Central Valley PACE First Tier, Downstream and Related Entity (FDR) Compliance & FWA Program Guide

Introduction

Central Valley PACE is a PACE Medicare Health Plan and a Part D Prescription Drug Plan. As such, PACE must adhere to CMS requirements of a Medicare Health Plan with few exceptions. Central Valley PACE is also a department of Golden Valley Health Centers. Each share the same mission and goals. The Central Valley PACE Compliance and Fraud Waste and Abuse Program describes the plan to ensure compliance with CMS requirements. Part of that plan is to ensure partnering entities of Central Valley PACE adhere to CMS compliance requirements.

As a Medicare Health Plan, Central Valley PACE partners with individuals and organizations in support of providing the most robust and efficient services. Partnering entities are referred to as First Tier, Downstream and Related Entities by CMS. Partnerships are defined through contractual arrangements. It is the responsibility of Central Valley PACE to ensure that its contracting partners are committed to CMS compliance fulfillment including:

- reducing fraud, waste and abuse (FWA),
- complying with laws and regulations, and
- implementing compliance policies.

Compliance Fulfillment refers to adherence to CMS compliance and fraud waste and abuse (FWA) requirements found in Chapter 21 of the Medicare Managed Care Manual and Chapter 9 of the Prescription Drug Benefit Manual. These manuals reference the Code of Federal Regulations describing FDR compliance and FWA requirements. These requirements are discussed in the FDR Compliance Guide. It is the responsibility of the Medicare Health Plan to ensure First Tier Entities and their downstream contractors adhere to referenced CMS regulations. It is the responsibility of the First Tier Entities and their downstream contractors to comply with health plan audits.

What's a First Tier, Downstream or Related Entity?

A First Tier Entity is defined as any party that has entered into a direct CMS approved contract with a Medicare health plan. Chapter 21 of the Medicare Managed Care Manual and Chapter 9 of the Prescription Drug Benefit Manual describe the types of services an FDR performs. Services provided by the first tier entities include direct health care services and administrative services. Direct health care services include outpatient providers and inpatient providers as well as home delivered services including:

- Physicians
- Hospitals
- Home Health & Care

Administrative services include those services that aid in the processing of patient services that include patient data such as:

- Claims Processing
- Patient Management

- Broker Agencies
- Call Centers
- Pharmacies
- Coders
- Durable Medical Equipment
- Clinical Staffing Agencies
- Diagnostic Providers

Additionally, Credentialing Organizations are consider FDR's even though they do not process patient services or utilize patient data. This designation can be found here: Chapter 11 § 100.5 of the Medicare Managed Care Manual.

Most Medicare health plans enter into agreements with other types of services providers. Not all contracted service providers are considered FDR's for the purposes of adherence to Medicare FDR compliance requirements. Examples of these types of service providers include:

- Housekeeping and Grounds Keeping
- Non-clinical Staffing Agencies
- Payroll or Human Resources
- Mail Services
- Machine Repair

A Downstream Entity is defined as a party that enters into a CMS approved agreement with a Medicare health plan's first tier contractors. Downstream Entities are not directly contracted with a Medicare health plan but are instead contracted to a contractor that is directly contracted to a Medicare health plan, hence the term downstream. The same types of organizations and their services as previously described are considered Downstream Entities. Downstream Entities must adhere to the same CMS requirements as First Tier Entities. It is up to the First Tier Entities to ensure that their downstream contractors adhere to CMS requirements. It is up to the Medicare health plan to ensure that its First Tier Entities do so.

A Related Entity is defined as a party related to a Medicare health plan by control such as ownership who also furnishes services described in an agreement of a nature previously described for First Tier Entities or sells or leases property to the Medicare health plan. This designation can be found here: 42 CFR §§ 422.500 and 423.501.

Compliance and Attestation

To assist with compliance program review, this guide provides a summary of activities that FDR's should complete annually to ensure they are in compliance with Medicare requirements. Review activities include but are not limited to:

- Distribution of compliance policies;
- Distribution of a Code of Conduct;
- Exclusion screening;
- Educate the workforce on reporting requirements including reporting FWA and other compliance concerns to Central Valley PACE;

- Request permission to use offshore contractors;
- Monitor and audit FDR's;
- Moreover, comply with federal and state compliance requirements.

The consequences of noncompliance may include:

- Developing a corrective action plan to address deficiencies;
- Additional training;
- Termination of the FDR contract with Central Valley PACE.

It is the FDR's responsibility to detect compliance issues and to take steps to correct them.

Evidence of compliance materials and records of carrying our compliance activities **must be retained for no fewer than 10 years**. Documents such as employee FWA training logs, exclusion screenings and other similar documents are examples of records that must be retained for 10 years.

Annually, a representative of the FDR organization must verify compliance with the provisions contained in this guide. This person must have direct or indirect responsibility for employees, contractors, and vendors. This person may be a Compliance Officer, other Executive Officer or a practice administrator or manager.

Compliance Program Requirements

A **Code of Conduct** along with a **Compliance Policy** must be distributed to employees and downstream entities. These documents must satisfy the provisions described in Chapter 21 § 50.1 of the Medicare Managed Care Manual. These materials must be distributed annually, within 90 days of hire or contracting, and when there are changes. The FDR must be able to show proof of distribution. These requirements are found within:

- Chapter 21 Section 50.1 of the Medicare Managed Care Manual;
- 42 CFR § 422.503 (b)(4)(vi)(A); and
- 42 CFR § 422.504 (b)(4)(vi)(A).

Compliance and FWA Training is a requirement to combat Fraud, Waste and Abuse. Training must occur annually, within 90 days of hire or contracting, and when there are changes to the training requirements. A log of employee training sessions must include names and dates of training completion. The FDR training program my include Medicare training materials or mirror them in context. The FDR may also us the Central Valley PACE training materials found here: https://www.cvpace.org/fraud-waste-and-abuse-training/ .

The FDR must attest or certify to training by either submitting the Training Attestation or Training Certification documents found here: https://www.cvpace.org/fraud-waste-and-abuse-training/. When read and signed, the Training Certification document satisfies CMS FWA and Compliance training requirements for individuals. When signed, the Training Attestation document attests that the FDR provides its own training program to its employees and contractors. If you are an individual needing training, complete the Training Certification document. If you are an FDR Compliance Officer or manager and provide training to your organization, complete the Training Attestation document.

Additional information about training requirements may be found within:

- Chapter 21 Section 50.1 of the Medicare Managed Care Manual;
- 42 CFR § 422.503 (b)(4)(vi)(C); and
- 42 CFR § 422.504 (b)(4)(vi)(C).

Fraud, Waste, and Abuse is intentional persuasive misuse of information to cause another to surrender something of value or cause surrender of a legal right, consuming-spending-expending resources carelessly, and improperly using resource for personal gain without sufficient evidence to prove criminal intent.

Federal laws describing Fraud, Waste and Abuse may be found within:

- Federal False Claims Act;
- Anti-kickback Statute;
- Stark Law;
- Social Security Act;
- United States criminal code.

Consequences for violating these laws may include:

- Nonpayment of claims or invoices;
- Fines;
- Barring form federal health care programs;
- Criminal and civil prosecution.

Exclusion Screening must be performed to ensure that federal health care programs such as Central Valley PACE are not paying for services and items provided by an entity or person excluded from federal health care programs. The General Service Administration system for Award Management website (https://www.sam.gov/SAM/pages/public/searchRecords/search.jsf) and the Office of Inspector General list of Excluded Individuals Entities website (https://oig.hhs.gov/exclusions/index.asp) may be used to perform screenings.

Evidence of screenings must be maintained for 10 years. This may be accomplished through the use of logs and other records documenting screenings of employees and downstream entities. These documents must include names, dates and results. Employees and contractors who are on the exclusion lists, must be removed from direct and indirect Medicare business responsibilities and the contract terminated for all Medicare business.

Screenings must be conducted regularly before hiring or contracting. Medicare recommends screening monthly after that. It is the FDR's responsibility to attest that screenings are conducted at least annually and to provide evidence upon Central Valley PACE request.

Federal laws describing exclusion screening may be found within:

- Social Security Act, 1862€(1)(B);
- 42 CFR § 422.503 (b)(4)(vi)(F), 422.752(a)(8), 423.504(b)(4)(vi)(F), 423.752(a)(6), 1001.1901
- Medicare Managed Care Manual Chapter 21 § 50.6.8

FDR employees subject to screening and Medicare compliance requirements include those employees directly or indirectly participating in Medicare business. Examples of direct participation include

diagnosing and treating health conditions for health plan members, adjudicating claims for the health plan, and other similar activities. Examples of indirect participation include accounting of business directly provided to the health plan, reception or administrative assistant for person directly involved in health plan business, and similar activities.

Reporting Compliance Concerns to Central Valley PACE can assist in the management of preventing Fraud, Waste and Abuse. We will treat each report as confidential. Questions or concerns may be addressed to compliance@cvpace.org.

Offshore Operations must be reported and requested prior to initiating. Offshore Operations refers to an entity physically located outside the United States and its territories. If the offshore activities include the use of personal health information (PHI), an attestation must be submitted to CMS. Examples of PHI include diagnosis, images, and other related information.

Monitoring FDR's is a requirement of CMS. Not only must Central Valley PACE monitor its FDR's but our First Tier Entities must monitor their First Tier Entities and so on downstream. Each FDR must participate in Central Valley PACE's monitoring and auditing activities. These activities will be conducted periodically and ensure compliance with applicable laws and regulations. Failure to participate may result in corrective action plans or contract termination. Monitoring and auditing activities may include:

- Ensuring contracts and agreements contain CMS requirements;
- Ensuring conformity with CMS compliance program requirements previously described;
- Ensuring operational requirements meet Medicare standards.

Central Valley PACE will maintain evidence of FDR monitoring and auditing activities for 10 years. FDR's need to as well. When deficiencies are noted, root causes must be identified and corrective action plans developed and carried out. These requirements may be found within:

- Chapter 21 Section 50.6.6 of the Medicare Managed Care Manual;
- 42 CFR § 422.503 (b)(4)(vi)(F); and
- 42 CFR § 422.504 (b)(4)(vi)(F).

We are here to help

Direct questions or concerns to compliance@cvpace.org or call 209-724-6000 and ask to speak to a health plan specialist about Medicare compliance.