Plan or applicable laws and regulations may result in such disciplinary action as the Compliance Officer deems necessary and appropriate under the particular circumstances of the violation. Failure to report violations may also subject Covered Persons to disciplinary action.

The Compliance Officer, in consultation with HealthTronics' senior management and/or Board of Directors, as appropriate, shall determine on a case-by-case basis whether disciplinary action is warranted, and shall have flexibility in enforcing these disciplinary procedures. In determining whether disciplinary action is appropriate, and if so, what level of disciplinary action to impose, the Compliance Officer shall consider factors such as the following:

- whether the violation was willful, reckless, or negligent
- whether the violation is a first offense or a repeat violation
- the severity of the violation and surrounding circumstances
- the degree of cooperation by the violator during the investigation and corrective action processes
- other mitigating or aggravating factors, as appropriate

### **B. DISCIPLINARY ACTION**

Any violation of this Compliance Plan or applicable laws and regulations is grounds for disciplinary action up to and including termination of employment and possible legal prosecution, imprisonment, and fines.