



## COMPLIANCE PROGRAM

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**McGregor PACE  
Compliance Program**

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## I. INTRODUCTION

### A. Purpose

McGregor PACE has adopted this Compliance Program (“Compliance Program” or “Program”) to reaffirm its commitment to complying with all applicable federal and state laws, and PACE program requirements. This Program is intended to follow all relevant compliance program regulations as well as guidelines issued by CMS from time to time, including, but not limited to, [§460.63 of the PACE regulations](#), [§423.504\(b\)\(4\)\(vi\) of the Part D regulations](#), and [Chapter 9 of the Medicare Prescription Drug Benefit Manual/Chapter 21 of the Medicare Managed Care Manual](#). This Program:

- Articulates McGregor PACE’s commitment to complying with applicable federal and state standards;
- Articulates McGregor PACE’s commitment to detecting, correcting, and preventing noncompliance with CMS’s program requirements, including detecting, correcting, and preventing fraud, waste, and abuse;
- Describes standards of conduct (*See Tab A: Model Standards of Conduct*) and compliance expectations that the Board, employees, contractors, vendors, and volunteers of McGregor PACE are expected to adhere to;
- Outlines procedures that McGregor PACE follows to monitor and audit compliance with CMS requirements and the overall effectiveness of the compliance program; and investigate and resolve any potential improper conduct when identified;
- Provides guidance for McGregor PACE’s employees, contractors, vendors, and volunteers in reporting compliance issues and addressing questions relating to fraud, waste, and abuse; and
- Identifies specific risk areas for McGregor PACE’s overall as well as McGregor PACE Prescription Drug Plan (PDP) that merit attention and monitoring.

McGregor PACE has a policy of non-intimidation and non-retaliation for good faith participation in the Compliance Program.

### B. Glossary

These terms will have the following meaning when used in the Program:

*Abuse* includes actions that may, directly or indirectly, result in unnecessary costs to the Medicare and Medicaid Programs, improper payment, payment for services that fail to meet professionally recognized standards of care, or services that are medically unnecessary. Abuse involves payment for items or services when there is no legal entitlement to that payment and the provider has not knowingly and/or intentionally misrepresented facts to obtain payment. Abuse cannot be differentiated categorically from fraud because the distinction between “fraud” and

“abuse” depends on specific facts and circumstances, intent and prior knowledge, and available evidence, among other factors. Examples of abuse include:

- Payment for services not provided as billed;
- Failure to provide medically necessary services, or other services determined necessary by the interdisciplinary team to maintain or improve participants’ health status;
- Payment for services provided by an individual who is not appropriately qualified to provide the billed service (e.g., an unlicensed person or a person acting outside the scope of his or her license);
- Encouraging disenrollment in response to decline in participant’s health status;
- Reporting diagnoses for risk adjustment that are not supported by the participant’s medical condition;
- Inadequate controls that result in failing to report rebates or discounts;
- Drug-seeking behavior on the part of beneficiaries; and
- Issuing refills for a prescription that is not medically necessary.

*Anti-Kickback Statute (“AKS”)* means the Medicare and Medicaid Patient and Program Protection Act (found at 42 USCA §1320a-7b(b)). The AKS makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal Health Care Program. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal Health Care Program, the AKS is violated. “Remuneration” is defined in the AKS as including the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

*Appeal* means any of the procedures that deal with the denial of service delivery or payment requests, enrollment denials, or involuntary disenrollments.

*Audit* means a formal review of compliance with internal (e.g., compliance plan, policies and procedures) and external (e.g., laws and regulations) standards used as base measures.

*CMS* means the Centers for Medicare and Medicaid Services (CMS), the federal government agency in charge of administering Medicare and Medicaid.

*Compliance Officer* means the individual appointed by McGregor PACE as responsible for the Organization’s Compliance Program.

*Conflict of interest* means a situation in which the outside professional activities, private financial interests or other interests of, or the receipt of benefits from third parties impair, or appear to impair, an individual’s independent, unbiased judgment.

*Contractor* means an outside organization, agency, or individual, including a First Tier Downstream Related Entity (FDR), that furnishes administrative or care-related services on behalf of McGregor PACE.

*Downstream Entity* means any party that enters into a written agreement, acceptable to CMS, with persons or entities involved with the Part D benefit, below the level of McGregor PACE and a First Tier Entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

*FDR* refers to First Tier, Downstream or Related Entity that has entered into an agreement with McGregor PACE and provides services under the Part D program. Medicare Part D program requirements apply to FDRs to whom McGregor PACE has delegated administrative or health care functions relating to its Medicare Part D plan.

*Federal Health Care Program* means any plan or program that provides health care benefits to any individual, whether directly, through insurance or otherwise, which is funded directly, in whole or in part, by a United States Government or state health care program, including Medicare, Medicaid, CHAMPUS, and Department of Veterans Affairs but excluding the Federal Covered Persons Health Benefit Program (FEHBP).

*First Tier Entity* means any party that enters into a written arrangement, acceptable to CMS, with McGregor PACE to provide administrative services or health care services for a Medicare eligible individual under the Part D program.

*Formulary* means the entire list of Part D drugs covered by McGregor PACE's Part D plan and all associated requirements outlined in Pub. 100-18, Medicare Prescription Drug Benefit Manual, Chapter 6.

*Fraud* is knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any health care benefit program or to obtain (by means of false or fraudulent pretenses, representations or promises) any of the money or property owned by, or under the custody or control of, any health care benefit program. Examples of fraud include:

- Embezzlement of Medicare and/or Medicaid program funds;
- Enrolling, and receiving payments for, fictitious individuals;
- Misrepresenting information about potential participants to enroll individuals who would not otherwise be eligible for PACE;
- Knowingly submitting unsupported diagnoses to CMS for use in risk-adjusting Medicare capitation payment amounts;
- Falsifying encounter data;
- Altering Pharmacy Drug Event(s) (PDE) data, or submitting fictitious PDE data, to CMS for the purpose of increasing risk-sharing and other CMS subsidies; and

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- Reporting that a brand-name drug was dispensed when a generic was dispensed, with the intent of receiving increased federal reimbursement.

*FWA* means Fraud, Waste, and Abuse.

*Governing Body* means that group of individuals at the highest level of governance of McGregor PACE such as the Board of Directors or the Board of Trustees, who formulate policy and direct and control McGregor PACE in the best interest of the organization and its Participants. As used in this chapter, governing body does **not** include C-level management such as the Chief Executive Officer, Chief Operations Officer, Chief Financial Officer, etc., unless persons in those management positions also serve as directors or trustees or otherwise at the highest level of governance of McGregor PACE.

*MEDIC* means any Medicare Drug Integrity Contractor retained by CMS to assist with Parts C and D fraud prevention and detection. *MEDIC* activities include: data analysis to identify potential Parts C and D fraud; investigation of potential Parts C and D fraud; development of potential Parts C and D fraud cases for referral to law enforcement; liaison to law enforcement for Parts C and D issues; and audits of sponsor and subcontractor Parts C and D operations.

*MMA* means the Medicare Prescription Drug, Improvement and Modernization Act of 2003, the federal statute that created the Part D drug benefit.

*OIG* means the Office of the Inspector General for the federal Department of Health and Human Services (HHS).

*Participant* means an individual enrolled in McGregor PACE.

*Prescription Drug Plan (PDP)* means a Medicare Part D Prescription Drug Plan sponsored by McGregor PACE.

*Pharmacy Benefits Manager (PBM)* means an entity contracted by McGregor PACE to administer the Medicare Part D drug benefit, which activities may include formulary development, claims processing, pharmacy network management, and data reporting.

*Prescription Drug Event (PDE) data* means the data elements constituting a summary record that documents the final adjudication of a dispensing event that must be submitted to CMS on a monthly basis.

*Related Entity* means any entity that is related to McGregor PACE by common ownership or control and: (1) performs some of McGregor PACE's Part D management functions under contract or obligation; (2) furnishes services to Medicare Participants under an oral or written agreement; or (3) leases real property or sells materials to the Part D plan sponsor at a cost of more than \$2,500 during a contract period.

*SAM* means the General Services Administration (GSA) System for Award Management database service at ([SAM.gov](https://sam.gov)) that combines several federal procurement systems and the Catalog of Federal Domestic Assistance into one system to search for excluded, sanctioned or debarred persons or companies.



*Search Warrant* means a judicial order issued by a judge or magistrate which authorizes government or law enforcement agents to locate and remove specific documents or items from the premises. To be valid, a search warrant must be signed by a judge or magistrate, must be supported by an affidavit, and must not have expired.

*State Administering Agency (SAA)* refers to the state agency which enters into the three-way PACE program agreement with CMS and McGregor PACE, and which is responsible for oversight of McGregor PACE.

*Subpoena* means a legal document ordering the production of either testimony (a *subpoena ad testificandum*, ordering a witness to appear and give testimony) or documents (a *subpoena duces tecum*, directing the recipient to produce books, papers, documents and other things). Subpoenas usually do not require the production of the witness or documents immediately; they may set a time-frame within which information must be produced.

*Third-Party Administrator (TPA)* means an entity contracted by a Prescription Drug Plan to process claims for the Medicare Part D drug benefit and provide related services (such as enrollment management, risk adjustment and encounter data submission)

*Waste* means the overutilization of services, or other practices that, directly or indirectly, result in unnecessary costs to the Medicare and Medicaid programs. Waste is generally not considered to be caused by criminally negligent actions but rather the misuse of resources. Examples of waste include:

- Ineffective Interdisciplinary Team decision-making or utilization management activities that lead to unnecessary utilization of goods and services and/or unnecessary costs;
- Poor or inefficient record-keeping that results in additional costs;
- Improper drug utilization or other protocols that result in poor quality of care, requiring additional medications paid for with federal health care program dollars; and
- Failing to adequately differentiate between Part A, Part B and Part D drugs and receiving higher Medicare payments as a result.

## **II. HIGH-LEVEL OVERSIGHT**

### *A. Governing Body*

#### *1. Duties of the Board*

McGregor PACE's Board of Directors (herein referred to as the "Board") shall exercise reasonable oversight with respect to the implementation and effectiveness of the Compliance Program. When compliance issues are presented to the Board, it should make further inquiry and

take appropriate action to ensure the issues are resolved. The Board may delegate compliance program oversight to the Compliance Committee, or designee, but the Board as a whole remains accountable for reviewing the status of the Compliance Program. The scope of the delegation from the full Board to the Compliance Committee must be clear in the Committee's charter and reporting. The Board shall receive training and education as to the structure and operation of the Compliance Program.

Reasonable oversight shall include (assisted by the Compliance Committee if desired):

- Approving the Standards of Conduct (which shall be done by the full Board) (*See Tab A: Model Standards of Conduct*);
- Understanding the Compliance Program structure;
- Remaining informed about the Compliance Program outcomes, including results of internal and external audits;
- Remaining informed about governmental compliance enforcement activity;
- Receiving regularly scheduled, periodic updates from the Compliance Officer and Compliance Committee; and
- Reviewing the annual results of performance and effectiveness assessments of the Compliance Program.

The Board may wish to be involved in, or may delegate to senior management or to the Compliance Committee, the following activities:

- Development, implementation and regular review of compliance policies and procedures;
- Approval of compliance policies and procedures;
- Review and approval of compliance and FWA training;
- Review and approval of compliance risk assessment;
- Review of internal and external audit work plans and audit results;
- Review and approval of corrective action plans resulting from audits;
- Evaluation of the senior management team's commitment to ethics and the compliance program; and
- Review of dashboards, scorecards, self-assessment tools, etc., that reveal compliance issues.

## 2. *Reviewing the Effectiveness of the Compliance Program*

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The Board should collect and review measurable evidence that the Compliance Program is detecting and correcting noncompliance on a timely basis.

Some indicators of an effective Compliance Program are:

- Use of quantitative measurement tools (e.g., scorecards, dashboard reports, key performance indicators) to report, and track and compare over time, compliance with key PACE program and other legal requirements;
- Use of monitoring to track and review open/closed corrective action plans;
- Implementation of new or updated Federal and State requirements and confirm appropriate and timely implementation;
- Increase or decrease in number and/or severity of complaints from employees, contractors, providers, participants, caregivers;
- Timely response to reported noncompliance and potential FWA, and effective resolution (i.e., non-recurring issues);
- Consistent, timely and appropriate corrective action; and
- Detection of noncompliance and FWA issues through monitoring and auditing:
  - Whether root cause was determined and corrective action appropriately and timely implemented and tested for effectiveness;
  - Detection of noncompliance trends and schemes via daily claims reviews, outlier reports, audits (e.g., Part D pharmacy audits), investigative findings, etc.; and
  - Actions taken in response to compliance reports.

McGregor PACE should ensure that CMS and the SAA are able to validate, through review of the Board's meeting minutes or other documentation, the active engagement of the Board in the oversight of the Compliance Program.

#### *B. Senior Management Involvement in Compliance Program*

The CEO and other senior management shall be engaged in the Compliance Program.

##### *1. Duties of CEO*

The CEO shall:

- With the cooperation of other senior management, ensure that the Compliance Officer is given the credibility, authority and resources necessary to operate a robust and effective Compliance Program;

- Receive periodic reports from the Compliance Officer of risk areas facing McGregor PACE, the strategies being implemented to address them, and the results of those strategies; and
- Be advised of all governmental compliance enforcement activity, including formal enforcement actions.

### III. COMPLIANCE OFFICER AND COMPLIANCE COMMITTEE

#### A. Compliance Officer

The Compliance Officer (*See Tab B: Model Compliance Officer Job Description.*) shall be a member of senior management and shall develop, operate, and monitor the Compliance Program. The Compliance Officer shall report directly to the Board on matters related to program compliance, as necessary. The Compliance Officer will oversee the Compliance Committee, which shall advise the Compliance Officer and assist in the implementation of the Compliance Program.

The Compliance Officer's job duties include:

- Develop and update compliance policies and procedures;
- Report on a periodic basis to the Board, the CEO, other senior management, and the Compliance Committee regarding the activities and status of McGregor PACE's Compliance Program, including: the identification, investigation, and resolution of potential or actual instances of noncompliance; the results of auditing and monitoring activities, including the effectiveness of the Compliance Program; areas of risk facing McGregor PACE, strategies used to address the areas of risk, and the results of those strategies; and any instances of government compliance investigation, compliance enforcement or compliance penalties such as Notices of Non-compliance, Warning Letters or more formal sanctions;
- Develop and implement training programs regarding McGregor PACE's Compliance Program;
- Develop and maintain compliance reporting mechanisms that are accessible and confidential and that allow employees and contractors to report suspected fraud, waste, abuse and other non-compliance on an anonymous basis and without fear of retaliation;
- Develop and maintain effective lines of communication between the Compliance Officer and members of the Compliance Committee, McGregor PACE's senior leadership, McGregor PACE employees, and McGregor PACE contractors, including receiving regular reports on the results of auditing and monitoring activities and widely publicizing compliance policies and procedures throughout McGregor PACE and its contractors;

- Respond to reports of compliance issues concerning McGregor PACE, including compliance concerns involving contractors, and coordinating investigations and developing corrective action plans;
- Report instances of fraud to the appropriate NBI MEDIC, CMS, and/or the SAA and other state-specific entities as required, when McGregor PACE determines that such a report is appropriate;
- Maintain appropriate documentation regarding the Compliance Program performance;
- Enforce corrective action plans;
- Ensure HHS OIG and SAM exclusion lists, CMS preclusion list, Ohio Medical Board, Ohio nurse aide registry, Medicare opt-out list, and state Medicaid exclusion lists, as applicable, have been checked monthly with respect to employees, governing body members, and contractors, as applicable, and coordinating results with Human Resources, Security, Legal fiscal, or other departments as appropriate; and
- Regularly check the CMS website for relevant new or revised regulations, guidance materials, and making recommendations to the Board for incorporating new or revised regulations and guidance into the Compliance Program, as appropriate.

The Compliance Officer shall have the authority to:

- Provide unfiltered, in-person reports to McGregor PACE's executive leadership, i.e., the CEO, CFO, and the Board, at the Compliance Officer's discretion;
- Interview McGregor PACE employees and other relevant individuals regarding compliance matters;
- Review contracts and other pertinent documents;
- Review the submission of data to CMS and the SAA to ensure that it is accurate and in compliance with applicable reporting requirements;
- Independently seek advice from legal counsel;
- Report potential fraud or misconduct to CMS, the SAA, their designee or law enforcement, as appropriate;
- Conduct and/or direct audits and investigations of contractors; and
- Conduct and/or direct audits of any area or function of McGregor PACE's program.

*B. Compliance Committee*

The Compliance Committee serves to advise the Compliance Officer and is accountable, and must provide regular compliance reports, to McGregor PACE's Board, CEO, and other senior management.

The Compliance Committee's duties include:

- Meet semi-annually, or more frequently as necessary to enable reasonable oversight of the Compliance Program;
- Develop strategies to promote compliance and the detection of any potential violations;
- Review and approve compliance training, and ensuring that training and education are effective and appropriately completed;
- Assist with the creation and implementation of the Compliance Program risk assessments and the monitoring and auditing work plan;
- Assist in the creation, implementation and monitoring of effective corrective actions;
- Develop ways to implement appropriate corrective and preventative action;
- Review the effectiveness of the Compliance Program;
- Support the Compliance Officer's needs for sufficient staff and resources to carry out his/her duties;
- Ensure that McGregor PACE has appropriate, up-to-date compliance policies and procedures;
- Ensure that McGregor PACE has a system for employees, contractors, and volunteers to ask compliance questions and report potential instances of program noncompliance and potential FWA confidentially or anonymously (if desired) without fear of retaliation;
- Ensure that McGregor PACE has a method for Participants to report potential program noncompliance and FWA;
- Review and address reports of monitoring and auditing in areas in which McGregor PACE is at risk for program noncompliance or potential FWA and ensuring that corrective action plans are implemented and monitored for effectiveness; and
- Provide regular and ad hoc reports on the status of compliance with recommendations to McGregor PACE's Board.

The Compliance Committee should include individuals with a variety of backgrounds, including members of senior management including, but not limited to, McGregor PACE's

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Compliance Officer, CEO, Medical Director, Quality Director, CFO, Director of Clinical Services, Director of Operations, and Health Plan Operations managers (to the extent that McGregor PACE has these positions on staff). Members of the Compliance Committee should have decision-making authority in their respective areas of expertise.

### *C. Communications and Reporting*

The Compliance Officer shall coordinate regular meetings of the Compliance Committee to ensure appropriate oversight and discussion of compliance activities. At least quarterly, and more frequently as circumstances warrant, the Compliance Officer shall provide regular reports to the Board, the CEO, and other senior management on the operation and effectiveness of the Compliance Program, including reports on Compliance Program risk assessments; monitoring and auditing activities; and, as necessary, on any potential violations, government enforcement activities or other compliance concerns, including reports about investigations into such matters and correction of any problems identified.

## **IV. EFFECTIVE LINES OF COMMUNICATION**

An open line of communication between the compliance officer and McGregor PACE's personnel, as well as among the organization, volunteers, contractors and participants, is critical to the successful implementation of a compliance program and the reduction of any potential for fraud, abuse and waste.

McGregor PACE shall establish and implement effective lines of communication, ensuring confidentiality between the Compliance Officer, members of the Compliance Committee, employees, managers and the Board, volunteers, and McGregor PACE's contractors and participants. Such lines of communication shall be accessible to all and allow compliance issues to be reported, including a method for anonymous and confidential good faith reporting of potential compliance issues as they are identified. For more information on reporting of compliance issues refer to Section VIII: Internal Reporting of Wrongdoing.

In addition, McGregor PACE shall have an effective way to communicate information from the Compliance Officer to others. Such information should include:

- The Compliance Officer's name, office location and contact information;
- Applicable/relevant laws, regulations, and guidance for McGregor PACE and contractors, such as statutory, regulatory, and sub-regulatory changes (e.g. HPMS memos);
- Changes to policies and procedures and Standards of Conduct (*See Tab A: Model Standards of Conduct*).

McGregor PACE may communicate information via physical postings of information, e-mail distributions, internal websites, and individual and group meetings with the Compliance Officer. The Compliance Officer shall disseminate information within a reasonable time and to all appropriate parties.

## V. RISK ASSESSMENT

Referring to Section 50.6.2 Development of a System to Identify Compliance Risks, in Chapter 9 of the CMS Prescription Drug Benefit Manual/Chapter 21 of the CMS Medicare Managed Care Manual, “Areas of particular concern for Medicare Parts C and D sponsors include, but are not limited to, marketing and enrollment violations, agent/broker misrepresentation, selective marketing, enrollment/disenrollment noncompliance, credentialing, quality assessment, appeals and grievance procedures, benefit/formulary administration, transition policy, protected classes policy, utilization management, accuracy of claims processing, detection of potentially fraudulent claims, and FDR oversight and monitoring.” These are among the areas of concerns for PACE organizations as well.

McGregor PACE shall establish and maintain a risk assessment system to determine where the organization is at risk for noncompliance and to prioritize (rank) such risks. Under this system, the Compliance Officer (or his/her designee) shall conduct an overall risk assessment annually to identify priority compliance risk areas where additional safeguards may be needed. (*See Tab C: Base-line Compliance Risk Assessment Tool; Tab D: Part D Compliance and Fraud, Waste and Abuse Risk Assessment Tool; Tab G: FDR Oversight and Monitoring Risk Assessment Tool*) The Compliance Program risk assessment will identify priority risk areas by referencing: areas of concern identified by CMS, the SAA or other regulators; areas of concern identified by McGregor PACE; and areas of concern identified by participants, providers, contractors, or others. McGregor PACE will document the procedures used to implement the risk assessment. The Compliance Risk Assessment will include a section addressing Part D/FWA specifically. (*See Tab D: Part D Compliance and Fraud, Waste and Abuse Risk Assessment Tool; Tab G: FDR Oversight and Monitoring Risk Assessment Tool.*)

The Compliance Risk Assessment should inform the compliance priorities in the yearly audit and monitoring work plan described below in Section VI.A of this Compliance Program.

In developing and updating its annual Compliance Risk Assessment, McGregor PACE will consider, and incorporate as appropriate, relevant information from the following resources:

- Internal corrective action plans;
- McGregor PACE’s past CMS and SAA audit reports;
- CMS PACE Audit and Enforcement Report (See [https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PACE\\_Audits](https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PACE_Audits))
- OIG Annual Work Plan (See <http://oig.hhs.gov/publications/workplan.asp>);
- Current CMS PACE Application (See <https://www.cms.gov/Medicare/Health-Plans/PACE/Overview> );



- Current CMS PACE Part D Application (See [https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting\\_ApplicationGuidance](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ApplicationGuidance) );
- CMS PACE Audit Guide (See [https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PACE\\_Audits](https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PACE_Audits) );
- CMS review and audits;
- State review and audits;
- Enforcement and compliance actions (See <https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PartCandPartDEnforcementActions> );
- Current Call Letter for Medicare Advantage Organizations and PDP sponsors, as applicable to PACE (See <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html> );
- Relevant guidance/information provided through the Health Plan Management System (“HPMS”);
- Recent guidance from CMS, the SAA, the OIG and/or other relevant authorities;
- Recent amendments or additions to the PACE or Part D regulations (See [https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title42/42cfr460\\_main\\_02.tpl](https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title42/42cfr460_main_02.tpl) and [https://www.ecfr.gov/cgi-bin/text-idx?SID=810c06305ee5c7d97bd208d69b0147a8&mc=true&tpl=/ecfrbrowse/Title42/42cfr423\\_main\\_02.tpl](https://www.ecfr.gov/cgi-bin/text-idx?SID=810c06305ee5c7d97bd208d69b0147a8&mc=true&tpl=/ecfrbrowse/Title42/42cfr423_main_02.tpl) ); and
- Recent amendments or additions to Chapter 9 of the Medicare Prescription Drug Benefit Manual/Chapter 21 of the Medicare Managed Care Manual (See <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals> ).

## VI. MONITORING AND AUDITING

### A. Risk Area Monitoring and Audits, including Preclusion/Exclusion Checks

I. Consistent with its annual risk assessment as described in Section V- above and in response to specific issues as they arise, McGregor PACE will conduct periodic monitoring and auditing activities to detect and prevent potential noncompliance, including FWA and to ensure compliance with all applicable federal and state laws, PACE program requirements, and McGregor PACE’s policies and procedures. The Compliance Officer shall develop a monitoring and auditing work plan outlining, and include a schedule of, the planned monitoring and auditing activities for each contract year. (See Tab E: Annual Compliance Monitoring and Auditing Work Plan.) Any

monitoring and auditing work plans so developed should meet the relevant requirements of Sections 50.6.3 through 50.6.6, Chapter 9 of the CMS Prescription Drug Benefit Manual/Chapter 21 of the CMS Medicare Managed Care Manual (<https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals>). Monitoring may occur to ensure corrective actions for any identified issues are undertaken or when no specific issue has been identified to confirm ongoing compliance.

Monitoring and/or auditing will extend to all areas of McGregor PACE's operations, including its Part D plan, that are vulnerable to noncompliance, including:

- Marketing, including agent/broker misrepresentations, if applicable
- Enrollment and Disenrollment
- Credentialing
- Service delivery requests, appeals, and grievances;
- Clinical appropriateness and care planning;
- Emergency preparedness;
- Personnel records;
- Quality Improvement;
- Risk Adjustment Processing System (RAPS), Encounter Data System (EDS) and other data submissions;
- Contractor oversight and monitoring;
- Provider claims adjudication to assure payments are consistent with contract requirements, etc.;
- Part D plan-specific areas (refer to Part D Compliance Section VII.D. for more detail)
  - Transition policy, if applicable;
  - Protected classes policy, if applicable;
  - Utilization management;
  - Operations of FDRs (*See Part D Compliance, Section VII.D.1., Compliance by First Tier, Downstream, and Related Entities and Section VII.D.7., Monitoring PBMs and Pharmacies*);
  - Part D claims processing;

- Pricing, rebates and other price concessions;
- FDR oversight and monitoring;
- CMS payments (PDE and other data submission, comparison to the bid, etc.); and
- Other areas identified through McGregor PACE's Compliance Program risk assessment.

2. Monitoring and auditing for compliance issues shall include, but will not be limited

to:

- Review of CMS-Issued Fraud Alerts and McGregor PACE's past paid claims from entities identified in the fraud alerts to determine whether such claims should be removed from its prescription drug event data submissions;
- Maintenance and review of files of in-network and out-of-network providers who have been the subject of complaints, investigations, violations, and prosecutions over the past ten (10) years;
- Engage in regular analysis of data maintained and/or submitted for McGregor PACE's Part D plan. Data will be compiled, sorted, and analyzed to identify any anomalies, outliers, or patterns of aberrant and potentially abusive utilization. (*See Part D Compliance, Section VII.D.2., Data Reporting Compliance.*) Data analysis procedures will be provided to CMS upon request; and
- Review of the OIG Annual Work Plan and related reports to determine priority risk areas.

3. The Compliance Officer may also utilize any of the following methods to monitor and audit risk areas:

- Review of medical records and other related documentation;
- Interviews with employees and/or contractors and on-site observation of activities;
- Review of complaints/reports submitted to the compliance hotline (216-268-8400) and compliance e-mail ([compliance@mcgregoramasa.org](mailto:compliance@mcgregoramasa.org)) at McGregor PACE;
- Use of objective, independent auditors that are knowledgeable regarding CMS, State and other requirements and not employed in the area under review;
- Sampling and extrapolation;

- On-site visits with contractors, such as home care agencies, transportation providers, medical specialists, pharmacies and PBMs;
- Unannounced “spot checks” or internal audits of McGregor PACE and/or its contractors; and
- Executing internal audit assessments by engaging in regular monitoring and analysis of key interdepartmental processes and procedures.

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4. Employees and contractors found to be excluded will be removed immediately from any work on programs involving Federal Health Care Programs. Board members found to be excluded will be removed from the Board in accordance with the Code of Regulations of the McGregor Foundation. McGregor PACE will also screen applicable providers against CMS’s preclusion list, Ohio Medical Board, Ohio nurse aide registry and Medicare opt-out list.

The Compliance Officer shall maintain documentation of all exclusion/preclusion checks performed.

#### *B. Audits of the Compliance Program*

Audits of the effectiveness of the Compliance Program shall occur at least annually. In order to avoid self-policing, the compliance department may not conduct the formal audit of the effectiveness of the Compliance Program. The Compliance Officer may train employees who are not part of the compliance department to perform the audit or outsource the audit to external auditors. In addition to the above, the Compliance Officer shall develop informal audit and monitoring mechanisms to evaluate the effectiveness of the Compliance Program itself, including compliance with McGregor PACE’s policies and procedures. Evaluations of the Compliance Program shall include effectiveness of training, use of the compliance hotline and compliance email, completion of audit work plans, effectiveness of internal investigations and corrective action plans, and how McGregor PACE responds to particular incidents under the Compliance Program. The Compliance Officer will report the results of such informal evaluations and shall present the results of the external audit to the Board of Directors.

#### *C. Monitoring Reports of Suspected Noncompliance*

1. McGregor PACE will ensure that any complaints, reports, or concerns are logged and tracked. Any complaints, reports, or concerns are logged on the “Compliance Hotline and E-mail Tracking Spreadsheet (‘spreadsheet’)”. The date and time of the complaint or report, the route of the complaint or report (i.e. voicemail or email,) the contact information for the complainant or reporter, the subject of the complaint or report, and the action taken in response to the complaint or report shall be recorded on the Spreadsheet. The Compliance Officer or his/her designee will address complaints, reports, and concerns regarding noncompliance on an individual basis in accordance with this Compliance Program. (See Section IX, Responding to Incidents of Noncompliance.)

2. The Compliance Officer or his/her designee will review compliance complaints,

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reports, and concerns on a quarterly basis to identify any trends or recurring incidents of noncompliance. The data recorded on the Spreadsheet shall be used in this review. The Compliance Officer, in conjunction with the Compliance Committee, will ensure that any identified systemic problems or recurring incidents of noncompliance are addressed.

*D. External Audits*

1. If McGregor PACE identifies a serious issue for which external consultation would be appropriate or helpful, the Compliance Officer or his/her designee, in consultation with the Compliance Committee, will arrange for external audits by independent outside auditors or legal counsel as appropriate. When legal counsel is engaged to conduct the audit or to retain the outside auditors, the Compliance Officer will review the steps necessary to protect any attorney-client privilege and attorney work product. Upon completion of an external audit, the Compliance Officer or his/her designee will provide a written report to the Board. Based on a review of the report, the Compliance Officer and the Compliance Committee will recommend and oversee the implementation of any of the following, as necessary to correct identified compliance issues and to deter recurrence of such issues:

- Modification to existing policies and procedures;
- Implementation of new policies and procedures;
- Additional training and education initiatives;
- Corrective action;
- Modification or termination of contractual arrangements or other business relationships;
- Report and refund of any overpayments received;
- Report any inaccuracies discovered in data submitted to CMS; and
- Make such other reports as McGregor PACE may deem necessary to contractors and applicable government authorities in accordance with the procedures in *Section IX. B., Self-Reporting*

2. Notice of modifications to the Compliance Program or other policies and procedures will be disseminated to employees, volunteers, and contractors as appropriate. The Compliance Officer or his/her designee may conduct a follow-up audit or review of specific issues or practices to ensure responsive action was appropriate and effective.

## **VII. KICKBACKS, FALSE CLAIMS, PART D AND OTHER LEGAL REQUIREMENTS**

### *A. Anti-Kickback and False Claims*

1. As a recipient of federal funds from the Medicare and Medicaid programs, McGregor PACE is subject to the requirements of various federal and state laws, including laws prohibiting the payment of kickbacks or other remuneration in order to influence Federal Health Care Program business. Specifically, the Anti-Kickback Statute prohibits:

- the knowing and willful solicitation or receipt of any remuneration (direct or indirect, overtly or covertly, in cash or in-kind, including kickbacks, bribes or rebates) in return for a referral for the furnishing of any item or service payable under a Federal Health Care Program; or
- the knowing and willful solicitation or receipt of any remuneration (direct or indirect, overtly or covertly, in cash or in-kind, including kickbacks, bribes or rebates) in return for purchasing, leasing or ordering or recommending purchasing, leasing or ordering, any good, facility, service or item payable under a Federal Health Care Program.

For purpose of McGregor PACE, the Anti-Kickback Statute prohibits conduct such as:

- Payment to any provider for referrals of participants to McGregor PACE;
- A contracted vendor giving McGregor PACE an inducement for a contractual arrangement;
- A pharmaceutical company's payment of a fee to a physician for every prescription the physician writes for that company's drugs; and
- A Pharmacy & Therapeutics (P&T) Committee member accepting a free trip from a pharmaceutical company in exchange for including the company's new drugs on a plan formulary.

2. A violation of the Anti-Kickback Statute and similar federal and state laws may result in significant criminal and civil penalties, including civil monetary penalties and possible exclusion from participation in Medicare and Medicaid.

3. The False Claims Act prohibits knowingly presenting (or causing to be presented) a false or fraudulent claim for payment or approval. Additionally, it prohibits knowingly making or using (or causing to be made or used) a false record or statement material to a false or fraudulent claim. A "claim" could include PDE and other data submitted to CMS, McGregor PACE's "bid" and all other reports submitted to CMS for the purpose of receiving federal reimbursement. It also requires return of any overpayments within sixty (60) days of identifying the overpayment.

For purpose of McGregor PACE, the False Claims Act prohibits conduct such as:

- Submitting fabricated PDE data to CMS;
- Prescribing a particular drug for which there is no medical necessity;
- Falsifying data or providing misleading data in order to induce a higher reimbursement or capitation rate; and
- Submitting data to CMS or private reinsurer showing actual costs incurred for purposes of reinsurance or other subsidy, when in fact such costs were not incurred.

Submission of a false claim in violation of the False Claims Act and similar federal and state laws could result in significant criminal and civil penalties, including civil monetary penalties plus three times the amount of damages the government sustained because of the false claim, and possible exclusion from participation in Medicare and Medicaid.

4. Any financial or other business arrangements between McGregor PACE and physicians, pharmacies, PBMs (if applicable), pharmaceutical companies and other health care entities or providers must be structured to comply with all applicable laws and regulations, including the Anti-Kickback Statute and the False Claims Act. If the Compliance Officer or other McGregor PACE personnel have questions regarding whether a proposed business arrangement is in compliance with such laws, legal counsel must be consulted to determine whether the proposed arrangement is acceptable.

5. When McGregor PACE personnel or contractor are in a position to make referrals or recommendations, they must make such referrals based on the best interests of the Participant and the arrangements McGregor PACE has with contracted providers. McGregor PACE personnel and contractors must not receive anything of value in exchange for making a referral or accepting a referral, or for recommending a health care service provider. In addition, McGregor PACE personnel and contractors must not offer anything of value in order to obtain referrals of patients or services covered under a Federal Health Care Program.

6. The following activities are specifically prohibited by McGregor PACE, and will not be tolerated:

- Payment to any provider for referrals of participants to McGregor PACE;
- Providing to a vendor or receiving from a vendor any inducement for the provision of McGregor PACE's services;
- Submitting false data to CMS for purposes of obtaining reimbursement (including reinsurance and LICS payments) for items or services not provided as claimed, or other costs not incurred as claimed;
- Submitting data for items or services that are known not to be reasonable and medically necessary;

- Intentionally misrepresenting the type of drug that was actually dispensed (e.g., claiming that a brand-name drug was dispensed when in reality a generic was dispensed); and
- Knowingly submitting data for prescription drugs dispensed to, or obtained by, individuals not eligible for Medicare Part D.

7. McGregor PACE personnel and contractors must be trained periodically on these requirements. The Compliance Officer will monitor the compliance hotline and compliance e-mail account utilized by McGregor PACE for any allegations regarding kickbacks or false claims.

#### *B. Other Legal Requirements*

There are numerous other federal and state laws applicable to McGregor PACE's operations, including the HIPAA Privacy and Security Rules, the Deficit Reduction Act of 2005 ("DRA"), Section 504 of the Rehabilitation Act of 1973, Section 1557 of the Patient Protection and Affordable Care Act and implementing regulations, Americans with Disabilities Act, and other state and federal laws with which McGregor PACE must comply. With regard to DRA compliance, McGregor PACE will disseminate the summary of information on laws concerning false claims (*see Tab F: Summary of Information on Federal [and State] Laws Concerning False Claims*) to McGregor PACE's employees, contractors, and agents, consistent with Section 6032 of the DRA.

#### *C. Conflict of Interest Disclosures/Attestations*

##### *1. Conflict of Interest Questionnaire*

All employees, including senior management and Board of Trustees, with involvement in McGregor PACE's PDP, must complete a questionnaire relating to conflicts of interest upon hire and annually thereafter. This questionnaire will require disclosure of all actual and potential conflicts of interest. McGregor PACE will also ensure compliance with its policy and procedures for disclosing and addressing actual or potential conflicts of interest on the part of the Board, in accordance with §460.68(b) of the PACE program requirements. *See* Employee Handbook, § Integrity 3.2 - Conflicts of Interest.

##### *2. Procedures*

(i) The Compliance Officer or his/her designee will review the conflict of interest questionnaires when submitted by new employees, and on an annual basis, to determine whether any actual conflicts of interest exist. When a conflict is identified, the Compliance Officer will determine the appropriate course of action, including (but not limited to) "walling off" the affected individual from any involvement in particular matters.

(ii) If an employee determines that he or she has a conflict of interest regarding a matter under consideration, the individual must inform the Compliance Officer, and refrain from making any decisions, exercising any authority or taking any action with respect to the matter.



(iii) Employees are under a continuing obligation to disclose conflicts of interest as they arise. If an individual's circumstances change after submission of the annual conflicts of interest questionnaire such that a potential or actual conflict later arises, the individual is required to notify the Compliance Officer and Human Resources as soon as possible.

*D. Part D Compliance*

*1. Compliance by First Tier, Downstream, and Related Entities (FDRs)*

(i) McGregor PACE shall determine which of the entities it contracts with are properly classified as FDRs and are therefore required to comply with the provisions of this Compliance Program pertaining to FDRs or Part D Medicare program requirements. McGregor PACE should consider the following factors to evaluate and categorize its third-party contractors as an FDR:

- Functions performed by the delegated entity; such functions may include, but are not limited to:
  - Sales and marketing;
  - Utilization management;
  - Quality improvement;
  - Application processing;
  - Enrollment, disenrollment, membership functions;
  - Claims administration, processing and coverage adjudication;
  - Appeals and grievances;
  - Licensing and credentialing;
  - Pharmacy benefit management;
  - Hotline operations;
  - Customer service;
  - Bid preparation;
  - Outbound enrollment verification;
  - Provider network management;
  - Processing of pharmacy claims at the point of sale;

- Negotiation with prescription drug manufacturers and others for rebates, discounts or other price concessions on prescription drugs;
  - Administration and tracking of Participants' drug benefits, including TrOOP balance and processing;
  - Coordination with other benefit programs such as Medicaid, state pharmaceutical assistance or other insurance programs;
  - Entities that generate claims data;
  - Health care service providers; and
  - Information Technology.
- Whether the function is something McGregor PACE is required to do or to provide under its contract with CMS, the applicable federal regulations or CMS guidance;
  - The extent to which the function directly impacts Participants;
  - The extent to which the delegated entity interacts with Participants, either orally or in writing;
  - Whether the delegated entity has access to Participant information or personal health information;
  - Whether the delegated entity has decision-making authority (e.g., enrollment vendor deciding time frames) or whether the entity strictly takes direction from McGregor PACE;
  - The extent to which the function places the delegated entity in a position to commit health care fraud, waste, or abuse; and
  - The risk that the entity could harm Participants or otherwise violate Medicare program requirements or commit FWA.

(ii) The McGregor PACE will require all FDRs with which it contracts or does business (including PBMs, TPAs and pharmacies) in connection with its PDP to comply with all applicable laws, rules, and regulations, and shall develop procedures to promote and ensure FDR compliance, including a method to demonstrate that FDR employees have received the McGregor PACE's Standards of Conduct, Compliance Program, and applicable policies and procedures. Even if McGregor PACE has delegated particular PDP-related tasks to a third party through a contract, McGregor PACE maintains ultimate responsibility for fulfilling the terms and conditions set forth in its contract with CMS, and for complying with all applicable laws and regulations.

(iii) McGregor PACE, via its Compliance Officer, shall have a system in place to monitor FDRs with respect to compliance in its Part D delegated responsibilities and shall be able to demonstrate that the method of monitoring is effective.

(iv) McGregor PACE will screen FDRs against the OIG and SAM exclusion lists, the CMS provider preclusion list and/or any state exclusion lists maintained by Ohio Medicaid programs at the time of contract and at least monthly thereafter. Any party found to be excluded will be removed immediately from any work on programs involving Federal Health Care Programs and the situation will be assessed to determine whether non-compliance must be reported.

(v) McGregor PACE will ensure that all agreements with FDRs include provisions indicating that the entity:

- Has reviewed McGregor PACE's written standards and policies and procedures as they pertain to FWA;
- Agrees to comply with such standards, policies and procedures;
- Will require others who provide services to McGregor PACE on behalf of the entity to comply with such standards, policies and procedures;
- Will notify McGregor PACE of all subcontractors utilized by the entity;
- Represents that it is not on the CMS preclusion list and has not been excluded from participation in Federal Health Care Programs and that it screens employees and contractors against the OIG and SAM exclusion lists and/or any state exclusion lists maintained by state Medicaid programs at the time of hire or contract, and at least monthly thereafter;
- Will notify McGregor PACE immediately if it ~~is~~ is excluded from participation; and
- Agrees that its contract with McGregor PACE will terminate automatically if it is excluded in the future.

(vi) McGregor PACE shall require FDRs to report immediately to the Compliance Officer any detected errors, possible fraud on the part of beneficiaries, employees or contractors, subcontractors, or outliers, and other relevant matters related to FWA. McGregor PACE will require any contractor found to have violated contractual or regulatory requirements to cooperate with McGregor PACE in implementing additional internal and/or external compliance procedures and cost containment recovery provisions as necessary. McGregor PACE shall require FDRs to correct their deficiencies. (*See Section VII.D.7., Monitoring PBMs and Pharmacies.*)

(vii) McGregor PACE shall maintain documentation of all FDR deficiencies identified and corrective action taken by McGregor PACE and/or each FDR.

## 2. Data Reporting Compliance

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(i) *Monitoring and Safeguards*

a. To ensure the truth and accuracy of data submitted to CMS, and to identify areas where data collection and submission practices could be improved, McGregor PACE will periodically monitor the following:

- Prescription Data Event (“PDE”) information;
- Cost data;
- Diagnoses information reported through Risk Adjustment Processing Data System (“RAPS”) and include information submitted via the Encounter Data Reporting System (EDRS);
- Information reported through HPMS;
- Deletion records (generated when a prescription for which a plan has already submitted PDE data is not picked up);
- Data on direct and indirect remuneration;
- Information pertaining to formulary development;
- Enrollment and disenrollment data (submitted through monthly attestations);
- Submission of claims under the appropriate reimbursement program (e.g., Medicare Part B claims vs. Medicare Part D claims); and
- All other information required to be reported, including information about vaccines; generic drug utilization; Pharmacy & Therapeutics Committees (if applicable); formulary exceptions (if applicable); overpayments; pharmaceutical manufacturer rebates, discounts and other price concessions; and long-term care (“LTC”) rebates.

b. McGregor PACE will maintain appropriate safeguards to ensure the accuracy, completeness and truth of all data pertaining to the PACE PDP (including all data listed in (1) above) that is submitted to CMS (or, if a contractor is responsible for collecting, compiling, or submitting data on McGregor PACE’s behalf, that such contractor maintains appropriate safeguards). Such safeguards may include:

- Systems configurations that detect errors;
- Access to source data (e.g., original prescriptions and claims adjudication data from the pharmacy);
- Monitoring and auditing policies and procedures;

- Periodic review of data collection, compilation, and submission practices to determine whether such practices comply with all applicable requirements; and
- Review of any issues identified as a result of monitoring or auditing activities, and any issues identified by CMS, the OIG, SAM, or other federal or state agencies with FWA oversight or enforcement authority.

c. If an FDR submits data on McGregor PACE’s behalf, McGregor PACE will periodically review such entity’s compliance policies, procedures, and other internal controls to ensure that it maintains sufficient mechanisms for monitoring compliance and mitigating risks of FWA.

d. The Compliance Officer will arrange for and conduct (or have conducted and documented) regular, random reviews of data both before and after submission of the data to CMS (“pre-submission review” and post-submission review,” respectively). Such reviews may include an evaluation of a representative sampling of claims included in a monthly submission of data (e.g., review of ten (10) prescription claims for ten (10) different PACE Participants), “spot checks” of a particular field or data element (e.g., review of all claims for a particular drug or from a particular prescriber to ensure some measure of consistency), and review of any “outlier” claims (e.g., review of non-NCPDP 5.1 data format claims, above-average dispensing fees, etc.).

▪ Pre-submission Review

The Compliance Officer will direct any questions regarding apparent discrepancies or errors detected via pre-submission review to the individual(s) or entity(s) responsible for gathering, compiling, recording, and/or submitting the relevant data, and will see to it that necessary clarifications and/or amendments to documentation are made prior to submission. The Compliance Officer will ensure that disciplinary action is taken if appropriate.

▪ Post-submission Review

The Compliance Officer or his/her designee will conduct random audits of data submitted by McGregor PACE or on its behalf over a specified period of time. Methods will include: (i) comparison of submitted data with original source data; (ii) review of reports sent by CMS to McGregor PACE summarizing PDE and other data; and (iii) comparison of data to previously established thresholds to identify any outliers.

(ii) *Corrective Actions*

The Compliance Officer or his/her designee will review any errors or discrepancies detected with the individual(s) or entity(s) responsible to determine what actions are necessary to

correct the errors (e.g., submission of revised data, refunding of overpayments, reporting to appropriate government or law enforcement authorities) and prevent reoccurrence.

### *3. Price Concession Generally*

The Compliance Officer will be alerted to any arrangement whereby McGregor PACE PDP receives price concessions, rebates or other discounts for drugs generally, even if not in connection with formularies, so proper documentation is maintained and the concessions are reported, if required.

### *4. Monitoring Participant FWA*

McGregor PACE will monitor the utilization patterns of PACE Participants to ensure Participants, or Participants' family members, are not improperly using or seeking to obtain prescription drugs. McGregor PACE will periodically review Participant complaints and grievances for indications of possible Participant fraud and shall follow the additional procedures outlined in this section to meet these responsibilities.

#### *(i) Establishing Baseline Data*

McGregor PACE will obtain utilization data of its PDP and compile it in a manner that outlines the normal range of utilization, number and types of prescriptions, average number of prescriptions per PACE Participant and per prescriber, and other baseline data as McGregor PACE may need for use as a benchmark for comparing subsequent periods. McGregor PACE will compare subsequent data with baseline data to track prescribing and utilization patterns over time and identify aberrant and potentially abusive utilization. McGregor PACE also will review available resources, such as National Association of Boards of Pharmacy's ("NABP") National Specified List of Susceptible Products (drugs determined to be susceptible to adulteration, counterfeiting or diversion) to identify particular drugs that should be monitored for possible abuse.

McGregor PACE will update and redefine baseline data as appropriate to allow for meaningful comparisons over time.

#### *(ii) Integration into Participant Care Management Process*

a. McGregor PACE's initial assessment of a Participant will include a review of the Participant's prescription drug history and family situation, and identification of the appropriate pharmaceutical therapy in the plan of care.

b. During periodic reassessments, Participants' prescription drug records will be analyzed, and any changes to pharmaceutical therapies or drugs prescribed (including switches from brand-name-drugs to generics) will be examined to confirm that the changes are appropriate for the Participant's condition.

c. The Participant's [primary care provider/Pharm.D./pharmacist] will be responsible for monitoring drug-drug interactions and drug changes, but the

interdisciplinary team also must regularly review a Participant's drug records and highlight any inconsistencies or potential overutilization.

d. McGregor PACE's social workers, home health care providers and other staff members or contractors with regular contact with Participants' families will report any observations or suspicions to a member of the interdisciplinary team suggesting Participants' family members may be engaged in any improper drug-seeking behavior or other conduct leading to increased utilization. The interdisciplinary team will assess the report as part of the care management process. Clear instances of improper drug-seeking behavior on the part of Participants or family members shall be immediately reported to the Compliance Officer. All affected staff members and contractors, including FDRs, are required to receive training on these requirements.

e. The interdisciplinary team shall report conduct suggesting improper utilization or potential fraud or abuse on the part of Participants or Participants' families to the Compliance Officer, who promptly will investigate the situation.

*(iii) Prescription Drug Event Data and Overutilization Review*

a. McGregor PACE is required to report prescription drug event (PDE) data to CMS on a regular basis (at least once a month). On a periodic basis, the Compliance Officer or his/her designee will review the PDE data (and the benchmark data compiled as noted in Section VII.D.2. above) as well as reports from the Medicare Part D Overutilization Monitoring System to monitor for potential Participant FWA by looking at, among other factors, the following:

- Significant outliers (i.e., Participants whose drug utilization patterns far exceed those of the average PACE Participant, in terms of cost or quantity);
- Disproportionate utilization of controlled substances for individuals or groups; and
- Use of prescription medications for excessive periods of time (e.g., multiple refills for drugs commonly prescribed for short-term pain, prescriptions refilled prior to the end of the 30- or 90-day prescription, etc.).

b. To the extent specialized knowledge is required to determine aberrations in any of the above, the Compliance Officer may call on the provider, pharmacist, members of the P&T Committee or the PBM for assistance in this review. The Compliance Officer will investigate any potential FWA issues revealed through this review by discussing the Participant's condition with the participant's primary care provider or interdisciplinary team, as appropriate, reviewing the source data for the PDE (actual prescriptions, etc.), and discussing prescription drug utilization with the Participant (if appropriate).

(iv) *Reporting Participant FWA*

If after the investigation, the Compliance Officer determines that a Participant or a Participant's family member has engaged in improper drug-seeking behavior or other conduct potentially leading to FWA, the Compliance Officer will report the instance to McGregor PACE's MEDIC. The Compliance Officer and other affected staff members will cooperate, and McGregor PACE's contracts with FDRs shall require such entities to cooperate, with any MEDIC investigation, in accordance with Section X. Cooperating with Government Investigations. The Compliance Officer will document the results of the investigation and the referral to the MEDIC in the Participant's medical record. McGregor PACE will not disenroll a PACE Participant for improper drug utilization unless the Participant has been counseled by McGregor PACE regarding such behavior, and he or she continues to refuse to comply.

5. *Monitoring Prescriber FWA*

McGregor PACE will track and monitor prescribing patterns to guard against FWA on the part of prescribers. Aberrations or unwarranted changes in a prescriber's prescribing patterns may indicate that other factors (such as pharmaceutical company marketing efforts or the fact of Part D payment) have influenced the prescriber's medical judgment. To guard against such conduct, the McGregor PACE PDP will follow the procedures outlined below.

(i) *Establishing Baseline Data*

McGregor PACE will obtain utilization data of its PDP and compile it as necessary to outline the normal range of utilization, number and types of prescriptions, average number of prescriptions per PACE Participant and per prescriber, and other baseline data that McGregor PACE may need to use as a benchmark for comparing subsequent periods. McGregor PACE will compare subsequent data with baseline data to track prescribing patterns over time and identify aberrant and potentially abusive utilization. McGregor PACE also will review available resources, such as the NABP's National Specified List of Susceptible Products (drugs determined to be susceptible to adulteration, counterfeiting or diversion) to identify particular drugs that should be monitored for possible abuse. McGregor PACE will update and redefine baseline data as appropriate to allow for meaningful comparisons over time.

(ii) *Procedures*

a. McGregor PACE will consult with its PharmD, pharmacist or other professionals involved in pharmaceutical therapy management about any anomalies in prescribing patterns indicating possible fraud or abuse (such as sudden switches to a particular company's drug without therapeutic justification, significantly increased numbers of prescriptions or prescriptions for drugs on the National List of Susceptible Products). The PharmD or pharmacist will notify the Compliance Officer or his/her designee if prescribing patterns suggest a prescriber may be engaged in fraud or abuse.

b. The PDE data compiled and submitted by the PACE PDP (or by a PBM or other third-party submitter on the PDP's behalf) will be reviewed periodically by the Compliance Officer or other designated individual in



accordance with *Section VII.D.2. Data Reporting Compliance*. Such data will be sorted by prescriber and compared against benchmark data and other resources. The Compliance Officer will review the data for anomalies such as:

- High-volume prescribing of a particular manufacturer's drugs or of drugs particularly susceptible to addiction or abuse;
- Excessive prescriptions for off-label uses; and/or
- Physicians who prescribe more controlled substances than other physicians.

c. If the Compliance Officer identifies outliers or anomalies that he or she believes may suggest improper prescribing patterns, the Compliance Officer may consult with McGregor PACE's consulting pharmacist, PharmD, Medical Director or others to determine whether there may be therapeutic reasons for the prescribing pattern. If the Compliance Officer discovers clear evidence that a prescriber is engaged in fraudulent or abusive conduct with respect to prescription drugs, he or she will report the instance to McGregor PACE's MEDIC. The Compliance Officer and other affected staff members will cooperate, and McGregor PACE will require FDRs to cooperate, with any MEDIC investigation, in accordance with *Section X. Cooperating with Government Investigations*.

d. All prescribers who write prescriptions for PACE Participants will be checked against the OIG List of Excluded Individuals/Entities, the GSA Excluded Parties Listing System, the CMS Preclusion List, and/or any state exclusion lists maintained by state Medicaid programs at the time of contract and monthly thereafter. The McGregor PACE PDP shall not pay for medications prescribed by excluded providers.

#### 6. *Monitoring PBMs and Pharmacies*

If McGregor PACE has delegated any of its responsibilities as a PDP sponsor to a PBM or a pharmacy, McGregor PACE must monitor those entities and must obtain adequate contractual assurances that both PBMs and pharmacies will comply with all applicable laws. McGregor PACE also will obtain, when possible, contractual provisions requiring PBMs or pharmacies to indemnify McGregor PACE for any harm resulting from the PBM's/pharmacy's failure to comply with legal requirements.

All PBMs and pharmacies with which McGregor PACE contracts will be checked against the CMS Preclusion List, the OIG List of Excluded Individuals/Entities, the GSA Excluded Parties Listing System and/or any state exclusion lists maintained by Ohio Medicaid programs, at the time of contract and monthly thereafter. See *Section VII.D.1., Compliance by First Tier, Downstream, and Related Entities*.

##### (i) *Monitoring PBMs*

**Commented [MM3]:** Portion for Procedure Use: McGregor PACE has not delegated any of its responsibilities as a PDP sponsor to a PBM and does not maintain a formulary list of prescription drugs. Instead of designating a PBM, McGregor PACE contracts with a PACE-centric, medication management and distribution pharmacy that focuses on reducing pharmaceutical costs and medication-related risks. McGregor PACE has an interdisciplinary team involving physicians, nurse practitioners, social workers, and other health care professionals that work with the contracted pharmacy to coordinate patient care that produces the best clinical and economic outcomes. McGregor PACE analyzes and monitors utilization data, reviews utilization override reporting, and prescription prices. McGregor PACE maintains a referral authorization process that requires PACE participants to obtain prior authorization from their primary care providers to receive services from an out-of-network provider or use an out-of-network pharmacy. McGregor PACE's guidelines prefer for providers to prescribe generic medications unless brand name medications are necessary. Through ongoing monitoring, auditing and collaboration McGregor PACE ensures the contracted pharmacy provides high-quality and cost-effective medication therapy. See Section VII.D.7., *Monitoring Pharmacies*, for detailed McGregor PACE procedures and policies for monitoring pharmacies. Should McGregor PACE delegate any of its responsibilities as a PDP sponsor to a PBM the following procedures will be adopted.

a. Through its contract or otherwise, McGregor PACE will ensure that the PBM meets the following requirements relating to auditing and compliance:

- PBM shall provide access to all facilities and records associated in any manner with McGregor PACE’s PDP for ten (10) years from the end of the final contract period. Access shall be provided to any government auditor, agency or contractor acting on behalf of the federal government to conduct an onsite audit (including, but not limited to, CMS, OIG and the MEDIC), as well as to a designated representative of McGregor PACE for purposes of monitoring compliance.
- PBM shall report all instances of potential or actual fraud identified in the PACE PDP and all complaints received by the PBM alleging or demonstrating potential fraud to the Compliance Officer or his/her designee at McGregor PACE.
- PBM shall furnish all information (including claims data) requested from McGregor PACE to respond to the MEDIC or other government auditors within twenty (20) days of the request, unless McGregor PACE must receive the information under a more immediate timeframe.
- PBM and McGregor PACE will establish a coordinated reporting structure whereby PBM and McGregor PACE regularly communicate regarding any FWA concerns, active internal investigations, outliers, and other matters. PBM should designate a contact person responsible for FWA issues, and the Compliance Officer or his/her designee at McGregor PACE should speak regularly with the PBM contact.
- McGregor PACE will conduct regular audits of PBM’s performance through “spot checks” of the data submitted to CMS; comparison of data to actual drug claims; reviewing PBM’s efforts to distinguish between Part B and Part D drugs; and auditing PBM’s compliance with other Part D requirements.

**Commented [JH4]:** @Mary Monroe Let's verify and see if we can change this to 30 days. 20 seems a bit tight to respond.

**Commented [MM5R4]:** Okay I will research.

**Commented [MM6R4]:** Checked

Even if all of the above requirements are specifically set forth in the PBM agreement, the contract between the PBM and McGregor PACE at the least must contain provisions relating to the following:

- PBM must have an effective compliance program in its own right, and must provide information about that compliance program to McGregor PACE on request;
- The PBM must allow McGregor PACE to conduct ongoing audits to ensure PBM is meeting all applicable Part D requirements;

- PBM must agree to implement cost containment and recovery measures to make McGregor PACE and/or CMS whole in the event there are infractions or errors by PBM in meeting contractual obligations;
- To the extent PBM has negotiated rebates or other discounts with pharmaceutical manufacturers or other entities, the contract must specify which portion of those rebates will be passed on to McGregor PACE and
- The contract must allow termination by McGregor PACE in the event the PBM's right to provide services under Part D is revoked by CMS.

b. McGregor PACE will exercise any audit rights it has under the contract and consider retaining a third-party auditor if McGregor PACE has any concerns regarding PBM's performance. Audits will be conducted regularly, and the frequency of the audits should be determined and agreed to at the inception of the agreement. McGregor PACE's audit rights will extend to any subcontractor or affiliate performing services for PBM relating to the PACE PDP. McGregor PACE may also seek indemnification from the PBM for any FWA occurring as a result of the PBM's actions or inaction. All audits of PBMs will be documented.

c. To the extent McGregor PACE's auditing and monitoring activities identify any potential FWA on the part of the PBM, such FWA shall be reported and handled in accordance with McGregor PACE policy and Medicare requirements. (*See Section IX, Responding to Incidents of Non-Compliance.*)

(ii) *Monitoring Pharmacies*

a. McGregor PACE shall monitor the pharmacy(ies) it has contracted to provide prescription drug benefits to PACE Participants to ensure the PACE pharmacy is complying with all applicable Part D requirements. In particular, McGregor PACE shall monitor to ensure the following:

- Pharmacy must bill for name-brand drugs only when a name-brand drug is dispensed;
- If a prescription is a "partial fill," Pharmacy must not bill for the complete fill amount (i.e., billing for a 30-day prescription when only 28 tablets are dispensed);
- Pharmacy must accurately credit the PACE PDP for returned prescriptions and for prescriptions that are never picked up (e.g., prescriptions left in the "will-call" bin at the pharmacy) or delivered;

- Pharmacy shall not solicit or receive payment from pharmaceutical companies or others for effecting drug switches;
- Pharmacy may not bill for expired drugs, drug samples, or drugs diverted from other locations (e.g., nursing homes, hospitals, etc.);
- Pharmacy’s dispensing fees must be reasonable and in accordance with any applicable contracts;
- Pharmacy must have sufficient inventory controls to prevent theft or spoilage of prescription drugs, and controls relating to drug pedigree to ensure only drugs from valid sources are dispensed to PACE Participants; and
- Pharmacy must have standards and protocols to ensure quality of care (monitoring of drug-drug interactions, drug utilization, etc.).

b. To the extent McGregor PACE contracts directly with pharmacy(ies), the contract should allow McGregor PACE to audit the pharmacy for compliance regularly, whether through on-site audits, requests for reports or other means. In addition, McGregor PACE will:

- Regularly review PDE data submitted to CMS and compare it to the actual claims data to confirm accuracy and completeness;
- Review any Participant complaints or grievances relating to prescription drugs to ensure Participants are receiving the prescription drugs prescribed for them; and
- On a periodic basis, conduct “spot checks” and compare the prescription issued to the Participant, the prescription drug claim that was processed by the pharmacy, and the PDE data that was submitted to CMS.

c. To the extent McGregor PACE’s auditing and monitoring activities identify any potential FWA on the part of a pharmacy, such FWA shall be reported and handled in accordance with McGregor PACE policy and Medicare requirements. (*See Section IX, Responding to Incidents of Non-Compliance.*)

(iii) *Monitoring Third-Party Submitters*

a. To the extent a PBM, pharmacy or other third-party compiles and submits PDE or other data to CMS on McGregor PACE’s behalf, McGregor PACE will ensure, through its contract or otherwise, that the third party meets the following requirements relating to compliance:

- The third-party submitter must certify to CMS regarding the accuracy, completeness and truthfulness of the data and acknowledge that it is being submitted on behalf of McGregor PACE’s PDP for purposes of obtaining federal reimbursement.
- The third-party submitter must have the capability to maintain audit trails that link the submitted data to the source data (i.e., individual claims transactions).
- The third-party submitter must allow McGregor PACE to monitor the accuracy of the data it submits by any reasonable mechanism (conducting “spot checks,” comparison to reports received back from CMS, etc.).

b. To the extent McGregor PACE’s auditing and monitoring activities identify any potential FWA on the part of a third-party submitter, such FWA shall be reported and handled in accordance with McGregor PACE policy. *See Section IX, Responding to Incidents of Non-Compliance.*

## VIII. INTERNAL REPORTING OF WRONGDOING

### A. *Duty to Report Actual or Suspected Violations*

Each employee, each member of the Board, each volunteer, each contractor, and each of such contractor’s employees shall immediately report any suspected violations of the Standards of Conduct, the Compliance Program, and any laws or regulations. The individual making such report may do so anonymously if he/she chooses. To the extent feasible, all communications shall be kept confidential. McGregor PACE shall not tolerate intimidation of or retaliation against any person making such report of suspected violations. Under no circumstances will an employee, volunteer, contractor, contractor’s employee, or Board member be discharged, demoted, suspended, threatened, harassed or in any manner discriminated against for reporting in good faith any actual or suspected violation of the Standards of Conduct or applicable laws or regulations.

### B. *Reporting the Actual or Suspected Violations*

An employee must report the actual or suspected violation to his/her manager, the Compliance Officer, a member of the Compliance Committee or the Compliance Hotline (216) 268-8400. Board members must report actual or suspected violations to the Compliance Officer, a member of the Compliance Committee or the Compliance Hotline (216) 268-8400.

### C. *Contractor Reporting*

Contractors and their employees are expected to report actual or suspected wrongdoing to the Compliance Officer. This obligation will be included in a written agreement with the contractor as appropriate. The Compliance Officer, with assistance from the Compliance Committee, shall widely publicize and ensure that contractors and their employees are made aware of the Compliance Line and of the obligation to report actual or suspected wrongdoing.

*D. Compliance System*

The Compliance Officer, with assistance from the Compliance Committee, shall establish and maintain a system to receive, record, respond to, and track compliance question or reports from employees, members of the Board, contractors, and contractors' employees. This system shall allow for anonymous, confidential reporting and shall emphasize policies of non-retaliation and non-intimidation for persons making reports of suspected or actual compliance violations.

*1. Establishment of a Compliance Line*

The Compliance Officer, with assistance from the Compliance Committee, shall establish and maintain a telephone line for receiving reports of potential violations, which may be anonymous (the "Compliance Line"). To the extent feasible, all calls to the Compliance Line shall be kept confidential. The Compliance Line shall be accessible 24 hours a day, 7 days a week, 365 days a year.

*2. Guidelines*

The Compliance Officer shall develop appropriate guidelines for the operation of the Compliance Line, which shall address procedures for receiving and logging calls, follow-up and response to calls and confidentiality safeguards.

*3. Reporting*

The Compliance Officer shall make regular reports to the Compliance Committee, the Board, and other senior management on the reporting system, including the number of calls received and the status and disposition of any resulting investigations.

*4. Compliance Officer Accessibility*

The Compliance Officer shall maintain an "open door" policy for questions and concerns that employees, volunteers, contractors, or Board members may have concerning adherence to legal standards and organizational policies.

*5. Documentation of Questions*

The Compliance Officer shall document all compliance questions raised other than through the Compliance Line, including the nature of the question raised and how it was answered/resolved.

**IX. RESPONDING TO INCIDENTS OF NONCOMPLIANCE**

The Compliance Officer or his/her designee shall be responsible for promptly responding to incidents of noncompliance, including violations of McGregor PACE's Compliance Program, McGregor PACE policies and procedures, applicable federal and state laws, PACE program

requirements, and for developing appropriate corrective action initiatives relating to such offenses. (See Tab H: Post-Incident Response Checklist.)

A. *Internal Investigations*

1. *Commencement of Investigation*

The Compliance Officer or his/her designee will review all identified potential compliance problems to determine the severity of the potential violation and the extent of further investigation deemed necessary, if any. The appropriate response will be determined based on the nature and severity of the potential violation. Investigative techniques may include:

- Interviews with persons who report, witness, or have knowledge or information regarding a potential violation. To the extent reasonably practicable, interviews will take place in private and will be conducted in as confidential a manner as possible;
- Review of relevant documents (e.g., contracts, claims, reports, clinical documentation);
- Review of applicable policies and procedures; and
- Consultation with legal counsel.

The Compliance Officer or his/her designee shall initiate all investigations into identified compliance problems as promptly as possible, and no later than two weeks of receiving the initial complaint or report. If the Compliance Officer has a potential or actual conflict of interest or is otherwise not available to conduct a prompt investigation, the CEO and/or Board will appoint another managerial employee to conduct the investigation.

2. *Responsibilities/Procedures*

Based on the severity of the potential violation, the Compliance officer or his/her designee may determine that further internal investigation is appropriate and/or necessary. The depth of the internal investigation will depend on the nature and extent of the potential violation; not all instances of potential compliance problems identified may merit further internal investigation. Prior to commencing an internal investigation, the Compliance Officer shall consult with the CEO and the Compliance Committee to:

- Identify and assemble the investigative team;
- Establish the lines of responsibility, supervision and reporting;
- Define the factual and legal issues to be resolved;
- Determine whether the organization should engage legal counsel and/or consultants to conduct the investigation and review the steps necessary to protect the attorney-client and work product privilege; and

- Implement mechanisms to ensure that relevant documents are not destroyed and to ensure the comprehensiveness, integrity and control of all documents collected during the investigation.

Appropriate human resources personnel should be consulted/involved in any investigation to ensure consistency with employment policies and procedures.

In conducting the internal investigation, the Compliance Officer shall ensure that the investigative team follows all guidelines and procedures established by the Compliance Officer regarding document review and employee interviews.

The Compliance Officer and the investigative team shall keep the investigation confidential and shall not disclose the name of any complainant(s) involved except as otherwise required by law.

The investigation should include interviews with the complainant(s), any witnesses or persons with knowledge, and any alleged wrongdoer. All interviews should be conducted confidentially and in private; it is best not to interview persons in “groups.” Individuals interviewed should be assured that their participation in the investigation will not result in retaliation and that if they experience intimidation or retaliation, they should report it immediately to the Compliance Officer.

The Compliance Officer shall document all interviews conducted and maintain copies and/or a log of all pertinent documents reviewed.

### *3. Presentation of Findings*

Upon completion of the internal investigation, the Compliance Officer shall present the findings of the investigation to the Compliance Committee, the CEO, CFO and other senior management, and the Board of Directors, as appropriate.

The Compliance Officer shall consult with outside counsel if involved, on the appropriate means of documenting the findings of any internal investigation and on guidelines to follow in the event a written report is prepared.

### *4. Response to Findings of Internal Investigation*

Following the Compliance Officer’s report on the investigation, the Compliance Committee shall determine what action, if any, should be taken in response, and ensure that any necessary action is implemented.

For significant compliance infractions, the Compliance Committee shall include the Board, CEO, CFO, and other senior management in determining what action should be taken in response.

If the investigation indicates that illegal or unethical conduct has occurred, at a minimum, the Compliance Committee must:



- Ensure that the conduct is stopped and institute any corrective action necessary (*See Section IX.C., below*);
- Work with human resources to discipline personnel involved, which may result in employment separation;
- Institute appropriate measures to ensure that the conduct does not reoccur (e.g., revise policies and procedures or deploy additional auditing mechanisms);
- As further detailed in Section IX.B below, determine, in consultation with legal counsel, whether the incident should be reported to the government, whether any refunds should be made to the government or a third-party payor and whether other notices or disclosure are required;
- Review the effectiveness of the Compliance Program and procedures in light of the incident and make recommendations to the Board as appropriate concerning any necessary modifications to the Compliance Program; and
- If a complainant is involved, report to the complainant that the complaint was investigated, that findings were made and that appropriate action was taken in response.

#### 5. *Documentation of Investigation*

The Compliance Officer, in consultation with any outside counsel involved, shall ensure that an appropriate record is maintained of the internal investigation (*e.g.*, description of matter investigated, activities undertaken, log of persons interviewed, and documents reviewed, results of investigations, disciplinary and corrective action taken).

#### B. *Self-Reporting*

The determination of whether to report the results of an investigation to government authorities depends on the circumstances and nature of the particular incident. Likewise, the method of self-reporting will depend on the type of non-compliance at issue.

Incidents of criminal misconduct should be reported to appropriate law enforcement authorities. Incidents of significant Medicare program noncompliance should be reported to CMS, and the SAA, as appropriate, as soon as possible after their discovery.

McGregor PACE will consider, in consultation with counsel, whether fraudulent conduct or overpayments should be reported to other government authorities, such as the Office of the Inspector General (through the Self-Disclosed Protocol) or the Department of Justice.

With regard to non-compliance concerning FWA associated with the PACE PDP in particular, if a preliminary investigation uncovers potential fraud or abuse in the following areas, McGregor PACE will report the matter promptly to MEDIC:

- Suspected, detected or reported criminal, civil, or administrative law violations;

- Allegations that extend beyond the PDP involving multiple health plans, multiple states, or widespread schemes.
- Allegations involving known patterns of fraud; and
- Patterns of fraud or abuse threatening the life or well being of beneficiaries.
- A scheme with large financial risk to the Medicare program or Participant.

If a determination is made to refer an incident of noncompliance to the MEDIC, the Compliance Officer or his/her designee will develop a referral package that meets the requirements of Sections 50.7.3 through 50.7.5, Chapter 9 of the CMS Prescription Drug Benefit Manual/Chapter 21 of the CMS Medicare Managed Care Manual and will document all referrals to the MEDIC in accordance with CMS instructions.

Lastly, McGregor PACE shall consider reporting instances of regulatory non-compliance to its CMS account manager and SAA. If non-compliance occurring during an audit review period is reported, corrected and risk to participants was mitigated, CMS will not apply the ICAR condition classification to that condition on a subsequent audit.

The Compliance Officer and the Board and/or the Chief Executive Officer, with assistance from legal counsel as appropriate, shall act promptly to ensure that any self-report is made within a reasonable period of time from when it was determined that a violation may have occurred.

### *C. Corrective Action*

*1.* As soon as practicable after completion of an investigation, the Compliance Officer or his/her designee will establish a corrective action plan if appropriate and will set deadlines by which the prescribed corrective action must be taken. Depending on the nature of the particular compliance problem, corrective action may include the following:

- Disciplinary action, as prescribed by the Compliance Officer or his/her designee and the individual's immediate supervisor (in accordance with McGregor PACE's personnel policies and procedures and/or any applicable contractual requirements);
- Mandatory education and training;
- Modification of existing policies and procedures and/or implementation of new policies and procedures;
- Correction of erroneous data;
- Refunding any overpayment received;
- Focused reviews for individual departments and/or employees to ensure that the prescribed corrective action is being followed and is effective;

- Termination or suspension of any applicable contracts; and
- Self-reporting to government authorities, in accordance with this policy.

2. If senior management is involved in a compliance violation, the Compliance Officer may elect to refer final authority on the appropriate discipline to the Chief Executive Officer except when the compliance violation involves the Chief Executive Officer, in which case the Compliance Officer may elect to refer final authority on the appropriate discipline to the Board of Directors.

3. The Compliance Officer will monitor corrective actions after implementation to be sure that the plan is effective at remedying the problem identified.

*D. Documentation*

1. The Compliance Officer or his/her designee will maintain a record of all investigations, including:

- All relevant facts and information concerning the reported compliance problem;
- A summary of the investigation process;
- Interview notes and copies of key documents;
- A list of individuals interviewed, and documents reviewed;
- The results of the investigation, including any disciplinary action taken; and
- The prescribed corrective action plan.

2. McGregor PACE will maintain such records for a minimum of ten (10) years. Under no circumstances should such records be distributed or released outside of the organization by anyone other than legal counsel. Access to such records by individuals within the organization shall be limited to the Compliance Officer, the Compliance Committee, the Chief Executive Officer, the Board, and legal counsel. Any documents or information protected by the attorney/client privilege will be treated as such.

**X. COOPERATING WITH GOVERNMENT INVESTIGATIONS**

McGregor PACE will cooperate with CMS, MEDICs, the SAA, and other government auditors and law enforcement agencies.

*A. Procedures*

1. McGregor PACE employees must notify the Compliance Officer or his/her designee immediately upon being contacted by a law enforcement officer or government agent regarding McGregor PACE's business. Any employee served with an OIG or Grand Jury subpoena, summons, court order or complaint in connection with McGregor PACE business

should contact the Compliance Officer or his/her designee immediately and provide him or her with copies of the served documents.

2. The Board, CEO, and other senior management shall be notified of all governmental compliance enforcement activity from Notices of Non-compliance to formal enforcement actions.

3. McGregor PACE will provide the MEDIC, CMS, the SAA, and law enforcement with any requested information, including claims data, within thirty (30) days from the date of the request, unless some other timeline is specified. McGregor PACE will allow access to any government auditor acting on behalf of the federal or state government, CMS or the SAA to conduct an audit at the facilities of McGregor PACE or any of its FDRs. To the extent the information requested is maintained by a contractor, the Compliance Officer or his/her designee will contact such party immediately and invoke any contractual rights to require it to provide the requested information in the necessary timeframe.

4. McGregor PACE shall comply with requests by law enforcement, CMS, or the SAA regarding monitoring of providers within McGregor PACE's network that CMS has identified as potentially abusive or fraudulent.

5. In the event McGregor PACE refers a case to the MEDIC in accordance with Section IX, Responding to Incidents of Noncompliance, the Compliance Officer or his or her designee will track all aspects of the case as specified by the MEDIC and will provide updates to the MEDIC as needed.

6. a. McGregor PACE will respond to specific government requests for information. Employees will fully cooperate with law enforcement officers and government agents and will not interfere with or prevent investigators from accessing information listed in a search warrant. Employees should not give investigators permission to search an area that is not listed on the warrant, unless advised otherwise by legal counsel. The execution of a search warrant will trigger an immediate investigation by the Compliance Officer

6. b. Service of Subpoenas

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If McGregor PACE is served with an OIG, Grand Jury or other government subpoena, the Compliance Officer will be notified immediately, and will proceed in accordance with the following Policy.

- The Compliance Officer will contact legal counsel immediately, who will attempt to contact the government, clarify the scope of the subpoena and establish a timeframe for responding.
- McGregor PACE should identify a records custodian who will be responsible for producing the documents and maintaining a log and copies of documents provided to the government. The custodian must be someone who is prepared to testify under oath about the steps taken to gather the information called for in the subpoena.

- The Compliance Officer will issue a directive to employees that a subpoena has been served, instructing employees not to discuss the subpoena or any other aspect of the investigation with other employees or anyone else.

**Commented [JH7]:** This is a procedure as well - we should just reference a policy here as well

The service of an OIG, Grand Jury or other government subpoena will trigger an immediate investigation by the Compliance Officer.

a) Law enforcement interviews with McGregor PACE employees

The following guidelines apply when a law enforcement officer or government agent contacts or requests an interview of a McGregor PACE employee:

- Employees are not required to consent to an interview by government investigators but may volunteer to do so;
- Employees are entitled to their own individual legal counsel, and may request that an interview be stopped at any time and resumed only after legal counsel is present;
- Employees may request that another representative of McGregor PACE (other than legal counsel) be present with them during any interview;
- Employees should obtain the name, title, agency affiliation, and business telephone number of any investigator involved in an interview, and should ask for an explanation of the nature of the investigation and the reason for the interview; and
- Under no circumstances should any supervisor prohibit an employee from responding to or cooperating with government investigators.

*B. Document Retention and Document Destruction*

Once McGregor PACE has received notice of an investigation, the Compliance Officer will communicate with employees as necessary to ensure that any routine document destruction is stopped and that documents are retained as appropriate. *See* Form Document Retention Policy – v1; Employee Handbook, Employee Conduct § 15.5 - Document Retention. McGregor PACE will provide the MEDIC, CMS, the SAA, and law enforcement with access to all requested facilities and any records as required by law and consistent with any CMS contractual obligations.

**XI. DISCIPLINARY GUIDELINES**

*A. Disciplinary Standards*

McGregor PACE shall publicize its disciplinary standards to its Board, employees, and contractors. The following are examples of methods of publication that may be used:

Compliance Program 44

- Newsletters;
- Regular presentations at department staff meetings;
- Communication with contractors;
- General compliance training;
- Employee Handbook;
- Posters prominently displayed throughout employee work and break areas; and
- Cafeteria table tents.

The disciplinary standards shall identify noncompliant or unethical behavior by using examples of violative conduct employees may encounter in their jobs. Such examples may be publicized by way of compliance training materials or any of the above methods of publication.

*B. Compliance as a Condition of Employment/Contract*

All McGregor PACE employees, volunteers, and contractors are expected to comply with the applicable provisions of McGregor PACE’s Compliance Program and related compliance policies as a condition of employment or contract. McGregor PACE expects its employees and contractors to meet the highest ethical standards and comply with all applicable laws. Failure to do so may result in appropriate disciplinary action, up to and including termination of employment.

*C. Procedures for Imposing Discipline*

1. In a case where an employee has engaged in improper conduct or violated this Compliance Program in any way, the Compliance Officer or his/her designee, in conjunction with the individual’s supervisor and/or human resource personnel, is responsible for determining the appropriate discipline. All discipline will be imposed in a timely and consistent manner and in accordance with the terms of any applicable collective bargaining agreements, union rules, requirements of law, and McGregor PACE policies governing the discipline of employees. In a case where a contractor has engaged in improper conduct or has acted in a manner that is inconsistent with applicable provisions of this Compliance Program, the Compliance Officer or his/her designee, in conjunction with the Chief Executive Officer is responsible for determining the appropriate course of action.

2. If the Compliance Officer determines that an employee or contractor has materially and willfully violated this Compliance Program or other compliance-related policies and the violation was of a serious nature, the Compliance Officer may recommend that the employee be terminated from employment immediately, or that the contractor’s agreement be terminated immediately. Employees and contractors should be aware that violations of a serious nature may result in notification of law enforcement officials and licensure authorities.

3. If the Compliance Officer determines that the violation resulted from carelessness or inadequate understanding of McGregor PACE’s policies, the Compliance Officer may decide,

for a first offense, that a verbal warning be given to the employee or contractor. The Compliance Officer may also decide that the employee or contractor be trained/re-trained regarding McGregor PACE's policies and applicable legal requirements. Subsequent offenses by the same employee or contractor may warrant more severe disciplinary or remedial action.

4. All disciplinary and remedial actions, including verbal warnings, will be documented in the employee personnel file by the Human Resources Department or, in the case of a contractor, in the contractor's file. In addition, the Compliance Officer or his/her designee shall maintain a log of all disciplinary sanctions imposed and remedial actions taken. All disciplinary records for compliance violations shall be maintained for ten (10) years and shall include:

- the date of the report of the violation;
- a description of the violation;
- the date of investigation;
- a summary of findings;
- the disciplinary action taken; and
- the date it was taken.

## **XII. TRAINING**

McGregor PACE shall establish a program of regular compliance training.

### *A. General Compliance Training*

#### *1. Process*

McGregor PACE's employees, including temporary workers and volunteers, and members of the Board shall receive general compliance training within 90 days of initial hiring, and annually thereafter. (*See Tabs J and K: Compliance Program Training, for general compliance training slides.*) McGregor PACE shall review and update, if necessary, the general compliance training whenever there are material changes in regulations, policy or guidance, and at least annually.

#### *2. Content*

The compliance training shall consist of, among other things:

- A description of the compliance program, including a review of compliance policies and procedures, the Standards of Conduct, and McGregor PACE's commitment to business ethics and compliance with legal requirements;
- An overview of how to ask compliance questions or report suspected or detected noncompliance. Training should emphasize non-retaliation and non-

intimidation for compliance related questions or reports of suspected or detected noncompliance or potential FWA;

- The requirement to report to McGregor PACE actual or suspected noncompliance or potential FWA;
- Examples of reportable noncompliance;
- A review of the disciplinary action for non-compliant or fraudulent behavior, including mandatory retraining or termination of employment;
- A review of conflicts of interest and McGregor PACE's system for managing conflicts of interest;
- HIPAA/HITECH obligations and the importance of maintaining the confidentiality of personal health information; and
- An overview of the monitoring and auditing process.

*B. PDP FWA Compliance Training*

*1. Process*

All employees shall receive training appropriate to their involvement with McGregor PACE's PDP, including ensuring that employees are aware of the Medicare requirements related to their jobs. In addition, appropriate compliance training concerning FWA and the McGregor PACE PDP shall be provided to PACE managers and members of McGregor PACE's Board. Senior management, the Board, and compliance staff shall be trained with the McGregor PACE Compliance Program Training.

All FDRs (e.g., PBMs and pharmacies) must confirm that they have implemented FWA training. Any FDR may participate in McGregor PACE training programs (Tabs I and J together constitute the relevant McGregor PACE training program) if feasible and reasonable or may (i) elect to use the CMS standardized FWA training materials to conduct its own training program, (available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/ProviderCompliance.html> or Tab I: CMS Part D FWA Training), or (ii) receive Part D training from another PDP sponsor or other organization acceptable to McGregor PACE. McGregor PACE may provide its own Part D compliance training materials to a FDR to ensure the quality of the training received. (*See Tabs I and J* for the relevant McGregor PACE training.) McGregor PACE may require any FDR to certify (in the contract or otherwise) that relevant employees, agents and subcontractors of the FDR have received appropriate FWA training. McGregor PACE shall recognize that FDRs who have met the FWA certification requirements through enrollment into the Medicare program or accreditation as a Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) are deemed to have met the training and educational requirements for fraud, waste, and abuse and have thereby met McGregor PACE's FWA compliance program training requirements. In the case of chain pharmacies, each individual



location must be enrolled in Medicare Part A or Part B to be deemed as having met the training requirement.

## 2. Content

McGregor PACE shall ensure that all employees and all FDRs are aware, at a minimum, of the following:

- Laws and regulations related to Part D fraud, waste, and abuse (e.g., Anti-Kickback Statute, False Claims Act, etc.);
- Part D FWA risk areas/vulnerabilities;
- Obligations of FDRs to have appropriate policies and procedures to address FWA;
- The obligation of FDRs and their employees to report to McGregor PACE actual or suspected Medicare program noncompliance or potential FWA;
- Mechanisms available for McGregor PACE and FDR employees to anonymously and confidentially report suspected fraud, waste, and abuse or Medicare program noncompliance to McGregor PACE (or, as to FDR employees, either to McGregor PACE directly or to their employers who must then report it to McGregor PACE);
- Examples of types of FWA that can occur in the settings in which McGregor PACE and FDR employees work;
- Protections for individuals and entities who in good faith report suspected fraud, waste and abuse; and
- Potential consequences of non-compliant or fraudulent conduct, including, but not limited to, termination of employment or the relevant contract.

When appropriate, McGregor PACE also may educate PACE Participants about prescription drug fraud, waste, and abuse. Such education may be included in newsletters, postings in McGregor PACE's facilities or other means of Participant communication.

*C. Timing and Method of Training*

1. Training shall be provided within ninety (90) days of hire and annually thereafter. McGregor PACE should provide additional or “refresher” training courses to certain employees or departments when additional or new job functions are assigned, when the compliance program requirements change, when employees are found to be noncompliant, as corrective action to address a noncompliance issue, when an employee works in an area with past FWA issues and in any other circumstance that indicates additional training may be necessary. McGregor PACE document training of employees through a written certification signed by the employee or other document evidencing that the employee has received compliance training.

2. McGregor PACE shall utilize the method of training most appropriate to communicate the subject matter, including PowerPoint presentations at staff meetings, reminders in staff newsletters, individual one-on-one sessions with particular employees, regular quizzes or distribution of written materials.

3. The Compliance Officer or his/her designee shall be responsible for documenting all training sessions, including attendance, topic, and results of training and maintaining those records for ten (10) years.

4. FWA training for FDRs should occur prior to the time of contract with McGregor PACE’s PDP, and at least annually thereafter. FDRs must, at the time of contract, provide assurances that FWA training occurred at least within the last year, or within a shorter period (e.g., six months). The Compliance Officer or his/her designee shall be responsible for maintaining documentation evidencing that each FDR has received appropriate FWA training, that such training is current, and that each FDR maintains records of attendance, topic of training, certificate of completion (if applicable), test results (if test is given) for its employees for ten (10) years.

**XIII. DOCUMENT RETENTION**

As required by 42 CFR § 460.200, McGregor PACE will retain records including, but not limited to, medical records, personnel records, and financial books and records for the longest of the following periods:

- (1) The period of time specified in state law applicable to the McGregor PACE;
- (2) Ten years from the last entry date; or
- (3) For medical records of disenrolled participants, ten years after the date of disenrollment.

As required by 42 CFR § 423.505(d), McGregor PACE’s PDP will maintain, for a period of at least ten (10) years, books, records, documents and other evidence of accounting procedures and practices that:

- (1) Are sufficient to do the following:

- Accommodate periodic auditing of the financial records (including data related to Medicare utilization, costs, and computation of the bid for the PDP);
  - Enable CMS to inspect or otherwise evaluate the quality, appropriateness, and timeliness of McGregor PACE's services and facilities;
  - Enable CMS to audit and inspect any books and records of the PDP that pertain to the ability of McGregor PACE to bear the risk of potential financial losses, or services performed or determinations of amounts payable under the contract;
  - Properly reflect all direct and indirect costs claimed to have been incurred and used in the preparation of McGregor PACE's bid for the PDP and necessary for the calculation of gross covered prescription drug costs, allowable reinsurance costs, and allowable risk corridor costs; and
  - Establish the basis for the components, assumptions, and analysis used by McGregor PACE's PDP in determining the actuarial valuation of standard, basic alternative, or enhanced alternative coverage offered in accordance with the CMS guidelines specified in 42 CFR. § 423.265(c)(3);
- (2) Include records of the following:
- Ownership and operation of McGregor PACE's financial, medical, and other record keeping systems;
  - Financial statements for the current Part D contract period and ten (10) prior periods;
  - Federal income tax or informational returns for the current Part D contract period and ten (10) prior periods;
  - Asset acquisition, lease, sale, or other actions;
  - Agreements, contracts, and subcontracts;
  - Franchise, marketing, and management agreements;
  - Matters pertaining to costs of operations;
  - Amounts of income received by source and payment;
  - Cash flow statements;
  - Any financial reports filed with other Federal programs or state authorities;
  - All prescription drug claims for the current Part D contract period and ten (10) prior periods; and

- All price concessions (including concessions offered by manufacturers) for the current Part D contract period and ten (10) prior periods accounted for separately from other administrative fees.

The Compliance Officer or his/her designee is responsible for developing systems to maintain the necessary books, records, and other documentation, and for communicating those requirements to affected employees and contractors. All other records and documentation shall be maintained in accordance with McGregor PACE's customary document retention and destruction policies.

Approved by: \_\_\_\_\_

Date: \_\_\_\_\_