



U.S.

**CONTRACTUAL ARRANGEMENTS SUBJECT TO ANTI-KICKBACK
STATUTE POLICY**

Sorin Group is committed to complying with any and all applicable laws wherever we do business and has implemented compliance policies to provide practical guidance on issues that arise while transacting Sorin Group business.

This is a statement of each of the U.S. subsidiaries of Sorin Group (Sorin Group USA, Inc. and Sorin CRM USA, Inc.) policies and practices regarding the establishment of arrangements with individuals in a position to refer or recommend the purchase of Sorin Group products.

1. Introduction

As a medical device company, Sorin Group (“Sorin”) manufactures products that are reimbursed by Federal health care programs such as Medicare and Medicaid. Accordingly, Sorin requires that all its employees, contractors, independent sales representatives, and entities and persons with whom Sorin does business comply, at all times, with the federal Anti-Kickback Statute.

2. Regulatory Issues and Basic Concepts

- 2.01 Many Health Care Professionals provide consulting, training and education, and clinical research assistance to Sorin. Through these Arrangements, Health Care Professionals provide valuable *bona fide* services, including, but not limited to, research, participation on advisory boards, presentations at Sorin-sponsored trainings, training to Health Care Professionals or sales representatives, acting as clinical study investigators, providing other clinical trial assistance, and product collaboration.
- 2.02 Sorin provides charitable donations, product donations, and educational grants to Health Care Professionals, charitable entities, and other organizations in the interest of supporting indigent care, patient education, public education, medical education, or other charitable purposes.
- 2.03 Sorin provides evaluation machines to hospitals and other health care entities in order to improve patient care, facilitate the safe and effective use of products, improve patient awareness, and educate Health Care Professionals regarding the use of Sorin products.
- 2.04 Sorin purchases advertisements and exhibit space to advertise and display its products at educational conferences, provides rebates to hospitals and wholesalers, and pays administrative fees to group purchasing organizations (“GPO”).
- 2.05 The Anti-Kickback Statute prohibits payments of anything of value (including a reduction in price) in exchange for recommending or arranging for the purchase of services payable by a Federal health care program (e.g. Medicare or Medicaid). Generally, the Anti-Kickback Statute prohibits: 1) the offer, payment, solicitation, or receipt of any remuneration, directly or indirectly, in cash or in kind, for, among other things, the provision of items or services for which payment may be made under government health care programs; or 2) the purchase, lease, or order, or arranging for the purchase, lease, order, of any good, facility, service, or item for which payment made be made under government health care programs. A violation of the Anti-Kickback Statute constitutes a felony criminal offense punishable by imprisonment of up to five years, fines up to \$25,000, or both. In addition, violators are subject to certain civil sanctions, including civil monetary penalties and exclusion from the Medicare and Medicaid programs.
- 2.06 The Anti-Kickback Statute has several Safe Harbors that define practices that are not subject to the Anti-Kickback Statute because such practices would be unlikely to result in fraud or abuse. The Anti-Kickback Statute includes Safe Harbors for personal services, rebates, and GPOs, among other things, if certain standards are met. Failure to fit squarely within a Safe Harbor, however, does not necessarily violate the law. Instead, the legality of an arrangement will depend on the likelihood that the U.S. Office of Inspector General or a court would conclude that the parties’ intent was to induce or reward referrals.
- 2.07 Sorin has established an Arrangements Review and Tracking Process designed to review each Arrangement to ensure it does not violate the Anti-Kickback Statute or Sorin Compliance Policies and Procedures.

3. Definitions

- 3.01 **Sorin Employees, Contractors and Independent Sales Representatives**: Sorin directors, officers, employees, personnel, contractors, or independent sales representatives. Sorin

employees, contractors, and independent sales representatives including all sales and marketing personnel, whether employed or contracted.

- 3.02 **Health Care Professionals:** Physicians, hospital purchasing personnel, other clinicians or any other person or entity in a position to purchase, influence the purchase of, or make referrals for Sorin products. For example, Health Care Professionals include doctors of medicine or osteopathy, cardiologists, electrophysiologists, cardiac surgeons, nurse practitioners, physician assistants, perfusionists, pacemaker and catheterization technicians, hospital purchasing personnel, and other organizations and personnel that purchase medical devices.
- 3.03 **Arrangements:** Every arrangement or transaction entered into by or on behalf of Sorin that involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value and is between Sorin and any actual source of referral or sales payable by a Federal health care program. Arrangements include, but are not limited to, speaker fees and related costs, honoraria, consulting fees, travel costs, personal service arrangements, management or administrative arrangements, educational grants, charitable contributions, clinical or research grants, clinical or research agreements, advisory boards, continuing medical education sponsorships, marketing service fees, GPO administrative fees, evaluation machines, and rebates.
- 3.04 **Arrangements Review and Tracking Process:** Centralized tracking system for all Arrangements designed to ensure that all Arrangements are reviewed by both Sorin U.S. Legal Affairs and the Compliance Function to determine whether each Arrangement is in compliance with the Anti-Kickback Statute and Sorin's Compliance Policies and Procedures. In addition, it tracks remuneration to and from Health Care Professionals and the services rendered under Arrangements. See Sorin's **HCP Arrangements Tracking Process Manual** for more detailed information on the Arrangements Review and Tracking Process.

4. Issue Specific Policies and Procedures

- 4.01 All Arrangements that include any payments to a Health Care Professional or a Health Care Professional's entity, employer, or other affiliated entity should be structured to meet, or fall as closely as possible within, one of the Anti-Kickback Statute Safe Harbors.

The Safe Harbors applicable to most Arrangements are the personal services Safe Harbor, the discount Safe Harbor, or the GPO Safe Harbor.

- 4.02 The personal services Safe Harbor requires, at a minimum, all of the following specific requirements to be met:
- The Arrangement is set out in writing in an Agreement signed by the parties;
 - The Agreement covers all of the services the Health Care Professional will provide to Sorin for the term of the Agreement and specifies the services to be provided by the Health Care Professional;
 - If the Agreement is intended to provide for the services of the Health Care Professional on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the Agreement, the Agreement should specify exactly the schedule of such intervals, their precise length, and the exact charge for such intervals;
 - The term of the Arrangement is for not less than one (1) year;
 - The aggregate compensation paid to the Health Care Professional over the term of the Agreement is set in advance, is consistent with fair market value in arms-length transactions, and is not determined in a manner that takes into account the volume or

value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care program;

- The services performed under the Agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law; and
- The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the service.

4.03 The discount Safe Harbor requires, at a minimum, all of the following specific requirements to be met for a rebate program with a cost reporting entity, such as a hospital:

- The terms of the rebate discount program must be fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies;
- The existence of a discount program must be fully and accurately reported on the invoice;
- The buyer must be informed of its obligations to report the discount and provide information upon request;
- When the value of the discount becomes known, the buyer must be provided with documentation of the calculation of the discount identifying the specific goods or services purchased to which the discount will be applied; and
- Sorin must not do anything that would impede the buyer from meeting its reporting obligations.

4.04 The GPO Safe Harbor requires, at a minimum, all of the following specific requirements to be met:

- Sorin must have a written agreement with the GPO to furnish goods or services to an individual or entity;
- The agreement must state either: 1) Sorin will pay a fee to the GPO of 3 percent or less of the purchase price of the good or services made from Sorin; or 2) Sorin will pay a specified amount, or if not known, a maximum amount, to the GPO where such amount may be a fixed sum or a fixed percentage of the value of purchases made from Sorin.

4.05 Every Arrangement must be approved through the Arrangements Review and Tracking Process to ensure that each Arrangement is compliant with state and federal law, the Sorin Code of Conduct, Sorin Compliance Policies and Procedures, and the *AdvaMed Code of Ethics on Interactions with Health Care Professionals*.

4.06 Sorin Employees, Contractors and Independent Sales Representatives may initiate the Arrangements Review and Tracking Process to obtain approval for an Arrangement by contacting his or her Manager.

4.07 Each Business Unit (Cardiac Rhythm Management, Cardiopulmonary, and Heart Valves) will designate Arrangements Administrators who will be responsible for the administrative function of gathering the information necessary to initiate the Arrangements Review and Tracking Process.

- 4.08 The Business Unit Manager will notify the designated Arrangements Administrator to initiate and oversee the Arrangements Review and Tracking Process.
- 4.09 The Arrangements Administrator must fully complete all the required information on the Arrangements Tracking Form, including the Health Care Professional's identifying information, Social Security Number or Tax Identification Number, the business purpose for the Arrangement, and the terms of each specific Arrangement. Each type of Arrangement must comply with the specific requirements of any applicable Sorin policy, such as the Charitable Donations Policy, Consulting by Health Care Professionals Policy, or Travel and Facility Tour Policy.
- 4.10 The Business Unit Manager responsible for the Arrangement must certify, if applicable, that all payments or consideration under the Arrangement are fair market value for the service or non-service items received by Sorin.

Generally, fair market value is defined as the value derived by the parties as a result of "arms length transactions, consistent with the general market value." 42 U.S.C. § 1395nn(h)(3).

General market value is defined as follows:

"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. 42 C.F.R. § 411.351.

- 4.11 The Business Unit Manager responsible for the Arrangement must certify that each Arrangement is in compliance with any applicable Sorin policy, such as the Charitable Donations Policy, Consulting by Health Care Professionals Policy, or Travel and Facility Tour Policy. International travel must be approved by a Senior Business Unit Leader.
- 4.12 Each Arrangement and any amendments to existing Arrangements must be reviewed and approved by Sorin U.S. Legal Affairs and the Compliance Function.
- 4.13 Each Arrangement must be documented in writing utilizing the applicable contract template established and maintained by Sorin U.S. Legal Affairs. The applicable contract template must be utilized for all Arrangements that fall under the definition of this policy. The contract must be signed by all parties. The fully executed contract must be properly stored in the Arrangements Review and Tracking system.
- 4.14 No payment will be made to any Health Care Professional without a signed, effective contract that was approved under the Arrangements Review and Tracking Process and documentation or certification that services were rendered or the arrangement was performed by the non-Sorin party.
- 4.15 For training and education Arrangements, attendance of the Health Care Professional at the event is mandatory for any reimbursement or payment to be made. For consultation Arrangements, payment can only be made for services furnished: (1) upon completion and verification of services furnished in accordance with the Agreement; and (2) by direct wire transfer or check in the name and address or account of the contracting Consultant. For all other payments, the payment can only be made directly to the Health Care Professional who is specified in the executed contract.

- 4.16 Sorin may currently have or eventually develop other compliance policies and procedures which may affect the types of Arrangements covered under this policy. All Arrangements covered under this policy will be designed implementing the principles outlined above in conjunction with consideration of other relevant policies.