

PHYGEN, LLC.

COMPREHENSIVE COMPLIANCE PROGRAM

COMMITMENT TO COMPLIANCE

** Commitment to Compliance **

TABLE OF CONTENTS

	<u>Page</u>
I. INTRODUCTION	i
II. CODE OF CONDUCT AND ETHICS.....	2
III. COMPLIANCE POLICIES AND PROCEDURES	3
A. Specific Issues Related to Medical Devices.	3
B. Compliance with Federal and State Laws and Regulations.....	3
C. Anti-Kickback and Physician Self-Referral Concerns Generally	4
D. Additional Sales and Marketing Policies.....	5
E. Improper Inducements and Kickbacks.	6
F. Sponsorship of Third-Party Educational and Community Programs.....	8
G. Research Grants and Studies.....	9
H. Purchasing Services From Physicians and Other Potential Referral Sources.....	10
I. Business Courtesies.....	11
J. Free Goods or Discounts of Any Kind Contingent on Purchases.....	13
K. “Switching” Arrangements.....	13
IV. COMPLIANCE AS AN ELEMENT OF PERFORMANCE.....	14
V. OVERSIGHT OF COMPLIANCE: COMPLIANCE OFFICER; PRIVACY OFFICER; COMPLIANCE TASK FORCE	14
A. Compliance Officer.....	14
B. Compliance Task Force.....	16
C. Hotline.....	16
VI. TRAINING AND EDUCATION	17

TABLE OF CONTENTS
(Continued)

	<u>Page</u>
VII. LINES OF COMMUNICATION	18
VIII. ENFORCING STANDARDS, POLICIES AND PROCEDURES	19
A. Discipline Policies and Procedures.	19
1. Policies.	19
2. Discipline Procedures.	19
B. New Employees and Contractors.	19
IX. AUDITING AND MONITORING	20
A. Generally.....	20
X. CORRECTIVE ACTION.....	21
A. Violations and Investigations.....	21
B. Reporting.	22

I. INTRODUCTION

Phygen, LLC designs, develops, markets and distributes instrumentation (otherwise referred to as "implants") used in connection with certain spine-related surgeries. We are dedicated to advancing spine surgery by providing innovative, cost-effective solutions to the surgical community. Phygen's reputation for providing high quality products to our customers continues to grow. Fundamental to our ability to continue providing high quality products is the maintenance of demanding ethical and professional standards. As a manufacturer of FDA licensed therapeutic medical devices, Phygen operates in a highly regulated industry and strives to comply with both the letter and spirit of all laws and regulations. Phygen is firmly committed to compliance.

In the current health care environment, the interpretation of laws governing all types of health care-related activities, and, in particular, sales and marketing, and arrangements with referral sources, are constantly evolving and have become increasingly complex. To ensure compliance with these laws, regulations, rules, and other requirements, we have developed this Compliance Program (the "Compliance Program").

The success of this Compliance Program will depend on the commitment of Phygen and our employees. This Compliance Program is intended to ensure to the extent possible that Phygen, and our employees, contractors, and agents, act in compliance with federal and state laws, regulations, rules, and guidelines as they apply to our business and operations. The Compliance Program also sets forth our objectives and requirements regarding compliance, and our expectations for our employees, agents, and contractors. This Compliance Program may be supplemented by various additional compliance policies and procedures which may be adopted by us from time to time.

To further the Compliance Program, and because the acts of our managers, employees, or agents might in some instances be attributed to us, it is imperative that our employees, contractors, and agents be familiar with the federal and state laws which govern their activities on our behalf. As is set forth in more detail in this Compliance Program, that familiarity will be an essential part of every affected employee's job performance and a regular part of each such employee's performance evaluation.

All of our affected employees will be required to certify their acceptance of the requirements set out in this Compliance Program. Any action taken in violation of this Compliance Program is outside the scope of employment and could subject the individual to serious sanctions, including termination of employment and possibly even criminal prosecution.

Affected employees will receive education and information regarding the Compliance Program, and all relevant laws, regulations, rules, and guidelines addressed herein. Any employee who has questions or concerns about anything discussed in the Compliance Program should contact Phygen's Compliance Officer.

This Compliance Program should not be viewed as an unnecessary burden in the performance of job functions and our business affairs. Rather, this Compliance Program must be

viewed as a fundamental aspect of good professional and business practices. We are committed to compliance and expect our employees, contractors, and agents to share in this commitment.

II. CODE OF CONDUCT AND ETHICS

Our Board of Directors and management are firmly committed to full compliance with all applicable federal and state laws, regulations, rules, and guidelines. At the core of this commitment are our employees, and the manner in which they conduct themselves. To assure that commitment is shared by our employees, we have established the following Code of Conduct and Ethics, which each employee will be required to certify his or her acceptance of as a condition of employment:

- ❖ All affected employees will be responsible for reviewing and understanding our Compliance Program.
- ❖ All of our employees will conduct themselves with integrity, honesty, courtesy, and fairness in their professional and personal dealings related to our business.
- ❖ All of our employees will treat other employees, customers, and business contacts fairly and with respect.
- ❖ No employee will engage in any activity in violation of any of the policies and procedures set forth in, or adopted by, this Compliance Program, nor will any employee engage in any other conduct which violates any federal, state or local law, regulation, rule or guideline.
- ❖ All employees will promptly report any activities which they believe may violate the policies and procedures set forth in this Compliance Program, or any other applicable law, regulation, rule or guideline, in accordance with the reporting procedures set forth in this Compliance Program.
- ❖ All employees will promptly report all suspected violations of this Code of Conduct and Ethics by other employees, or by our contractors or agents, in accordance with the reporting procedures set forth in this Compliance Program.
- ❖ All employees will comply with not only the letter of this Compliance Program, but with the spirit of this Compliance Program as well. When in doubt, employees should consult with their direct supervisor or the Compliance Officer.

Our customers and the public at large have a right to expect that our business will be conducted in a professional manner consistent with the ethical guidelines set forth above, as well as commonly accepted standards for moral and ethical behavior. However, this Code of Conduct and Ethics is not intended to be an exhaustive list of all standards by which our employees are to be governed. Rather, it is intended to convey to our employees our commitment to this Compliance Program and the high standards we have set for each of our employees.

Each employee should perform his or her duties in good faith and in a manner that he or she reasonably believes to be in our best interests. All of our employees are expected to comply with the letter and spirit of all standards and policies set forth in this Compliance Program as well as other rules and policies adopted by us. Each employee must maintain a high level of integrity in business conduct and avoid any conduct that could reasonably be expected to reflect adversely upon our integrity, our officers, directors, or other employees.

III. COMPLIANCE POLICIES AND PROCEDURES

In keeping with our commitment to compliance, we have developed policies and procedures to address key areas of special concern to our operations. The areas of concern addressed by those policies and procedures, and some of the guiding principles underlying them, are described below. However, not all of our policies and procedures have been reduced to written form. Many policies and procedures have been and will continue to be established and maintained by practice. Our employees are expected to be aware of, and fully understand, all policies and procedures that affect their respective job functions, and should consult with their direct supervisor or the Compliance Officer if they are uncertain about any procedures.

A. Specific Issues Related to Medical Devices.

As a provider of medical devices requiring a prescription to be dispensed ("Legended Devices"), Phygen is subject to certain specific statutory and regulatory obligations. As with any other health care organization, Phygen may only provide Legended Devices where they are properly authorized. To further ensure compliance with the various laws and regulations applicable to the dispensing of medical devices, we have established the following policies and procedures:

- ❖ Legended Devices will be provided to hospitals or ambulatory surgical centers only pursuant to an order from an authorized person.
- ❖ Upon receipt of a purchase order number from the hospital or ambulatory surgical center, Phygen will generate complete and accurate invoices to the customer for payment, based on the terms of our fixed negotiated agreements with those customers.
- ❖ Phygen shall maintain records for every implant in accordance with federal and state laws and regulations.

B. Compliance with Federal and State Laws and Regulations.

As a company who manufactures, repackages, relabels and/or imports medical devices sold in the United States, Phygen is subject to federal and state laws and regulations. Our company is firmly committed to full compliance with all applicable federal and state laws and regulations. To assure that compliance is achieved, we have established the following policies and procedures:

- ❖ Phygen shall comply with all federal and state laws and regulations related to Legended Device operations, including but not limited to those laws and regulations related to FDA

approval for and licensing of Legended Devices dispensed to hospitals and ambulatory surgical centers.

- ❖ Phygen shall comply with all applicable state laws and regulations related to Phygen's operation as a medical device company in any state in which Phygen does business.

C. Anti-Kickback and Physician Self-Referral Concerns Generally.

Federal law, commonly known as the Medicare/Medicaid "antikickback statute," 42 U.S.C. §§ 1320a-7b(b), prohibits payment of remuneration directly or indirectly in any form to any entity to induce that entity to refer, or order or arrange for, goods or services for which payment may be made under a federal health care program. Federal law also prohibits any entity from offering or transferring remuneration to any person eligible for benefits under Medicare, Medicaid or other federal health care program that such entity knows or should know is likely to influence the person to order services from a particular provider. 42 U.S.C. § 1320a-7a(5).

Another federal law, commonly known as the "Stark Bill," generally prohibits physicians from referring Medicare patients to an entity for certain designated health services, which include medical equipment and devices provided by Phygen, when a physician has a financial relationship with that entity, unless the requirements of an exception under the Stark Bill are met. A financial relationship is any ownership interest or compensation arrangement.

Many states have statutes similar to the federal antikickback statute and the Stark Bill, which may apply to referrals for any patient, not just patients covered under federal health care programs.

We have established the following policies to promote compliance with federal and state anti-kickback statutes and regulations:

- ❖ All ownership interests by physicians in Phygen, and all contracts and other arrangements with referral sources, must comply with all applicable antikickback and physician self-referral statutes and regulations.
- ❖ No compensation, gift, or gratuity of any kind may be provided in exchange for, or to induce, the referral of customers to Phygen.
- ❖ All agreements with physicians, providers or others who are in a position to make referrals to Phygen, must conform to parameters established by Phygen legal counsel, and any deviation from such parameters must be approved by legal counsel prior to execution.
- ❖ All compensation or other payments to physicians or other sources of referrals to Phygen, must be consistent with fair market value and may not take into account the volume or value of referrals which may be made.
- ❖ All compensation received by Phygen for devices ordered by physicians with which Phygen has a financial relationship must be consistent with fair market value.

- ❖ Neither Phygen nor an employee shall provide any item, service, or other benefit to any provider, physician, or other customer at less than fair market value in order to induce referrals to, or for recommending or arranging for referrals to, Phygen.
- ❖ No discount, rebate or free goods or services shall be offered or given to any provider, physician, or other customer of Phygen, unless such discount, rebate or free goods or services conforms to parameters established by legal counsel. Any deviation from such parameters must be approved by legal counsel prior to execution.
- ❖ Phygen shall not provide free goods or services to Medicare, Medicaid, or other state or federal healthcare program providers or patients.
- ❖ All advertising and other marketing services shall be performed on behalf of Phygen only, by employees, must be in writing and must conform to parameters established by legal counsel. Any deviation from such parameters must be approved by legal counsel prior to execution.

D. Additional Sales and Marketing Policies.

Our reputation, integrity and the ability to generate demand for our products are paramount to our success. Sales and marketing activities are an opportunity for us to not only generate immediate business, but also to develop trust and relationships that are integral to our long term success. Also, Phygen may periodically engage individuals or companies to provide marketing services.

We believe that it is in our best interests and the best interest of our customers that the recipients of our marketing information accurately understand the medical devices offered by us. To that end, we shall maintain policies and procedures for sales and marketing activities. The guiding principles underlying those policies are as follows:

- ❖ All sales and marketing activities are to be performed in accordance with the highest of ethical standards.
- ❖ All sales and marketing information shall be clear, correct, non-deceptive, and fully informative as to the subject matter of the information.
- ❖ All sales and marketing information, materials, and methods shall be approved by Phygen's Compliance Officer prior to use.
- ❖ We are committed to providing adequate training and support of employees involved in sales and marketing activities, including the minimum Pharmaceutical Research and Manufacturers of America ("PhRMA") "Code on Interactions with Health Care Professionals," a copy of which is attached and is incorporated by reference in this Compliance Plan, as well as other relevant industry standards. Employees involved in sales and marketing will be trained on interactions with health care providers; informational presentations; third-party educational or professional meetings; use of consultants; speaker training meetings; scholarships and educational funds; education-and practice-related items; and any other materials related to the PhRMA Code standards.

- ❖ We are committed to sales and marketing activities that foster confidence, trust, and long term relationships with patients and other clients.

In addition to other forms of training provided elsewhere in this Compliance Program, all of our employees engaged in sales and marketing activities shall receive additional training specific to sales and marketing. Such training will focus on the application of our sales and marketing policies to sales and marketing methods and techniques in a manner that complies with all applicable laws.

All of our employees will be expected to fully comply with our sales and marketing policies and must not engage in sales and marketing activities that are considered a "common practice or technique" in the industry we serve where such practice or technique is inconsistent with our policies or applicable law. The conduct of our business in compliance with the law are essential to our reputation and our success. Inappropriate sales and marketing activities will not be tolerated.

Phygen maintains recordkeeping and reporting systems for the purpose of monitoring and tracking information related to sales and marketing activities to ensure that such activities are in compliance with this Compliance Program and applicable laws. All Phygen personnel are required to cooperate in providing information necessary for Phygen to maintain such systems.

E. Improper Inducements and Kickbacks.

The federal anti-kickback statute provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration in return for or to induce the referral of business reimbursable under Medicare, Medicaid, or another federal health care program. (42 U.S.C. § 1320a-7b(b).) The anti-kickback statute has exceptions for certain discounts and other price reductions, payments to bona fide employees, certain payments to purchasing agents for a group of individuals or entities, and certain arrangements with managed care organizations (42 U.S.C. § 1320a-7b(b)(3)).

If it is determined that an entity has violated the anti-kickback statute, the individual or entity can be excluded from participation in federal health care programs. In addition, there are civil monetary penalties for violating the anti-kickback statutes. (42 U.S.C. § 1320a-7a(b)(7), 42 U.S.C. § 1320a-7(a)(5).) The statute is designed to prohibit transactions that improperly influence sales of federally-reimbursed health care products and services. The statute potentially applies to many of our activities, because companies like ours could enter into a variety of arrangements with parties that may be capable of influencing sales of federally-reimbursed medical devices (e.g., physicians, hospitals, and other providers).

The federal anti-kickback statute covers remuneration intended to induce the purchase, lease, ordering, arranging for, or recommending of items or services reimbursable by a federal health care program, as well as remuneration intended to induce the referral of patients for the furnishing of such items or services. In this Program, we use the term "referral" as a shorthand to refer to all of these activities. Remuneration to induce "referrals" should therefore be understood as encompassing, for example, remuneration to induce prescriptions for a product reimbursable by a federal health care program. The Office of Inspector General, a federal

government agency (“OIG”), has explained that in assessing the potential risk of fraud or abuse under the anti-kickback statute, its concerns are principally four-fold: (1) increased risk of overutilization; (2) increased program costs; (3) diminished patient freedom of choice; and (4) unfair competition. In our context specifically, in the past and currently we have emphasized the importance of avoiding financial incentives that inappropriately influence decision-making by providers and physicians and that potentially adversely affect patient care. Such incentives could interfere with the roles of the provider and physician to recommend products in the best interests of the patient.

Also, companies such as ours sometimes provide physicians, or other parties that may be in a position to influence referrals, with various services or programs, such as billing assistance, reimbursement consultation, or value-added programs. Such programs, unless properly structured, can raise antikickback concerns, and therefore must be approved by Phygen legal counsel in advance.

A relevant consideration regarding the nature of such a program is whether it benefits patient care. In analyzing such programs, we will consider a number of factors. For example, the program would carry a higher antikickback risk the greater the degree to which it confers an independent financial benefit on the provider, doctor, or customer, or where there are restrictions limiting its availability to individuals or entities that can generate referrals for Phygen or its affiliates. Where a program has independent financial value to the provider, doctor, or customer, it is unlikely that it can be justified as a normal product-related activity. For another example, programs in which a company simply performs tasks that are normally the responsibility of the provider, doctor, or customer (and relieves them of the costs they would otherwise incur in performing these tasks) create risk under the anti-kickback laws. Similarly, restricted programs that are not openly available to any properly qualified provider, doctor, or customer but rather are only available to a select group of providers, doctors, or customers who are high-volume purchasers, utilizers, or prescribers of the Company’s products, will likely be viewed as being intended to reward the selected group for its purchases, utilization, or prescribing patterns and therefore must be avoided. We will subject all such activities to a careful anti-kickback analysis.

The OIG has recognized that some practices that potentially implicate the anti-kickback statute are unlikely to result in fraud or abuse, and in fact may benefit federal health care programs and their beneficiaries. As a result and as directed by Congress, the OIG promulgated safe harbor regulations that protect certain practices. These safe harbors set forth specific conditions that, if met, allow entities to avoid being prosecuted for the arrangement that qualifies for the safe harbor.

Safe harbor protection is only afforded to those arrangements that precisely meet all of the conditions set forth in the particular safe harbor. Some of these safe harbors may be relevant to our business, such as those that involve discounts, employees, and personal service contracts.

In order to comply with the federal antikickback law, we have developed the following guiding principles concerning particular activities or arrangements that could potentially implicate the anti-kickback statute:

- ❖ All arrangements involving actual or potential sources of referrals shall be reviewed by Phygen legal counsel, taking into account the statute, the underlying risks it was designed to prevent, and any safe harbors that may be relevant.
- ❖ All sales and marketing personnel shall be trained regarding safe harbor requirements that are related to the activities of such personnel.
- ❖ We shall develop specific compliance policies that are consistent with explaining the overall requirements and intent of the anti-kickback statute and the requirements of applicable safe harbors.
- ❖ Reference contact points within the Company for answering questions or providing additional information about anti-kickback issues shall be identified and communicated to all affected personnel.

Another statute, closely related to the anti-kickback statute, that must be complied with is the beneficiary inducements statute. 42 U.S.C. § 1320a-7a(a)(5) deals specifically with inducements to beneficiaries, although it is important to note that the anti-kickback statute also covers inducements to beneficiaries (See, e.g., OIG Advisory Opinion No. 00-7 (Nov. 24, 2000)). This beneficiary inducements statute imposes civil monetary penalties against individuals or entities that offer remuneration to a beneficiary of Medicare or a state health care program that they know, or should know, is likely to influence the beneficiary's decision to order or receive items or services that are reimbursable under these programs from a particular provider, practitioner, or supplier. The OIG has made clear its position that compliance with this statute requires that, unless otherwise exempt, free gifts or services to federal program beneficiaries must not exceed limits of \$10.00 per item and \$50.00 aggregate annually per patient. It is the policy of Phygen that no gifts, payments, or other benefits be provided by any Phygen sales or other personnel directly to a federal program beneficiary unless such benefit is approved in advance by Phygen legal counsel.

F. Sponsorship of Third-Party Educational and Community Programs.

Traditionally, medical device companies have sometimes been sponsors of third-party educational programs on health care issues. The FDA has recognized the importance of such educational programs and the traditional role of the pharmaceutical industry in supporting such activities, which “provide valuable and sometimes vital information to health care professionals.” (62 Fed. Reg. 64074, 64076, 64094 (Dec. 3, 1997)). Like the FDA, we recognize the value of these activities. Legitimate educational events can assist health care professionals in making better treatment decisions and improving outcomes for patients. Among other benefits, such educational programs can help to reduce inappropriate selection of medical device decisions that may result in over or under utilization.

However, absent appropriate safeguards our sponsorship of educational events can also create risks to federal health care programs and their beneficiaries and risks of violating antikickback law. For example, there are circumstances in which sponsored educational events could be used as a subterfuge to give attendees valuable non-educational benefits intended to induce referrals for the sponsoring company. Consequently, inappropriate payments to

physicians or other providers in connection with industry-sponsored educational conferences (for example, paying travel expenses for physicians who are attending third-party continuing medical education seminars) are prohibited.

In addition, typically companies like Phygen support a variety of charitable and community service activities, some of which may relate to health care activities. These include, for example, donating implants for surgeries to be performed on underprivileged children. By supporting these programs, such companies provide benefits to the community, such as encouraging the appropriate treatment of disease in undertreated populations. When such activities involve providing financial or other support to health care providers and organizations, however, there is a risk they could implicate prohibitions on kickbacks and other inappropriate inducements absent sufficient safeguards.

To address these concerns, Phygen has developed the following policies regarding educational programs and charitable activities:

- ❖ Hospitals, ambulatory surgical centers and physicians who are in a position to order or recommend or arrange for the ordering of products from Phygen who attend third-party educational programs shall not be given non-educational benefits, such as travel expense reimbursement, in connection with their attendance at such programs.
- ❖ Phygen shall not contribute to charitable or community service activities where such contributions may benefit, directly or indirectly, healthcare providers or organizations that order products from, or arrange for products to be purchased from, Phygen, unless such contribution has been reviewed and approved by Phygen legal counsel or other counsel designated by Phygen.

Phygen has developed its policies taking into account the PhRMA Code. Phygen shall strive to ensure that, where applicable, its policies at all times be consistent with the standards set by the PhRMA Code.

G. Research Grants and Studies.

Companies such as Phygen may make payments for medical research under a variety of arrangements, which necessarily involve third parties (such as physicians, institutional health care providers, or academic organizations) potentially capable of making or influencing referrals. In some cases, companies may award research grants for projects independently initiated and carried out by third parties. In other cases, companies may acquire research services from third parties based on their own business needs (e.g., to conduct clinical trials or post-approval studies on the company's products). While there may be distinctions between these two types of research arrangements, each raises a number of common issues from a compliance perspective.

We recognize the value of supporting legitimate research projects that advance knowledge and improve patient care, and we also recognize that we must be able to tap the expertise of outside researchers in the course of developing, testing, and improving our products. However, arrangements which are actually intended to induce referrals cannot be protected by simply labeling them as "research" grants or studies. Previous analyses by the OIG have identified several factors suggesting that "research" payments may actually be designed to

induce referrals, including: (1) “research” activities involving minimal tasks having no scientific value (e.g., physicians making brief notes about treatment outcomes); (2) projects in which the researchers are selected based on considerations wholly unrelated to the research (e.g., physicians are selected based on their ability to include the company’s products on a formulary); (3) protocols that require prescribing the drug being studied to patients who were not previously taking it, when no scientific rationale exists for such a requirement; and (4) arrangements in which a physician receives full payment even if the research is not completed.

As a result, to guard against anti-kickback violations, we have developed the following guidelines for research projects:

- ❖ All research projects should have genuine scientific or clinical value requiring active scientific pursuit, and should not involve research that has already been performed and is unnecessarily repetitive.
- ❖ Payments for research must be commensurate with the work to be performed, contingent on the actual performance of the work, and may not be determined in a manner that takes into account, directly or indirectly, the volume or value of any referrals or other business generated for Phygen or its affiliates by the grant recipient.
- ❖ Researchers must be selected based solely on criteria relevant to the research effort.
- ❖ There must be a signed written agreement specifying the parties’ respective legitimate obligations in connection with any research arrangement, and there must be documentation that the payment is consistent with the fair market value of the research activities undertaken.

Phygen has developed its policies taking into account the PhRMA Code. Phygen shall strive to ensure that, where applicable, its policies at all times be consistent with the standards set by the PhRMA Code.

H. Purchasing Services From Physicians and Other Potential Referral Sources.

Sometimes the Company may need the services of physicians (or other parties that may be potential referral sources) for a number of purposes, including: to assist with the development, evaluation, and improvement of its products; to help detect or analyze problems or risks associated with its products; to help disseminate information about its products and their proper usage; and to obtain information about provider and patient reactions to its products. As a consequence, the Company may need to enter into arrangements in which it purchases services from potential referral sources. These arrangements include, for example, engaging physicians to perform research services and consulting services, to serve on advisory boards or participate in focus groups, or to speak at meetings.

Despite the legitimate business need for these services, they inevitably involve payments to parties that may order medical devices provided by Phygen or Phygen, or who may otherwise be in a position to influence referrals. Therefore, we have established the following basic principles designed to ensure that service payments to potential referral sources are not viewed as disguised payments for referrals.

- ❖ Only those services may be purchased that, in both their nature and amount, are necessary for commercially reasonable business purposes (e.g., only necessary services should be purchased, and services should be purchased only from the number of individuals that are necessary to obtain the needed services).
- ❖ Payment may not be made for any services that the other party is already obligated to perform, any services that the party fails to perform, or any services involving the counseling or promotion of illegal activities.
- ❖ There must be a signed written agreement specifying in good faith the services to be provided and the payment terms.
- ❖ Payment for services must be at fair market value and must be determined in a manner that does not take into account the volume or value of any referrals or business otherwise generated between the parties.
- ❖ The arrangement should be structured to satisfy the personal services safe harbor (42 CFR § 1001.952(d)), whenever possible.
- ❖ Phygen shall maintain documentation related to establishing the fair market value for the services being rendered.
- ❖ Phygen shall maintain documentation evidencing the actual performance of the services being provided.
- ❖ Service providers must be selected based on their suitability to perform the particular services needed by the Company, and not as a reward for or to influence their prescribing or purchasing practices.
- ❖ All service agreements or other financial arrangements with physicians or other potential referral sources must be approved by legal counsel.

I. Business Courtesies.

Certain reasonable business courtesies have historically been part of the process through which a company's sales personnel develop relationships with customers that promote product information and awareness. For example, companies may periodically provide physicians and other customers with items designed to remind them of the company or its products (e.g., notepads, pens, coffee mugs, or medical textbooks). Similarly, companies may invite providers to meals or social events in connection with educational activities regarding the company's products. These practices can benefit patient care only if they are aimed at disseminating information about the company's products that can help providers to make better treatment decisions, as well as gathering feedback that can help the company to improve its products.

However, gifts and business courtesies that create incentives that could inappropriately influence a physician's or other provider's medical judgment can violate federal antikickback law. Therefore, to comply with the anti-kickback statute, Phygen prohibits any gift or payment:

- ❖ Only those services may be purchased that, in both their nature and amount, are necessary for commercially reasonable business purposes (e.g., only necessary services should be purchased, and services should be purchased only from the number of individuals that are necessary to obtain the needed services).
- ❖ Payment may not be made for any services that the other party is already obligated to perform, any services that the party fails to perform, or any services involving the counseling or promotion of illegal activities.
- ❖ There must be a signed written agreement specifying in good faith the services to be provided and the payment terms.
- ❖ Payment for services must be at fair market value and must be determined in a manner that does not take into account the volume or value of any referrals or business otherwise generated between the parties.
- ❖ The arrangement should be structured to satisfy the personal services safe harbor (42 CFR § 1001.952(d)), whenever possible.
- ❖ Phygen shall maintain documentation related to establishing the fair market value for the services being rendered.
- ❖ Phygen shall maintain documentation evidencing the actual performance of the services being provided.
- ❖ Service providers must be selected based on their suitability to perform the particular services needed by the Company, and not as a reward for or to influence their prescribing or purchasing practices.
- ❖ All service agreements or other financial arrangements with physicians or other potential referral sources must be approved by legal counsel.

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Phygen has developed its policies taking into account the PhRMA Code. Phygen shall strive to ensure that, where applicable, its policies at all times be consistent with the standards set by the PhRMA Code.

J. Free Goods or Discounts of Any Kind Contingent on Purchases.

Our industry has various types of charitable programs involving free goods. It is also common practice in the medical device industry to offer reductions in price to certain customers.

However, free goods and discounts of any kind may raise two related compliance issues, both of which involve accurate discount reporting. First, we must ensure that the discounts resulting from free goods or discounts of any kind that are tied to a sale are appropriately reflected on all of our invoices and related commercial documents. Second, we must provide the customer with the information necessary to comply with any discount disclosure obligations that the customer may have. In such circumstances, we must inform customers that they may have obligations to disclose discounts or free goods, or make such discounts or free goods obvious on the face of any billing or invoice documents sent to the customer, and refrain from doing anything that would impede customers from complying with any such obligations.

Because of the potential compliance issues raised by discounts and free goods, it is Phygen's policy that all such arrangements must be reviewed and conform to parameters established by Phygen legal counsel. Any deviation from such parameters must be approved by legal counsel prior to execution.

K. “Switching” Arrangements.

The federal government has noted its particular concern with product conversion arrangements (commonly known as “switching” arrangements) and the implication of such arrangements under the federal anti-kickback statute. (OIG Special Fraud Alert, 59 FR 65372 – Dec. 19, 1994). “Switching” arrangements involve pharmaceutical manufacturers offering pharmacies, physicians, providers, entities that can influence utilization of a manufacturer’s products, or other prescribers' cash payments, discounts, rebates, or other benefits each time a patient’s prescription is changed to the manufacturer’s product from a competing product. One common example of a switching arrangement involves payments by a pharmaceutical manufacturer to a pharmacist for contacting patients or their physicians to encourage them to change a prescription from another product to the manufacturer’s product. While switching arrangements may be permissible in certain managed care arrangements, they risk violation of the federal anti-kickback statute if the products are reimbursable by a federal health care program such as Medicare, Medicaid, or TRICARE.

Phygen has established the following policies to guard against switching arrangements that violate the anti-kickback statute:

- ❖ No Phygen sales, marketing, or other personnel shall offer or provide anything of value to a physician, provider, or entity that could influence product utilization in exchange for such entity changing a patient’s prescription from a competitor’s product to an Phygen product, unless such offer or payment is approved in advance by Phygen legal counsel.

- ❖ Phygen shall not adopt or maintain any program intended to reward customers for switching to an Phygen product from a competitor's product unless such program is approved in advance by Phygen legal counsel.

IV. COMPLIANCE AS AN ELEMENT OF PERFORMANCE

The promotion of, and adherence to, the elements of this Compliance Program are factors in evaluating the performance of all of our employees. Affected employees will be periodically trained regarding the Compliance Program, and any new compliance policies and procedures that are established. In particular, all managers and supervisors are required to comply with the following:

- ❖ Discuss with all supervised personnel and all contractors and agents utilized, the compliance policies, procedures, and legal requirements set forth in this Compliance Program which are applicable to their function.
- ❖ Inform all supervised personnel of any description that strict compliance with this Compliance Program is a condition of continued employment or continued engagement.
- ❖ Disclose to all supervised personnel of any description that disciplinary action will be taken, up to and including termination of employment or revocation of any hiring agreement, for violation of this Compliance Program.

Managers and supervisors will be subject to discipline for failure to adequately instruct their contractors, consultants, or subordinates, or for failing to detect noncompliance with applicable components of the Compliance Program, where reasonable diligence on the part of the manager or supervisor would have led to the discovery of a problem or violation and provided us with the opportunity to take corrective action earlier.

In accordance with Health and Safety Code section 119402, we shall annually declare, in writing, that we are in compliance with our Comprehensive Compliance Program and Health and Safety Code section 119402. We shall make our Comprehensive Compliance Program and our written declaration of compliance with the program available to the public on our web site and shall also provide a toll-free telephone number where a copy or copies of these documents may be obtained.

V. OVERSIGHT OF COMPLIANCE: COMPLIANCE OFFICER; PRIVACY OFFICER; COMPLIANCE TASK FORCE

A. Compliance Officer.

The Compliance Officer occupies a high-level position within the organization and has the authority to carry out all compliance responsibilities set forth in this Compliance Program. The Compliance Officer is responsible for assuring that the Compliance Program is administered so as to ensure that Phygen and each of our directors, officers, employees, agents and contractors

maintain at all times the business integrity required of us, and that all applicable laws, regulations, rules and guidelines are followed. Proper execution of compliance responsibilities, and promotion of adherence to the Compliance Program, will be factors in the performance evaluation of the Compliance Officer.

The Compliance Officer reports to the CEO and the Board of Directors of Phygen on compliance issues. The Board of Directors is ultimately responsible for supervising the work of the Compliance Officer, and maintaining the standards of conduct enunciated in the Compliance Program. The Board of Directors oversees all of our compliance efforts, and take whatever actions are appropriate and necessary to ensure that we conduct our activities in compliance with the law and sound business ethics.

The Compliance Officer and Board of Directors consult with legal counsel as necessary on compliance issues raised by the ongoing compliance review.

The Compliance Officer's specific responsibilities include the following:

- ❖ Overseeing and monitoring the implementation of the Compliance Program.
- ❖ Reporting on a regular basis to the members of the Boards of Directors and CEO on the progress of implementation of the Compliance Program, and assisting them in establishing methods to reduce our risk of fraud, abuse, and waste.
- ❖ Periodically revising the Compliance Program in light of changes in our needs, and in the law, regulations, policies, and procedures of government agencies that govern our business and activities.
- ❖ Developing, coordinating, and participating in educational and training programs that focus on the elements of the Compliance Program, and seeking to ensure that all appropriate employees are knowledgeable of, and act in compliance with, pertinent federal and state requirements.
- ❖ Ensuring that we maintain records regarding the implementation and enforcement of this Compliance Program.
- ❖ Ensuring that independent contractors and agents who furnish services to us are aware of the requirements of this Compliance Program that affect the services being provided by such contractors and agents.
- ❖ Coordinating internal compliance review, monitoring, and auditing activities.
- ❖ Independently investigating and acting on matters related to compliance, including the design and coordination of internal investigations and the implementation of any resulting corrective action.
- ❖ Developing policies and programs that encourage all our employees to report suspected non-compliance with this Compliance Program without fear of retaliation.

- ❖ Working with the Compliance Task Force to monitor compliance related activities and develop further standards of conduct and policies and procedures to promote compliance.
- ❖ Monitoring the PhRMA "Code on Interactions with Health Care Professionals," dated July 1, 2002, for any updates or revisions.
- ❖ Revise the Compliance Program and applicable policies and procedures related to PhRMA compliance within six months of any update or revision.

The Compliance Officer has the authority to review all documents and other information relevant to compliance activities, including, but not limited to, records concerning sales and marketing efforts, and all arrangements with third parties, including without limitation employees, independent contractors, suppliers, and agents.

B. Compliance Task Force.

Phygen will establish a task force to address particular areas of concern when they are identified. The Compliance Officer will choose members of the task force depending upon the particular area(s) of concern. It is our policy that members of the task force will represent the highest levels of responsibility and expertise within Phygen. The Task Force will report on its findings and recommendations to the Compliance Officer.

C. Hotline.

We have established the following Compliance Hotline so that employees have every opportunity to report concerns or possible wrongdoing regarding compliance issues:

Hotline Telephone Number: (800) 939-7008

The Compliance Hotline number shall be posted in a conspicuous location at all times. Calls to the Hotline will be treated confidentially, and will not be traced. If the caller desires, the caller need not provide his or her name. The Compliance Officer may work in connection with or under the supervision of legal counsel in investigating all calls and initiating follow-up actions as appropriate.

Communications via the Hotline will be treated as privileged to the extent permitted by applicable law; however, it is possible that at some point in time the identity of a person making a report may become known, or that governmental authorities or a court may compel disclosure of the reporting person.

Matters reported through the Hotline that suggest violations of compliance policies or procedures, or regulations or statutes, will be documented and investigated promptly to determine their veracity. A log shall be maintained by the Compliance Officer that records such calls, including the nature of any investigation and its results. A summary of such information, redacted of individual identifiers, will be included in reports by the Compliance Officer to Phygen's Board of Directors and CEO.

It is our policy to prohibit any retaliatory action against an employee simply for making a Hotline call regarding compliance. However, employees may not use the Hotline in an effort to insulate themselves from the consequences of their own wrongdoing or misconduct. It will be considered a potential mitigating factor that an employee makes a forthright disclosure of an error made by that employee. In no event will the sanction be increased solely because an employee has chosen to report improper conduct committed by that same employee.

VI. TRAINING AND EDUCATION

We know that this Compliance Program can only be effective if it is communicated to our employees on a regular basis in ways that explain in a practical manner what is required. To that end, we require our personnel to attend specific training applicable to their job functions on a periodic basis, including appropriate training in federal and state statutes, regulations and guidelines and the policies of private payors, the policies and procedures set forth in this Compliance Program, and in corporate ethics. New employees are targeted for training early in their employment.

These training programs may, depending on the employee's job function, include sessions highlighting this Compliance Program, summarizing fraud and abuse laws, anti-kickback laws, and sales and marketing practices that reflect current legal standards, as well as publications that explain specific requirements, such as fraud alerts issued by the federal government, audit and inspection reports, and advisory opinions. All formal training undertaken as part of the Compliance Program is documented by the Compliance Officer.

A variety of teaching methods are employed so that all affected employees are knowledgeable of the required standards of conduct, as well as the policies and procedures for alerting us to compliance problems and concerns. Training and education may be provided by our employees or outside companies or firms with expertise in compliance matters. Targeted training is provided to corporate officers, managers, and staff whose actions affect the accuracy of the claims submitted, such as personnel involved in the coding, billing, and sales and marketing processes, subject to the coordination and supervision of the Compliance Officer.

Specific training for appropriate corporate officers, managers, sales personnel, and other employees covers, but is not limited to, the following:

- ❖ General prohibitions on paying or receiving remuneration to induce referrals.
- ❖ Proper confirmation of orders.
- ❖ Proper documentation and maintenance of records.
- ❖ Dispensing products without proper authorization.
- ❖ Duty to report misconduct.
- ❖ Policies regarding “switching” arrangements as discussed in Section III K.

- ❖ Policies regarding discount programs.

Attendance and participation in applicable compliance training programs is a condition of continued employment, and failure to comply with training requirements will result in disciplinary action, including possible termination when such failure is serious.

In addition, adherence to all of the provisions of this Compliance Program, including training requirements, is a factor in the annual evaluation of each of our affected employees. Where feasible, outside contractors and agents, will be afforded the opportunity to participate in, or encouraged to develop their own, compliance training and educational programs, which complement our standards of conduct, and compliance policies and procedures. The Compliance Officer will ensure that records of the training of employees, including attendance logs and copies of materials distributed at training sessions, are maintained.

The above compliance training is in addition to any periodic professional education courses that may be required by law, statute, or regulation for certain personnel. We expect that employees will comply with such education requirements, and the failure to do so could result in disciplinary action.

VII. LINES OF COMMUNICATION

We recognize that clear and open lines of communication between the Compliance Officer and our personnel is important to the successful implementation and maintenance of this Compliance Program. To that end, confidentiality and non-retaliation policies and procedures have been developed to encourage communication and the reporting of incidents of potential non-compliance with the Compliance Program.

Communications with the Compliance Officer may be direct, or through anonymous written correspondence. All written correspondence will be treated confidentially. However, it is possible that at some point in time we will be compelled to disclose the contents of a written correspondence or other forms of communication, or that governmental authorities or a court may compel disclosure of the reporting person. All matters reported to the Compliance Officer that suggest violations of this Compliance Program shall be documented and investigated promptly.

It is generally our policy to prohibit retaliatory action against an employee simply for making a report, anonymous or otherwise, regarding compliance. However, employees should not use complaints to the Compliance Officer in an effort to insulate themselves from the consequences of their own wrongdoing or misconduct. It will be considered a potential mitigating factor that an employee makes a forthright disclosure of an error made by the employee.

VIII.
ENFORCING STANDARDS, POLICIES AND PROCEDURES

A. Discipline Policies and Procedures.

1. Policies.

It is our policy to render appropriate discipline for the failure of any of our employees to comply with the standards of conduct, policies, and procedures set forth in, or adopted by, this Compliance Program, or any federal and state laws, rules, or regulations.

The guiding principles underlying this policy include the following:

- ❖ Intentional or reckless noncompliance shall subject violators to significant sanctions, which could range from oral warnings to termination.
- ❖ Negligent failure to comply with the policies and procedures set forth in this Compliance Program, or with other applicable law, may also result in sanctions.
- ❖ Disciplinary action shall be considered or taken where a responsible employee fails to detect a violation and that failure is attributable to his or her negligence or reckless conduct.
- ❖ All levels of employees shall be subject to the same disciplinary action for the commission of similar offenses.
- ❖ Our employees will acknowledge by signing a certification that they have received, read, understand, and will abide by these standards, policies, and procedures.

2. Discipline Procedures.

Any of our employees found to have violated any provision of this Compliance Program shall be subject to discipline in a manner consistent with the policies set forth herein, including termination if deemed appropriate by us. Any disciplinary action taken shall be fair and equitable, and within our sole discretion.

Upon determining that one of our employees has committed a violation of this Compliance Program, such employee shall meet with his or her supervisor and the Compliance Officer to review the conduct that resulted in a violation of the Compliance Program, and discuss any actions that may be taken to remedy such violation. We shall promptly determine the discipline, if any, to be rendered.

B. New Employees and Contractors.

For all new employees who have discretionary authority to make decisions that may involve compliance with the law or compliance oversight, we will conduct a background investigation, including a reference check, as part of every such employment application. Application for employment requires the applicant to disclose any criminal conviction or action

to exclude that individual from participation in any federal healthcare program. It is our policy not to employ individuals who have been convicted of a criminal offense related to health care, or who are listed by a federal agency as debarred, excluded, or otherwise ineligible for participation in federal health care programs. In addition, pending the resolution of any criminal charges or proposed debarment or exclusion of a current employee, that employee will be removed from direct responsibility for or involvement in any federal health care program.

Further, the execution of contracts with companies that have been convicted of a criminal offense related to health care within the past five years, or that are listed by a federal agency as debarred, excluded, or otherwise ineligible for participation in federal health care programs, is prohibited. With regard to either current employees or independent contractors, if resolution of any matter under investigation results in conviction, debarment, or exclusion, it is our policy to terminate the employment or other contract arrangement with the individual or contractor involved.

IX. AUDITING AND MONITORING

A. Generally.

We will conduct periodic monitoring of implementation of this Compliance Program. Compliance reports created by this ongoing monitoring, including reports of suspected noncompliance, are maintained by the Compliance Officer.

One tool utilized to promote and ensure compliance is the performance of periodic compliance audits by auditors who have expertise in federal and state health care related statutes, regulations, and program requirements. The audits focus on our specific programs or departments, including external relationships with third-party contractors, with a particular focus on those programs or departments with significant exposure to government enforcement actions. These audits are designed to address, at a minimum, compliance with laws governing kickback arrangements, provider issues, and sales and marketing.

We will conduct periodic reviews of whether this Compliance Program's elements have been satisfied. When monitoring discloses that deviations were not detected in a timely manner due to Compliance Program deficiencies, appropriate modifications to the Compliance Program will be implemented.

The monitoring process may include the following techniques:

- ❖ Interviews with personnel involved in management, operations, sales and marketing, and other related activities.
- ❖ Questionnaires developed to solicit impressions of our employees and staff.

Reviewers or auditors will present periodic written reports on compliance activities to us and specifically identify areas, if any, where corrective actions are needed. In certain cases, subsequent reviews or studies may be conducted to ensure that the recommended corrective actions have been implemented successfully.

In addition to regular monitoring activities, more thorough audits shall occur on a periodic basis, but not less than annually. We shall designate our managers and employees necessary to conduct such audits. We may also involve external auditors who are familiar with federal and state health care statutes, regulations, and program requirements, as well as private payor rules and contract requirements. All auditors will have the qualifications and experience necessary to adequately perform their respective functions in the audit and shall have the authority to review all materials necessary to perform a thorough and accurate audit.

Audits will focus on all aspects of our operations with particular emphasis in areas related to adherence to rules related to sales and marketing and relationships with third parties. We may employ any auditing approach or technique that we and our advisors determine necessary and appropriate to conduct a thorough review. In addition to the techniques discussed above in regards to monitoring compliance, auditing techniques may also include the following:

- ❖ Legal review of all contractual relationship with contractors, consultants, and potential referral sources.
- ❖ Questionnaires developed to solicit the impressions and opinions of our employees and contractors regarding such matters as compliance with this Compliance Program, and laws applicable to their respective positions within the company.
- ❖ Analysis of past survey reports to evaluate deficiencies and determine if proposed corrective action has been implemented.
- ❖ Review of records to determine compliance with record keeping requirements.
- ❖ Surveys of customers and vendors, and review of any of their complaints.

The auditors shall prepare a written report to the Compliance Officer detailing their findings from the audit. Our Compliance Officer or Compliance Task Force will then use the results of the audit to review and revise (if necessary) our procedures and to implement corrective action.

X. CORRECTIVE ACTION

A. Violations and Investigations.

Violations of this Compliance Program, failures to comply with applicable federal or state law, and other types of misconduct threaten our status as a reliable, honest, and trustworthy provider of products and services capable of participating in federal health care programs. Detected but uncorrected misconduct or undetected misconduct can seriously endanger our reputation and participation in federal and non-federal health care programs. Consequently, upon reports or reasonable indications of suspected noncompliance, prompt steps to investigate the conduct in question will be initiated under the direction and control of the Compliance Officer to determine whether a material violation of applicable law or the requirements of the Compliance Program has occurred. If such a violation has occurred, prompt steps will be taken to correct the problem. As appropriate, such steps may include an immediate referral to criminal

and/or civil law enforcement authorities, a corrective action plan, a report to the appropriate government organization, and the submission of any overpayments. The specific steps that are appropriate in a given case may be determined after consultation with legal counsel.

Depending upon the nature of the alleged violations, the Compliance Officer's internal investigation could include interviews with relevant staff and a review of relevant documents. Legal counsel, auditors, or health care experts may also be consulted or engaged by the Compliance Officer to assist in an investigation where the Compliance Officer deems such assistance to be appropriate. Complete records of all investigations will be maintained, which contain documentation of the alleged violations, a description of the investigative process, copies of interview notes and key documents, a log of the witnesses interviewed and the documents reviewed, the results of the investigation (e.g., any disciplinary action taken), and the corrective action implemented.

If an investigation of an alleged violation is undertaken and the Compliance Officer believes the integrity of the investigation may be at stake because of the presence of employees under investigation, those subjects will be removed from their current work activity until the investigation is completed. In addition, where necessary the Compliance Officer will take appropriate steps to secure, or prevent the destruction of, documents or other evidence relevant to the investigation.

B. Reporting.

If the Compliance Officer or a management official discovers credible evidence of misconduct from any source and, after a reasonable inquiry, has reason to believe that the misconduct may violate criminal, civil, or administrative law, then the existence of the misconduct will be promptly reported by the Compliance Officer or legal counsel to the appropriate governmental authority or federal and/or state law enforcement agency having jurisdiction over such matter, within a reasonable period of time but not more than sixty (60) days after it is determined that there is credible evidence of a violation.