COMPLIANCE MANUAL

The Practice of

«LONG_PRACTICE_NAME»

«Address»

«City», «State» «Zip»

Compliance Officer: «COMPLIANCE_OFFICER_NAME»

«Date_»

PHYSICIANS' ALLY, INC.
Health Care Consulting

MGMA®
Medical Group Management Association

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ELEMENTS OF COMPLIANCE

Introduction

The Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) has declared that: "patient care is, and should be, the first priority of a provider practice." The OIG firmly believes that incorporating compliance measures into a practice will augment the ability to provide quality care. According to the OIG, compliance plans and programs should be viewed as *preventive medicine*—policies, procedures and practices that will prevent problems from occurring in the first instance. «LONG_PRACTICE_NAME» recognizes that the benefits of having an effective compliance plan and program include:

- demonstrating to providers and staff members and the community the Practice's strong commitment to honest and responsible provider conduct;
- identifying and preventing unethical and criminal conduct;
- improving the quality of patient care through better documentation;
- minimizing billing mistakes, thereby optimizing proper payment of claims;
- reducing chances of a negative outcome if audited by the government;
- minimizing the risk of violations of Federal and state laws, rules and regulations governing the operation of the Practice, including but not limited to the Anti-Kickback Statute and Stark Law;
- developing and maintaining a culture, and implementing reporting procedures, that encourage(s) providers and staff members to report potential problems; and
- the ability to promptly detect and report potential or actual violations and initiate immediate and appropriate corrective action, which

    a. reduces Practice exposure to administrative actions, civil damages and penalties, and criminal fines and sanctions, and

    b. minimizes losses incurred by the government as a result of overpayments.

Code of Conduct Policy

«SHORT_PRACTICE_NAME» is committed to conducting business in an ethical manner and in conformance with all applicable laws, rules and regulations. Our Code of Conduct contains written guidance for providers and staff members with regard to the Practice's standards of conduct. Our Code of Conduct is included in this Manual as **Appendix A** (p. 65).

1. The Code of Conduct will provide guidance concerning provider and staff member responsibilities related to compliance with Federal and state laws, rules and regulations, with a particular emphasis on preventing fraud and abuse. The Code of Conduct will also address issues related to our overall Compliance Program, including:
    a. quality of care;
    b. reimbursement;
    c. financial relationships;
    d. problem resolution process;
    e. open communications; and
    f. non-retaliation policy.
2. A copy of the Code of Conduct will be provided to all new providers and staff members as part of the orientation process, as well as to all of the Practice's existing providers and staff members. All recipients will sign a statement acknowledging receipt and that he or she has read the Code, understands its contents, and agrees to abide by its provisions.
3. Providers and staff members will participate in training that will include reviewing the Code of Conduct and learning to understand it as it relates to everyday work situations. Our Compliance Officer will maintain the documentation necessary to reflect that all providers and staff members have received appropriate training.
4. The Practice's Compliance Officer will have primary responsibility for maintaining and, if required, updating and modifying, the Code of Conduct.
5. The Compliance Officer will investigate actual or suspected violations of the Code of Conduct and the Compliance Program and ensure that appropriate disciplinary or corrective action is taken when necessary.

Compliance Officer

The Compliance Officer's primary responsibility is overseeing, and ensuring the effective operation of, «SHORT_PRACTICE_NAME»'s Compliance Program. The Practice appoints «COMPLIANCE_OFFICER_NAME» ("Compliance Officer") to the position of Compliance Officer for the Practice. The Compliance Officer will:

1. Oversee the development and implementation of our Compliance Program

2. Facilitate acknowledgement by Practice providers and staff members of receipt of the Code of Conduct and agreement to abide by its provisions

3. When necessary or appropriate, update the Code of Conduct to ensure it is current and relevant

4. Strive to maintain a culture of compliance within the Practice to ensure violations or suspected violations are timely reported without fear of retaliation

5. Ensure adequate compliance training

6. Institute processes and procedures, such as periodic audits, to improve the Practice's efficiency and quality of services, and to reduce the risk of liability resulting from fraud and abuse in the operation of the Practice

7. Utilize external compliance consultants, legal counsel, and other resources as necessary to ensure that the Compliance Program remains an effective tool for reducing fraud, waste, abuse and maintaining compliance with regulations such as HIPAA, OSHA, etc.

8. Oversee updates or other modifications to this Manual (including the Code of Conduct) and the Compliance Program generally and related policies, procedures, training and tools, as necessary or appropriate

9. Identify potential areas of compliance liability risk and provide specific direction for resolution

10. Respond to violations or suspected violations by conducting and overseeing compliance investigations, including, if required, notifying external agencies or other third parties

Resources

- Compliance Program Implementation Plan (**Appendix B** [p. 69] to this Manual)

Antitrust Laws Policy

Federal Antitrust laws outlaw or restrict business practices that are monopolistic or restrain interstate commerce. The Sherman Act outlaws arrangements that restrain trade or commerce among states. The Clayton Act (amended by the Robinson-Patman Act) prohibits discrimination among customers through pricing and disallows mergers, acquisitions or takeovers of one firm by another if the effect will "substantially lessen competition." The rationale for maintaining antitrust laws, rules and regulations is that individuals benefit when the capital markets operate free of restraints. Monopolies and "price fixing" are detrimental to consumers, resulting in higher prices, lower quality products and services, less innovation and fewer choices. Federal antitrust laws are enforced by the Federal Trade Commission (FTC) and the Department of Justice (DOJ). In addition, states also enforce their own antitrust laws under so-called "Little FTC" Acts.

Collaboration among physicians and/or practices to jointly negotiate with payers could result in violations of the antitrust laws if the collaboration is for the purpose of obtaining higher payments from a payer, rather than obtaining efficiencies from the collaboration, or if the result reduces competition among practices. Remedies for antitrust violations include injunctions, civil penalties or consumer redress.

1. «SHORT_PRACTICE_NAME» will use its best efforts to enter into business arrangements that promote for its patients a variety of innovative, high quality, products and services for reasonable prices.
2. If the Practice is contemplating a business arrangement that could implicate Federal or state antitrust laws, the Practice will take all reasonable steps necessary to ascertain whether or not the business arrangement could result in actual or potential violations under such laws. All reasonable steps include, but are not limited to, obtaining advice from the Practice's legal, financial and other professional advisors and adequately documenting the business arrangement.

Resources

- Sherman Act: 15 U.S.C. §§ 1-7: https://www.law.cornell.edu/uscode/text/15/chapter-1
- Clayton Act: 15 U.S.C. §§ 12-27: https://www.law.cornell.edu/uscode/text/15/12
- "FTC Guide to the Antitrust Laws": www.ftc.gov/bc/antitrust

Medicare Participation

Each year providers have an opportunity to change their participation status. The provider's designation as participating or non-participating determines the circumstances under which, and the amounts of, Medicare reimbursement payments the provider will receive.

«SHORT_PRACTICE_NAME» believes it is important that its providers and staff members know and understand these rules and regulations.

1. Providers who are enrolled in the Medicare Program have 90 days after enrollment to decide whether or not to be a participating (PAR) provider or non-participating (NON PAR) provider. PAR or NON PAR status continues for one year after designation.

2. Each year (in mid-November), during the Medicare open enrollment period, Medicare contractors send a letter to providers advising them of the upcoming year's payment rates and offering them an opportunity to change their participation status. Providers have until December 31 to make their participation decision (unless CMS extends the open enrollment period).

3. Participating Providers.

    a. In order to be a participating provider, the provider must fill out a CMS-460 Form and send it to each Medicare contractor from which the provider expects reimbursement.

    b. Participating providers are entitled to accept assignment of Medicare payments directly and receive 100% of the Medicare fee schedule for the services performed (80% from Medicare and 20% from the patient).

    c. Each year (in mid-November), Medicare contractors send letters out to physicians advising of their payment rates and offering the physicians' an opportunity to change their participation status.

4. Non-Participating Providers.

    a. If a provider wishes to enroll in the first instance as a non-participating provider, he or she may do so by submitting Forms 855-I and 855-R (but are not required to complete a CMS-460 application).

    b. Participating providers who choose to convert to non-participating status must submit a letter to Medicare (which includes their Medicare ID number) during the Medicare open enrollment period. Non-participating status commences on January 1 of the year following submission of the letter to Medicare.

c. If a provider chooses to be a non-participating provider, he or she may choose on a case-by-case basis whether or not to accept assignment of Medicare payments. If the provider does not accept assignment, Medicare will pay the patient directly.

d. A non-participating provider who accepts assignment receives 95% of the Medicare fee schedule, forfeiting 5% as a penalty for non-participation (80% from Medicare and 20% from the patient).

e. A non-participating provider who does not accept assignment must complete a Medicare beneficiary's claim form and submit the claim directly to Medicare. Medicare pays the patient directly, and the provider bills the patient for services rendered. The provider cannot charge the patient for the cost of filing the Medicare beneficiary's claim form; however, by refusing assignment, the non-participating provider can balance-bill patients up to the amount of the Medicare limiting charge (115% of Medicare).

5. Medicare Opt-Out.

   a. A provider may opt-out of Medicare altogether by filing certain Opt-Out forms (including an Opt-Out Affidavit) with Medicare. In this case, the provider agrees that neither the provider nor the patients will bill Medicare for services rendered. This opt-out status must be renewed every two years. In the event the opt-out provider changes his or her mind, it may do so within 90 days of the Opt-Out Affidavit's effective date. Once the opt-out status has been reversed, the opt-out provider must refund all moneys collected from Medicare beneficiaries in excess of the Medicare limiting charge.

   b. An opt-out provider must inform patients of the provider's opt-out status.

6. Advance Beneficiary Notices (ABNs).

   a. Participating providers who provide services that are not covered by Medicare must provide the patient an ABN regarding Non-Covered Medicare Services in order to bill the patient (it is also best practice to provide a "financial responsibility" form similar to an ABN to non-Medicare patients).

   b. The Participating provider must ensure the beneficiary receives all available information to make an informed decision about whether to obtain potentially non-covered services. This includes making a good faith effort to insert a reasonable estimate for all the items or services listed. In general, Medicare expects an estimate to fall within $100.00, or 25%, of the actual costs, whichever is greater. For example, an acceptable estimate for a service that costs $250.00 would be "between $150.00 to $300.00," or "no more than $500.00."

Compliance Program Implementation Plan

	Objectives
STEP I **Develop a Compliance Program Infrastructure**	• Identify the Practice's compliance officer. • Establish policies and compliance program infrastructure. • Identify proper support/resources for operation of the compliance program. • Involve the Practice Manager in understanding his/her/their compliance role/responsibility. • Analyze the current operating environment of the Practice to identify Practice-specific risks and ensure the compliance program addresses mitigation of such risks. • Encourage providers and staff members to raise questions about compliance.
STEP II **Develop Standards of Conduct**	• Develop a Practice Code of Conduct and Code of Conduct policy. • Provide simple, explicit guidelines for providers and staff members. • Ensure all providers and staff members understand what is expected of them. • Ensure providers and staff members are implementing compliance standards into daily practice.
STEP III **Establish Open Door Policy**	• Establish and publicize the existence of an "open door" philosophy. • Ensure that providers and staff members understand that they may report issues or concerns without fear of retaliation. • Ensure the confidentiality of reports to the maximum extent possible. • Establish a mechanism to act upon information received from reports and, when appropriate, take corrective action.
STEP IV **Staff member Communication and Education**	• Publicize and inform *all* providers and staff members of the adoption of the Code of Conduct and the compliance program. • Develop and implement an initial education program and document efforts to educate providers and staff members in compliance. • Develop and implement a continuing education program. • Document the training of all providers and staff members on the Practice's Code of Conduct.
STEP V **Continuous Improvement**	• Assess and update the Practice's compliance program each year to determine its effectiveness. • Re-assess the Practice's current risk environment. • Implement any changes deemed necessary. • Consult with external resources as necessary.

Claims Submission Audit Form

This claims submission audit consisted of a review of _____(% or # of charts) of the Practice's provider charts including dates of service from _____ to _____.

These charts were reviewed **retrospectively** or **concurrently** (***circle one***) with the claims submission process.

These charts were reviewed to ensure the following:

- Bills are accurately coded and reflect the services provided.
- Documentation is complete and correct.
- Services or items provided are reasonable and necessary.
- No incentives existed for unnecessary services.

_____
Signature

_____
Date

_____
Title

Periodic audits should review a randomly selected number of provider charts to ensure that coding is being performed accurately. The government suggests five or more charts per Federal payer, or five to ten charts per provider as an appropriate audit size; however, the Practice may consider a review of claims from a number of different payers in additional to governmental submissions.

COMPARISON OF THE ANTI-KICKBACK STATUTE AND STARK LAW*

	THE ANTI-KICKBACK STATUTE (42 USC § 1320a-7b(b))	**THE STARK LAW** (42 USC § 1395nn)
Prohibition	Prohibits offering, paying, soliciting or receiving anything of value to induce or reward referrals or generate Federal health care program business	• Prohibits a physician from referring Medicare patients for designated health services to an entity with which the physician (or immediate family member) has a financial relationship, unless an exception applies • Prohibits the designated health services entity from submitting claims to Medicare for those services resulting from a prohibited referral
Referrals	Referrals from anyone	Referrals from a physician
Items /Services	Any items or services	Designated health services
Intent	Intent must be proven (knowing and willful)	• No intent standard for overpayment (strict liability) • Intent required for civil monetary penalties for *knowing* violations
Penalties	Criminal: • Fines up to $25,000 per violation • Up to a 5 year prison term per violation Civil /Administrative: • False Claims Act liability • Civil monetary penalties and program exclusion • Potential $50,000 CMP per violation • Civil assessment of up to three times amount of kickback	Civil: • Overpayment /refund obligation • False Claims Act liability • Civil monetary penalties and program exclusion for *knowing* violations • Potential $15,000 CMP for each service • Civil assessment of up to three times the amount claimed
Exceptions	*Voluntary* safe harbors	*Mandatory* exceptions
Federal Health Care Programs	All	Medicare /Medicaid

* This chart is for illustrative purposes only and is not a substitute for consulting the statutes and their regulations.

Chart accessible at: http://oig.hhs.gov

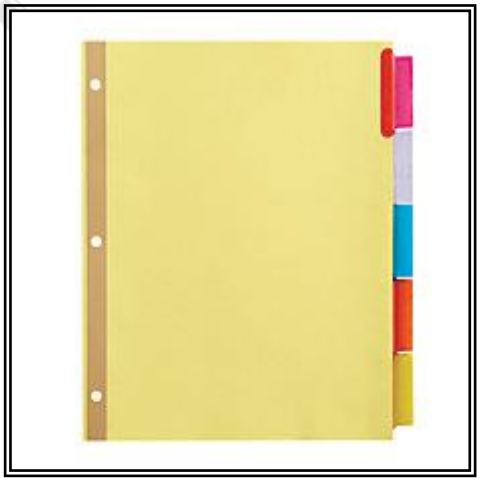
Glossary of Acronyms

Acronym	*NAME*
ABN	Advance Beneficiary Notice
ACO	Accountable Care Organization
ADA	American with Disabilities Act
AKS	Anti-Kickback Statute
AMA	American Medical Association
ARRA	American Recovery & Reinvestment Act of 2009
ASCA	Administrative Simplification Compliance Act
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CHC	Certified in Healthcare Compliance
CIIS	Colorado Immunizations Information System (Colorado)
CLIA	Clinical Laboratory Improvement Amendments of 1988
CMP	Civil Monetary Penalties
CMS	Centers for Medicare & Medicaid Services
CNA	Certified Nursing Assistant
CoPs	Medicare Conditions of Participation
CPC	Certified Professional Coder
CPT (Codes)	Current Procedural Terminology
DEA	Drug Enforcement Administration
DHS	Designated Health Services
DOJ	Department of Justice
DOL	Department of Labor
EDI	Electric Data Interchange
EEOC	Equal Employment Opportunity Commission
EHR	Electronic Health Records [Incentive Program]
EMTALA	Emergency Medical Treatment and Active Labor Act
eRx	Electronic Prescribing [Incentive Program]
FACTA	Fair and Accurate Credit Transaction Act of 2003
FCA	False Claims Act
FDA	Food and Drug Administration
FDCPA	Fair Debt Collection Practices Act
FMLA	Family Medical Leave Act of 1993
FTC	Federal Trade Commission
GPO	Group Purchasing Organization
GPRO	Group Practice Reporting Option
HCPCS (Codes)	Healthcare Common Procedure Coding System

Acronym	***NAME***
HCQIA	Health Care Quality Improvement Act of 1986
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HR	Human Resources
IC Standards	Joint Commission Infection Control Standards
ICD-10 (Codes)	International Statistical Classification of Diseases and Related Health Problems
MBMS	Medical Billing and Management Services
MIP	Medicare Integrity Program
NDC (Codes)	National Drug Code
NPDB	National Practitioner Data Bank
NPI	National Provider Identifier
NPP	Non-Physician Providers
OIG	Office of Inspector General
OSHA	Occupational Safety and Health Administration
PA	Physician's Assistant
PPACA	Patient Protection and Affordable Care Act
PQRS	Physician Quality Reporting System [Incentive Program]
RAC Program	Medicare Recovery Audit Contractor Program
Red Flag Rules	§§114 and 315 of FACTA Red Flag Program Clarification Act of 2010
STARK	Ethics in Patient Referrals Act of 1989
Sunshine Act	Physician Financial Transparency Reports (part of PPACA)

Recommended Documentation Tabs for activation of your Compliance Manual

In order to activate this Compliance Manual, it is recommended that the administrator organizing the physical version reprint this page on thicker stock paper and acquire insertable tab dividers identical or similar to those shown in this image **HERE**.



These insertable tab dividers can be purchased at any office supply store

The following titles should be included as the tab dividers, and are also provided in two different versions of cut-outs in the lower half of this page:

1. Compliance Correspondence
2. Compliance Plan Documentation
3. Physician Compliance Training
4. Staff Member Compliance Training

LARGER TAB VERSION

Please cut along the edges below.

Trebuchet MS font (size 10, bold) cutouts

Compliance Correspondence

Compliance Plan Documentation

Physician Compliance Training

Staff Member Compliance Training

SMALLER TAB VERSION

Please cut along the edges below.

Times New Roman font (size 6.5, bold, all caps) cutouts

COMPLIANCE CORRESPONDENCE

COMPLIANCE PLAN DOCUMENTATION

PHYSICIAN COMPLIANCE TRAINING

STAFF MEMBER COMPLIANCE TRAINING

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Notes

- **Bold page numbers** indicate online and other resources available to the user.
- *Italicized page numbers* indicate forms the user may need to review and/or fill out.

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