

# PATIENT SERVICES, INC.

## COMPLIANCE PLAN

### I. INTRODUCTION

Patient Services, Inc. (PSI) is subject to federal, state, and local laws and regulations as it carries out its mission. PSI is committed to compliance with applicable Federal health care program requirements including, but not limited to, the False Claims Act (codified at 31 U.S.C. §§ 3329-3733) and the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)) and the regulations and other guidance documents related to these statutes. These laws and regulations are voluminous and complex and change periodically. PSI is committed to compliance by both its Board and its personnel. To memorialize that commitment PSI's Board of Directors has adopted this Compliance Plan.

This Plan supersedes all previously adopted individual policies and acts to establish the overall framework for internal policies, procedures, and mechanisms that will give guidance to and assist each of us in complying with the laws and regulations that apply to our activities on behalf of PSI. The plan is not designed to provide detailed guidance but to serve as a roadmap to PSI's compliance efforts coupled with the additional detailed policies and procedures that promote compliance and ethical conduct.

The plan is designed to incorporate recommendations enumerated in the Department of Health and Human Services Office of Inspector General's ("OIG") Compliance Program Guidance as well as reflect the elements of an effective compliance plan as described in the Federal Sentencing Guidelines. The Plan also explains fraud and abuse as it relates to the provision of patient assistance services and the applicable enforcement laws which may be utilized both by the government and our employees should such activities be determined. The Plan is to be a guide and resource to help all personnel ensure that their behavior complies with all laws and regulations that affect their business dealings on behalf of PSI. It is also intended to serve as a resource for Board Members regarding their corporate responsibilities. The plan also describes the procedures that will be followed in enforcing these standards and ensuring that PSI stays in compliance with all applicable laws.

The Seven Fundamental Elements of an Effective Compliance Program

1. Implementing written policies, procedures, and standards of conduct.
2. Designating a compliance officer and compliance committee.
3. Conducting effective training and education.
4. Developing effective lines of communication.
5. Conducting internal monitoring and auditing.
6. Enforcing standards through well-publicized disciplinary guidelines.
7. Responding promptly to detected offenses and undertaking corrective action.

## II. THE IMPORTANCE OF THE COMPLIANCE PLAN

PSI is committed not only to providing patients with high quality and caring assistance, but also to providing those services pursuant to the highest ethical, business, and legal standards. Our compliance efforts are designed to perpetuate a culture within PSI that promotes prevention, detection and resolution of instances of conduct that do not conform to federal, state, and local laws and federal, state and private payor health care program requirements, or our Integrity Agreement. This is not only the right thing to do, but it is also important for our continuing reputation for honesty and integrity in our business and medical dealings with others.

The Compliance Plan is especially critical as an internal control in accepting donations and disbursing funds to patients with demonstrated need. Throughout the health care industry, support by medical device manufacturers or pharmaceutical companies raise concerns about potential kickbacks and abuse concerns and have been the focus of government reviews and sanctions.

Moreover, compliance with federal and state laws, rules and regulations is essential because of the potential for civil or even criminal liability if PSI were found to have violated the applicable legal standards. A governmental inquiry can lead to significant financial exposure and damage to our reputation for honesty and integrity. Prevention is the wiser business plan, and that is what our Compliance Program is designed to accomplish.

## III. PURPOSE AND EXECUTION OF THE COMPLIANCE PLAN

The purpose of the Compliance Plan is guiding PSI in its management and operation of compliance-related activities. PSI intends to demonstrate that it is both committed to, and exercises, due diligence in seeking to prevent and detect systemic problems and violations of law by developing and sustaining a rigorous Compliance Plan. The Compliance Plan has at its foundation, seven elements that federal guidelines have deemed necessary for an effective, high-quality compliance program. This document provides the framework to meet the seven elements:

- Written standards of conduct have been developed to promote the PSI's commitment to compliance. These standards establish the expectation of ethical behavior and compliant conduct and provide for disciplinary action for failure to adhere.
- PSI has established the position of Compliance Officer who is charged with the responsibility of operating and monitoring the Compliance Program.
- PSI provides regular and mandatory compliance education and training programs for all affected Personnel and the Board of Directors.
- PSI has published the Compliance Officer's contact information so that personnel, patients and vendors can make complaints and ask questions, without fear of retaliation, and has adopted procedures that emphasize non-retribution, nonretaliation.
- PSI has established a process to respond to allegations of improper or illegal activities and the enforcement of appropriate disciplinary action against personnel who have violated internal compliance policies, applicable statutes, regulations or federal or state health care

program requirements.

- PSI uses audits and other evaluation techniques are utilized to monitor compliance and make voluntary refunds or disclosures, as appropriate; and,
- PSI ensures that systemic problems are investigated and remediated, and has implemented policies to address the non-employment or retention of sanctioned individuals.

PSI is committed to upholding the highest standards of ethical conduct.

#### A. STANDARDS OF CONDUCT AND GENERAL POLICIES AND PROCEDURES

PSI is committed to following all applicable laws and regulations that governs its operations and those that address health care fraud, waste, and abuse. To assist in this effort, this Compliance Plan and associated policies are the subject of training and are available to all personnel and Board members. Policies cover, among other subjects, conflicts of interest, patient information, anti-retaliation, and many others. Compliance with the plan and associated policies and procedures is the responsibility of all PSI employees and Board Members. Failure to comply with applicable laws and regulations or other provisions of this Compliance Plan will be viewed as a serious matter and can result in disciplinary action.

All personnel are expected to report potential issues and raise questions as set forth in the Compliance Plan. Strict compliance with the Plan's legal and compliance standards is a condition of employment, and violation of any of these standards of conduct will result in discipline being imposed including, but not limited to, the following:

- Informing and discussing with the relevant personnel both the violation and how it should be avoided in the future;
- Providing remedial education (formal or informal) to ensure that the relevant personnel understand the applicable rules and regulations;
- Conducting a follow-up review to ensure that the problem does not recur;
- As required or, when appropriate, voluntarily disclosing to the appropriate government agency; and
- Discipline in accordance with the applicable affiliate disciplinary policy, up to, and including, termination from employment.

PSI is committed to complying with all laws and OIG Opinions that prohibit illegal remuneration, such as kickbacks, bribes, improper or excessive payments, free or below market rents or fees for administrative services, or interest-free loans. PSI personnel are prohibited from offering, providing, accepting, or asking for anything of value with the intent to influence or be influenced by patients, their families, suppliers, contractors, vendors, physicians, third-party payors, managed care organizations, or government officials. PSI personnel may not offer, provide, accept, or ask for anything of value for the referral of individuals for services covered by Medicare, Medicaid, or other federal health care programs. PSI personnel are also prohibited from accepting or requesting payment for the purchase or lease of any good, item, or service covered under any federal health care program.

## B. COMPLIANCE FUNCTION, STRUCTURE AND OVERSIGHT: BAORD AND COMPLIANCE OFFICER

The structure of and the reporting relationships for the PSI's compliance function shall be as set forth below.

The Board is charged with oversight of the Compliance Plan and all internal and independent auditing activity. The Committee comprises Board members and personnel who have an understanding of compliance issues delineated in this plan thereby ensuring compliance with legal and regulatory requirements.

### Compliance Officer

The PSI Board of Directors has designated a Compliance Officer to coordinate the development, implementation, communication and monitoring of the Compliance Plan and the implementation plan for the OIG Integrity Agreement.

The Compliance Officer reports directly to the Board and has access to the Committee and to the Board with respect to compliance issues always. The Compliance Officer is also vested with the authority to investigate instances of possible non-compliance with law or regulations or other provisions of the Compliance Plan and all PSI personnel are required to cooperate fully with the Compliance Officer in connection with any such investigative activities.

The Compliance Officer will oversee and coordinate all compliance activities, including education and training, and the compliance monitoring activities discussed below. The Compliance Officer maintains a record keeping system in connection with the Compliance Plan. These records shall include, but not be limited to, instances of possible non-compliance that come to the attention of the Compliance Officer, a record of disposition of these matters, and all documents submitted to the Board in connection with the administration of the Compliance Plan. All records shall be kept in a secure location to protect their confidentiality and shall be retained for at least the period required by law or regulation, and by sound business practice, in accordance with PSI's retention policy.

The Compliance Officer shall maintain liaison with in-house and outside counsel and with regulatory authorities in connection with the administration of the Compliance Plan and when appropriate, shall consult with independent outside counsel when significant compliance issues arise.

## C. EDUCATION AND TRAINING

PSI has various policies and education programs designed to teach personnel about the compliance functions and compliance issues, and the personnel's individual compliance responsibilities. One such policy establishes an initial, mandatory training program for new personnel. Building on these existing efforts, the Compliance Officer, the Director of Operations, Director of Program Development, Director of Finance and various subject matter compliance Managers and Directors have developed a standardized, comprehensive, and continuing compliance training program applicable to all appropriate personnel.

All PSI personnel are responsible for incorporating into practice Compliance Department sponsored education and training sessions. Compliance training and education may be provided in a variety of ways, including educational programs conducted by knowledgeable PSI personnel and the Compliance Officer, programs conducted by knowledgeable external experts, and attendance at outside seminars. Regardless of the presenter, the Compliance Officer shall, when appropriate, oversee, the program to ensure attendance and active participation. Participation in training may be a factor in each employee's performance appraisals.

Advance notice of training programs will be given to ensure attendance. Additionally, the Compliance Officer will meet routinely with management personnel to conduct educational sessions on all issues related to laws, rules, regulations and coverage decisions and the impact they have PSI's compliance.

#### D. INDIVIDUAL INTEGRITY POLICY AND DISCIPLINARY STANDARDS FOR COMPLIANCE VIOLATIONS

All PSI personnel will deal with PSI colleagues, PSI-served patients, donors, physicians and pharmacies with honesty and integrity. They will provide enough information in any such dealings so as not to be misleading. In addition, all PSI personnel shall perform their work in accordance with PSI's plan and related policies.

Personnel who are entitled to reimbursement for expenses by PSI shall keep accurate records of such expenses and shall not seek reimbursement except as permitted by applicable policies and procedures. PSI personnel involved in contracting with third parties and in the procurement of goods and services shall act in a professional and ethical manner. Personnel involved in such activities will not solicit or accept any gift or gratuity other than customary business courtesies which are reasonable in frequency and *de minimis* in value.

All PSI personnel shall disclose immediately to the Compliance Officer any potential conflict of interest that could influence any decision or action which personnel may take on behalf of the PSI. Examples of situations which constitute conflicts of interest include transacting PSI business with family members or close friends or with entities in which the PSI personnel involved has a direct or indirect financial interest.

#### E. MONITORING AND AUDITING COMPLIANCE

The most effective means to determine whether a compliance plan is successful is to monitor activities in relation to applicable laws and regulations to determine if those activities are being conducted in a compliant manner. To this end, the Compliance Officer, or her designee, will conduct various monitoring activities to measure compliance. Such activities may include, for example, unannounced audits of certain patient records, and periodic auditing of various areas by the Compliance Officer or outside consultants. All personnel are expected to cooperate fully with any such monitoring activities. The purpose of monitoring is constructive as it provides an opportunity to identify and correct any systemic problems or misunderstandings about regulatory requirements so that the same incident of non-compliance does not recur.

On an annual basis, the Compliance Officer prepares a work plan designed to assess and monitor compliance of the various PSI departments by performing a series of scheduled audits. The work plan is developed using a variety of sources and inputs such as PSI Department interviews, voluntary inquiries, and past investigations and audits. Additional information is obtained from outside sources – most notably, authoritative publications from the federal government such as the OIG, the Centers for Medicare and Medicaid Services, and the Medicare Contractors. Additional sources for the annual PSI Compliance Work Plan involve Medicare and Medicaid coverage decisions, special projects, individual requests and the reported incidences of noncompliance.

It is also important that there are regular evaluations of the effectiveness of the Compliance Program itself. This would include, but is not limited to, assessments made of the plans of correction instituted because of Compliance audits and investigations.

The Compliance Officer will make regular and periodic reports to the Board, and the Board shall be responsible for evaluating the performance of the Compliance Officer.

#### F. OPEN LINES OF COMMUNICATION

The reputation and integrity of both the organization and PSI employees are valued. PSI recognizes its employees' rights under the law, including the protections offered under the federal False Claims Act, as it relates to identifying compliance issues. PSI relies on its employees to help PSI comply with all the applicable legal and regulatory requirements by identifying potential problems, reporting them and asking questions.

All PSI personnel have a responsibility, and are expected, to promptly report instances of actual or suspected non-compliance with laws, regulations, and policies of which they become aware. Such reports are critical to the effectiveness of the Compliance Plan. Personnel who fail to make such reports in a timely manner may be subject to disciplinary action. Instances of suspected non-compliance often are not intentional but rather result from a lack of knowledge or understanding on the part of the person involved or some systemic problem with policies, procedures or systems that should be corrected.

PSI encourages all personnel to utilize the chain of command whenever practical to obtain answers to questions or to report actual or suspected instances of noncompliance. Under this approach, the first option for asking questions or making reports is to discuss the situation with a supervisor. If someone is uncomfortable talking to his or her supervisor or does not receive a satisfactory response, then the next option, depending on the issue involved, either Human Resources at 804.672.4596 or the Compliance Officer at 804.293.8353.

PSI employees can also report suspect noncompliance directly to the OIG for Health and Human Services at the HHS OIG Fraud Hotline 1-800-HHS-TIPS.

PSI personnel may report instances of actual or suspected non-compliance in confidence and without fear of retaliation or retribution. To allow for proper investigation of any reported non-compliance, as

much information as possible should be provided to assist the Compliance Officer. Procedures have been established so that reports and any accompanying information are handled and maintained in a manner to ensure confidentiality to the extent possible under the law, consistent with the PSI's obligations of investigation and remediation.

#### G. ACTIONS IN THE EVENT OF NON-COMPLIANCE

The Compliance Officer (or his or her designee) will investigate and may retain outside counsel, as necessary, to investigate instances of possible non-compliance which come to the attention of the Compliance Officer. If an investigation reveals that there has been non-compliance with laws, regulations, or other provisions of the Compliance Plan, the Compliance Officer will take appropriate steps to remediate the violation. Appropriate steps may include, but are not be limited to, recommending changes in policies or procedures to prevent recurrence, recommendations for appropriate personnel action to be taken with respect to persons involved in non-compliant activity, or reporting investigation results immediately to the CEO or Board, as appropriate. There may be additional reporting to and cooperating with governmental authorities with respect to violations of law or regulation in appropriate circumstances after obtaining the advice of counsel.

#### H. INDIVIDUAL RESPONSIBILITY

All prospective contracted and employed applicants are screened to identify any prior history of non-compliance with laws, regulations, and applicable policies as well as exclusion or sanctions from Medicare, Medicaid, or other Federal health care programs. The employment application process requires the applicant to notify the PSI about prior criminal convictions.

Once employed through PSI, personnel are required by PSI Policy to notify the PSI of any exclusion from the Medicare, Medicaid, or other Federal health care programs. Human Resources proactively screens employees for exclusions at hire and then monthly thereafter. PSI will not knowingly employ or retain persons or entities with such identified history. Intentional or repeated unintentional legal violations, dishonesty, non-disclosures and other acts and omissions (including compliance training sessions) of current employees that violate the letter or spirit of this Compliance Plan are considered equally significant. Adherence to this Compliance Plan will become an important element in the periodic evaluation of all personnel, supervisors, and managers. Serious violations of the Compliance Plan and related subject matter plans and policies may result in termination of employment.

The Compliance Officer will recommend to the CEO and Director of Human Resources appropriate changes in personnel policies consistent with the obligations of personnel under the Compliance Plan and CODE OF CONDUCT. This includes disciplinary policies for personnel who fail to cooperate or adhere to the Compliance Plan and procedures for screening of prospective employees to prevent the hiring of persons with a history of non-compliant activities.

### IV. CONCLUSION

In conclusion, it is important to stress that the PSI has prided itself on its commitment to operating in an ethical and legal manner since its founding. The success of the PSI depends on the personal and

professional integrity of all PSI personnel and volunteer Board members. This Compliance Plan has been developed as part of the PSI's commitment to compliance. The Compliance Plan is designed to provide helpful guidance to PSI personnel in reaching legal and ethical solutions to the problems they face daily in their work on behalf of the PSI. The Compliance Plan also establishes a mechanism for reporting and resolving potential problems and concerns. All PSI personnel are expected to cooperate with, and abide by, the Compliance Plan.