American Society of Ophthalmic Administrators Compliance Program Reference Tool for Physician Practices

Developed by Arnold & Porter Kaye Scholer LLP

This tool was developed to assist eye care practices in implementing a compliance program designed to address fraud and abuse risk areas. It is based on the Model Compliance Program Guidance for Individual and Small Group Physician Practices published by the Office of the Inspector General of the U.S. Department of Health and Human Services. This tool should be used as a reference only. It does not cover all issues that may present risk for a particular physician practice. A compliance program should be tailored to your business. This document is not legal advice and should not be construed as providing legal advice.

Pressure on physician practices has increased steadily over the last several years. With the wide variety of government and private programs in which patients are participating, each with its own set of complex rules and regulations, the burden to assure compliance with those program rules has become enormous. In addition, the enhanced enforcement efforts of both the government and private insurance has generated still further pressure for physician practices. While there is no magic formula to address these concerns, one step which will enable a practice to operate more efficiently and minimize its exposure is the development of a compliance program. Compliance programs are standard in the healthcare industry, both for large and small providers alike.

So, what is a compliance program? A compliance program is like a quality assurance program for legal and regulatory issues. It gives a physician practice a mechanism to identify activities which may be inconsistent with applicable rules, regulations, or program policies and which may subject a practice to sanctions. Under a compliance program, the practice establishes its expectations and standards of conduct, establishes a structure to investigate potential problems, resolve them, and impose discipline, where appropriate. A compliance program will also include a process to reduce the risk that similar problems could occur in the future.

A compliance program enables a practice to commit its own resources to assure compliance with appropriate rules and regulations rather than risk having the government or other outside entity identify problems and impose sanctions. While there will necessarily be a number of elements common to all physician practice compliance problems, the implementation and structure of each program should reflect the philosophy and culture of a particular practice and must be tailored to address that practice's needs and highest risk areas

This document is a Model Compliance Program for physician practices. The Model Program sets forth a basic template and structure for an effective compliance program, but it should be modified and tailored to adequately address the needs of your practice. Further, the Model Program is not intended to be exhaustive; there are many additional elements, policies, and procedures that practices should consider adding to the Model Program. Finally, adoption of a paper program is not enough. A compliance program is a dynamic process to which all individuals in the practice must be committed and must carry out the actions described in the Compliance Program adopted by the practice.

The Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) issued compliance program guidance for physician practices. The guidance also includes important information regarding the key risk areas for physician practices. These should be taken into consideration when you are building your compliance program. https://oig.hhs.gov/authorities/docs/physician.pdf In addition, the OIG issues an annual workplan where it identifies areas and arrangements it considers as possibly raising new risks that warrant audit or investigation. Physician practices should review the workplan to determine if its business operations are of the type the OIG believes require review.

American Society of Ophthalmic Administrators (ASOA)
MODEL COMPLIANCE PROGRAM FOR PHYSICIAN PRACTICES

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COMPLIANCE PROGRAM FOR PHYSICIAN PRACTICES

I. INTRODUCTION

The purpose of this Compliance Program and its component policies and procedures is to establish and maintain a culture within a physician practice that promotes quality and efficient patient care; high standards of ethical and business conduct; and the prevention, detection, and resolution of conduct that does not conform to practice's standards and policies, applicable law, and healthcare program or payor requirements. A Compliance Program applies to all members of a practice: the physicians, the employees and vendors who provide services to the practice.

II. APPLICABLE LAW

As a provider of healthcare services, physicians, practice employees and contractors are required to comply with federal and state laws. Many of these laws are designed to prevent fraud, waste, and abuse in the federal healthcare programs. The most relevant laws are the federal False Claims Act, Anti-Kickback Statute, the Physician Self-Referral Law (the "Stark Law"), and the Civil Monetary Penalties Law (the "Beneficiary Inducement Statute"). It is important for all members of a physician practice to have a basic understanding of these laws.

A. The Federal False Claims Act ("FCA")

The False Claims Act, 31 U.S.C. §§ 3729, et seq., is a federal anti-fraud statute that allows the U.S. government to recover monetary damages from parties who either file or cause the filing of fraudulent claims for payment by the federal government. In addition, the submission of false claims may also result in criminal penalties, including fines and/or imprisonment under 18 U.S.C. §287. The FCA prohibits anyone from knowingly presenting or causing to be presented a false claim. The FCA provides for penalties in the amount of $10,781 to $21,562 per false claim, as well as damages totaling up to three times the amount of loss caused by the false claims. Violation of the FCA also can be grounds for exclusion from participation in federal and state healthcare programs, such as Medicare, TRICARE, and Medicaid (i.e. excluded companies and/or their individual employees are not permitted to engage in business with these programs).

B. The Anti-Kickback Statute ("AKS")

Subject to certain statutory exceptions and regulatory safe harbors, the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), prohibits any person from knowingly and willfully offering, paying, soliciting, or receiving "remuneration" to induce the purchase, prescription, or recommendation of items or services payable under a Federal healthcare program. Many states have enacted their own anti-kickback statutes that may differ from the federal Anti-Kickback Statute in certain respects; for example, certain state anti-kickback laws apply to items or services that are not reimbursed by a Federal healthcare program, while others significantly narrow or eliminate altogether the exceptions and safe harbors available under the federal law. Violation of the AKS may result in FCA liability.

C. The Physician Self-Referral Law ("Stark Law")

The Physician Self-Referral law, commonly known as the Stark Law, prohibits a physician from making referrals for certain defined designated health services (DHS) payable by Medicare or Medicaid to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies. In contrast to the AKS, the Stark Law is a strict liability statute that imposes liability regardless of the intent of the parties involved. Subject financial relationships include ownership or investment interests, as well as compensation arrangements. The Stark Law further prohibits a DHS entity from presenting, or causing to be presented, claims to Medicare and Medicaid (or billing another individual, entity, or third-party payor) for those referred services. As a result, Medicare and Medicaid claims tainted by an arrangement that does not comply with Stark are not payable and CMS may impose up to a $15,000 fine for each service provided. And, although a less settled matter, in addition to the penalties assigned by the Stark law, violations of the Stark law may, in certain instances, give rise to FCA liability and potential exclusion from federal healthcare program participation.

D. The Civil Monetary Penalties Law ("Beneficiary Inducement Statute")

The Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a(a)(5), provides that a person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of Medicare or Medicaid payable items or services may be liable for civil money penalties ("CMPs") of up to $10,000 for each wrongful act. OIG interprets the term "remuneration" to include "waivers of copayments and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value."

III. ELEMENTS OF AN EFFECTIVE COMPLIANCE PROGRAM

According to the OIG, an effective compliance program incorporates the following seven elements:

1) **Written standards of conduct** —Adoption of a set of guidelines for everyone in the practice to follow, reflecting the practice's commitment to compliance in general, as well as addressing specific areas of concern for that practice.

2) **Designation of Compliance Officer or Compliance Committee** — Identification of an individual or group of individuals responsible for the operation and monitoring of the compliance program.

3) **Education and training for all individuals in the practice** — Programs must be developed to educate individuals about the existence of the compliance program, as well as the rules and regulations with which the practice must comply.

4) **Effective mechanism for communication** — Establishment of a reporting mechanism, through a hot line or other process, so that complaints may be communicated to the

Compliance Officer. The Compliance Officer must also be able to communicate with all individuals in the practice.

5) **Internal investigation and disciplinary process** —Development of a process to investigate allegations and, where appropriate, discipline individuals who have acted inappropriately.

6) **Periodic auditing and monitoring** —Development of a mechanism for performing periodic auditing and monitoring of its operation to assure compliance with applicable rules and regulations.

7) **Establishment of response mechanism** —Establishment of a mechanism to respond to identified problems, establish corrective action mechanisms to assure that those problems will not be repeated, and then follow-up audit to memorialize correction in behavior.

IV. MODEL COMPLIANCE PLAN

A. General Standards of Conduct

This Compliance Program sets forth standards of conduct that apply to all [insert name of **PRACTICE**[1]] employees and contractors, as well as our vendors and other business partners. Each of these individuals has a personal responsibility to ensure that his or her actions abide by the letter and the spirit of our Compliance Program. The standards set forth in this Program are supported by **PRACTICE's** other policies and procedures, and Employee Handbook [if applicable]. **PRACTICE** employees and contractors shall comply with the following standards:

1) **Ethical and professional standards**. Thoughtful, ethical behavior is expected of all our employees and contractors, and this Program focuses on key areas of ethical responsibility, provides guidance on appropriate behavior, and seeks to foster a culture of honesty and accountability throughout the **PRACTICE**. **PRACTICE** personnel shall treat patients, co-workers, and others in a professional manner. No **PRACTICE** employee shall take unfair advantage of any other employee, customer, patient, vendor, or competitor through manipulation, concealment, abuse of privileged or confidential information, misrepresentation of facts or any other unfair-dealing practice. All **PRACTICE** personnel shall abide by established standards of professional ethics.

2) **Compliance with this Program, PRACTICE policies, and the law.** The values and principles set forth in this Compliance Program are critically important to the **PRACTICE** and must be taken seriously. **PRACTICE** personnel shall comply with this Compliance Program and all other **PRACTICE** policies and procedures, including **[LIST OF POLICIES AND PROCEDURES, E.G., BILLING AND CODING POLICY, HIPAA POLICY, ETC.].**

[1] Replace the word **PRACTICE** with the name of the physician group throughout the plan documents.

3) **Non-discrimination**. **PRACTICE** employees shall not discriminate against patients, employees, or any others on the basis of race, color, sex, religion, age, national origin, ancestry, disability, or sexual orientation.

4) **Sexual harassment zero tolerance policy. PRACTICE** employees shall not sexually harass any other employees, patients, or others. **PRACTICE** has a zero-tolerance policy for sexual harassment.

5) **Offering or receiving items of value to induce referrals.** Federal and state law prohibit **PRACTICE** from offering or receiving anything of value to induce, or in exchange for, referrals of federal healthcare program business. **PRACTICE** personnel shall not offer, solicit, pay, or receive anything of value in exchange for healthcare referrals without first obtaining approval from the [**COMPLIANCE OFFICER**]. Similarly, **PRACTICE** employees shall not offer or provide patients with items of value to induce patients to use certain products, services, providers, or suppliers. **PRACTICE** employees shall not routinely waive beneficiary co-insurance, deductible, or other cost-sharing amounts, except pursuant to **PRACTICE's** financial hardship policy.

6) **Accurate billing and coding of services**. **PRACTICE** is committed to complying with the coding and billing requirements of all insurers to which **PRACTICE** submits claims for payment, including without limitation Medicare, Medicaid, and commercial insurers. **PRACTICE** employees must not engage in false, fraudulent, improper or questionable billing practices. **PRACTICE** employees agree to comply with all **PRACTICE** policies on billing and coding, including, but not limited to:

   - **PRACTICE** employees shall ensure that claims are only submitted for items and services actually rendered;

   - **PRACTICE** employees shall ensure that claims are only submitted for services that are medically necessary;

   - **PRACTICE** employees shall ensure that claims for services reflect the appropriate level of care provided and correctly indicate which clinician performed or supervised the service;

   - **PRACTICE** employees shall ensure that they have obtained an Advance Beneficiary Notice ("ABN"), when required to bill for potentially non-covered services, and that neither the patient nor payor is billed for services when an ABN that was required was not obtained;

   - **PRACTICE** employees shall ensure that all claims are supported by complete and adequate documentation in the medical record;

- **PRACTICE** employees are forbidden from forging, altering, revising, or in any other way changing medical records to obtain reimbursement or higher reimbursement for items or services; and

- **PRACTICE** employees are responsible for ensuring that all claims for services are otherwise properly coded and billed in accordance with payor guidelines and standards of practice.

7) **Privacy and confidentiality**. **PRACTICE** employees must respect and maintain the confidentiality and privacy of protected health information. **PRACTICE** employees agree to abide by **PRACTICE's** HIPAA and state privacy policies and procedures.

8) **Exclusion and debarment check requirements**. **PRACTICE** is prohibited from employing or contracting with persons or entities involved in the delivery of government-reimbursed healthcare services if they have been excluded from doing business with the federal government. Upon hiring or contracting, and periodically thereafter, **PRACTICE** verifies that relevant employees and contractors are not excluded, comparing them against the Department of Health and Human Services Office of Inspector General List of Excluded Individuals and Entities, and the General Services Administration Excluded Parties List System, amongst others.

B. Compliance Officer/Compliance Committee

PRACTICE has designated a Compliance Officer responsible for implementing, monitoring, and administering this Compliance Program. The Compliance Officer shall report on the status of **PRACTICE's** Compliance Program to the **PRACTICE's** board of directors at least once quarterly.

C. Education and Training

All **PRACTICE** employees are required to receive training on this Compliance Program and other **PRACTICE** policies and procedures upon hire and periodically thereafter. Additional training may be required as a result of a Compliance Investigation, period auditing of the Compliance Program, or for any other reason. **PRACTICE** shall track the training completed by all employees.

D. Compliance Reporting

PRACTICE has established internal compliance processes to allow for reporting and resolution of potential violations of law. **PRACTICE** encourages employees to contact the Compliance Officer to report potential compliance issues. Employees should consult with their supervisors if they are not sure who to contact.

If an employee feels uncomfortable raising a potential compliance issue with his or her manager in the first instance, the employee may anonymously report[2] the concern through the **PRACTICE** compliance [telephone and/or email] hotline at [**PHONE NUMBER/EMAIL ADDRESS**]. Contractors and vendors may also report potential compliance issues through the anonymous [**PHONE NUMBER/EMAIL ADDRESS**].

E. Investigating Compliance Concerns

All Compliance Complaints, regardless of how received or by whom, shall be promptly communicated to the Compliance Officer. The Compliance Officer shall begin tracking the complaint in the Compliance Tracking Log. The Compliance Officer shall conduct an initial evaluation of the complaint. Depending on the nature of the complaint, further evaluation may be required, and may include interviewing employees, reviewing e-mails, medical records, or other documents, and communicating with **PRACTICE's** Board of Directors. All reasonable steps shall be taken to maintain the confidentiality of the inquiry, and only those individuals with a need to know shall be involved in an inquiry. In all cases, the anonymity of the person making the allegations of wrongdoing shall be protected, unless required to be disclosed by law or to adequately conduct the inquiry.

At the completion of the Compliance Officer's evaluation, the Compliance Officer shall decide a final course of action regarding the complaint. The Compliance Officer may confer with the **PRACTICE** Board of Directors before confirming the final course of action. The Compliance Officer shall maintain all inquiry materials and any supporting documentation in accordance with **PRACTICE's** Records Retention Policy.

Violations of applicable law could expose **PRACTICE** and its employees and contractors to fines, civil liability and/or criminal liability, and could harm the **PRACTICE's** reputation. For that reason, violations of applicable laws, this Compliance Program, or other **PRACTICE** policies and procedures discovered as a result of a Compliance Investigation will lead to appropriate disciplinary action. Such disciplinary action may include reprimand, reimbursement of any loss or damage suffered by **PRACTICE**, or termination of employment or a contract. Under certain circumstances, **PRACTICE** may be obligated to disclose violations of the Compliance Program to law enforcement authorities or regulatory agencies.

F. Auditing and Monitoring

In addition to Compliance Investigations prompted by a Compliance Complaint, **PRACTICE** shall conduct periodic auditing and monitoring of the Compliance Program. The Compliance Officer shall be responsible for overseeing these periodic self-assessments, documenting the findings of the audits, and implementing corrective action, if necessary.

[2] Some mechanism should be established for anonymous reporting. It need not be a hotline, it could be a simple locked box accessible to all Practice staff.

G. Non-Retaliation and Rights of Employees

PRACTICE will not tolerate any attempt by an employee to retaliate against another as a result of good faith reports of alleged illegal or unethical behavior. Every employee (regardless of position with the **PRACTICE**) is prohibited from discharging, demoting, suspending, or in any manner threatening, harassing, or discriminating against another employee who provides information about a violation of the law, the Code of Conduct, or any **PRACTICE** policy. Moreover, the same prohibitions apply to any employee who assists in the investigation of any of the aforementioned types of violations or participates in bringing or brings a lawsuit. Protections for employees are provided under various federal and state laws, and under **PRACTICE's** policies. There will be no adverse employment action or consequence imposed on any employee or agent, as a result of the employee or agent making a good faith report of a suspected violation. A good faith report is one in which an employee or agent reports conduct that he/she reasonably believes has occurred and that may violate **PRACTICE's** policies/procedures, laws, regulations, or rules.

PRACTICE believes in a culture of collegiality and constructive problem-solving. Therefore, **PRACTICE** strongly encourages employees to report potential issues internally. However, if an employee feels they cannot do so, state and federal laws permit employees to report potential non-compliance with healthcare and other laws to the relevant government agencies.

H. Policies and Procedures

Other **PRACTICE** policies and procedures, which are incorporated by reference in this Compliance Program are **[LIST OF POLICIES AND PROCEDURES, E.G., BILLING AND CODING POLICY, HIPAA POLICY, ETC.].**

V. RESOURCES

Below is a list of websites that will help you to keep up to date on compliance issues.

Office of the Inspector General: compliance toolkit, including sample training materials
https://oig.hhs.gov/compliance/compliance-resource-portal

Office of the Inspector General: reports, workplans and other publications
https://oig.hhs.gov/reports-and-publications/index.asp

Office of the Inspector General: compliance guidance documents
https://oig.hhs.gov/reports-and-publications/index.asp

Office of the Inspector General: database for conducting program exclusion checks
https://oig.hhs.gov/exclusions/index.asp

Office of the Inspector General: special fraud alerts
https://oig.hhs.gov/compliance/alerts/index.asp

Public access to Laws and Regulations
https://www.law.cornell.edu

Anti-Kickback Statute Safe Harbor Regulations
https://oig.hhs.gov/compliance/safe-harbor-regulations/index.asp

Stark Law Materials
https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html