

Ascension Living PACE

*First Tier, Downstream and Related Entities Medicare
Compliance Guide*

The bottom of the page features two overlapping, stylized mountain-like shapes. The larger, outer shape is a medium blue, and the smaller, inner shape is a darker blue. Both shapes are composed of straight lines forming a triangular peak and a curved base, creating a modern, abstract graphic design.

Introduction

Ascension Living PACE is committed to practicing business ethically by reinforcing our commitment to compliance through detection and prevention of fraud, waste, and abuse (FWA) by ensuring compliance with applicable laws, rules, and regulations. We contract with the Centers for Medicare & Medicaid Services (CMS) to provide services under Medicare Parts C and D. To help fulfill its obligations to CMS, Ascension Living PACE may contract with external vendors or individuals to provide administrative or health care services like pharmacy benefit manager, physician-hospital organization and sales agents. These delegated services are what CMS refers to as First-Tier, Downstream, and Related Entities (FDRs). As an Ascension Living PACE FDR, you must fulfill specific Medicare compliance program requirements. The Code of Federal Regulations (CFR) outlines these requirements in [Chapter 21 of the Medicare Managed Care Manual and Chapter 9 of the Prescription Drug Manual](#).

What is an FDR?

CMS defines FDRs as follows:

First-Tier Entity means any party that enters into a written arrangement, acceptable to CMS, with a Medicare Advantage Organization or Part D plan sponsor or applicant to provide administrative services or health care services to a Medicare eligible individual under the Medicare Advantage program or Part D program.

Downstream Entity means any party that enters into a written agreement, acceptable to CMS, with persons or entities involved with the Medicare Advantage benefit, below the level of the arrangement between an Medicare Advantage Organization or applicant or a Part D plan sponsor or applicant and a first-tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

Related Entity means any entity that is related to a Medicare Advantage Organization or Part D sponsor by common ownership or control and:

- 1) Performs some of the Medicare Advantage Organization or Part D plan sponsor's management functions under contract or delegation
- 2) Furnishes services to Medicare enrollees under oral or written
- 3) Leases real property or sells materials to the Medicare Advantage Organization or Part D plan sponsor at a cost of \$2,500 during a contract period

See 42 C.F.R. §§ 422.500 and 423.501 for more information.

Health Services

Health Care providers are FDRs, too. The compliance requirements in this guide apply to health care providers contracted with our Medicare network. This includes physicians, hospitals and other provider types. Here are three reasons why:

- 1) CMS rules state that providers contracted with Ascension Living PACE to provide health care services are First Tier Entities.
- 2) Chapter 21 § 40 of the Medicare Managed Care Manual and Chapter 9 § 40 of the Prescription Drug Benefit Manual lists health care services as an example of the types of functions a third party can perform related to an MA organization's contract with CMS. This gives third parties "First Tier Entity" status.
- 3) The flowchart in the same chapter and paragraph shows that entities providing health services and hospital groups are First Tier Entities. So if we contract with a hospital group and don't have a direct contract with the group's hospitals and other providers, the hospitals and providers are Downstream Entities. This means the hospital group:
 - o Is a First Tier Entity.
 - o Must follow the CMS compliance requirements in this guide.
 - o Must ensure its Downstream Entities follow them, also.

Administrative Services

The Medicare compliance program requirements also apply to entities that we contract with to perform administrative service functions for our MA or Part D contracts. Some examples of administrative service functions include:

- o Claims Processing
- o Patient management
- o Credentialing Services
- o Utilization Management
- o Other individuals, entities, vendors, or suppliers contracted with us for administrative and/or health care services for our Medicare plans

To find more information about FDR administrative services refer to the Medicare Managed Care Manual Chapter 21 and Chapter 9 § 40, Stakeholder Relationship Flow Charts.

FDR Medicare Compliance Program and Attestation Requirements

Ultimately, we are responsible for fulfilling the terms and conditions of our contracts with CMS and meeting applicable Medicare requirements for services delivered to participants. Our FDRs are also responsible for complying with all applicable laws, rules, and regulations. Likewise, FDRs must ensure their Downstream Entities comply with applicable laws and regulations - including the requirements in this guide.

Compliance program requirements

- Complete Fraud, Waste and Abuse (FWA) and General Compliance Training that meets CMS requirements as described in the Medicare Managed Care Manual §§ 50.3.1.,50.30.2.
- Distribute Standards of Conduct/compliance program policies and procedures (ie. Ascension Living PACE or one that is comparable)
- Screen for excluded individuals and entities
- Establish and maintain communications and reporting mechanisms
- Report offshore subcontracting
- Monitor and audit First-Tier, Downstream, and Related Entities

Noncompliance

Your organization must comply with the compliance program requirements outlined in this guide. If your organization fails to meet the CMS compliance requirements outlined in this guide, depending on the severity of non-compliance could result in one of the following:

- Development of a corrective action plan (CAP).
- Retraining.
- Termination of your contract with Ascension Living PACE.

Attestation

FDRs must maintain evidence of compliance with Medicare compliance program requirements for no less than 10 years. On an annual basis, an authorized representative from your organization will attest to its compliance with the Medicare compliance program requirements described in this guide. An authorized representative is an individual who has the authority to act on behalf of your organization.

Understanding the requirements

Training

As a FDR, your organization is responsible for providing FWA and General compliance training to all your employees (including temporary workers and governing body members) and Downstream entities that provide administrative and/or health care services. This training must be conducted within 90 days of initial contract/employment and annually thereafter. FDRs must be able to demonstrate that their employees and Downstream entities have fulfilled this training requirement.

Note: FDRs that obtain FWA certification through enrollment into the Medicare Program or accreditation as Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) are deemed to have met their FWA training

Standards of Conduct

Your organization must provide either Ascension Living PACE Standards of Conduct or your own comparable Standards of Conduct to all applicable employees and Downstream Entities who provide administrative and/or health care services for Ascension Living PACE Medicare lines of business. The Standards of Conduct must contain all the elements set forth in Section 50.1 and subsections of Chapter 21 and Chapter 9. You must distribute the Standards of Conduct:

- Within 90 days of hire or the effective date of contracting.
- When there are updates to the Standards of Conduct.
- Annually thereafter.

You must retain evidence of your distribution of the Standards of Conduct.

You can find the Standards of Conduct requirements in 42 C.F.R. §§ 422.503 (b) (4) (vi) (A), 42 C.F.R. 423.504 (b) (4) (vi) (A), and the Medicare Managed Care Manual Chapter 21 and Prescription Drug Benefit Manual Chapter 9 § 50.1

OIG/GSA Exclusion and Debarment Screenings

Federal law prohibits Medicare health care programs from paying for items or services provided by an individual or entity excluded from participation in federal health care programs. Before hiring or contracting, and on a regular basis thereafter, each FDR must check exclusion lists to confirm your employees and Downstream Entities are not excluded from participating in federally funded healthcare programs. Use these websites to perform your exclusion list screening:

- [General Service Administration \(GSA\) System for Award Management \(SAM\)](#)
- [Office of Inspector General \(OIG\) List of Excluded Individuals and Entities \(LEIE\)](#)

You must also maintain evidence that you've checked these lists. You can use logs or other records to document that you've screened each employee and Downstream Entity. Evidence of the screening should include the date of occurrence, the results of the screening, and any actions taken if sanctioned individuals or entities were identified. If any of your employees or Downstream Entities are on these exclusions lists, you must immediately remove them from work directly or indirectly related to our plan and notify us immediately.

This exclusion list requirement is listed in § 1862 (e) (1) (B) of the Social Security Act, 42 C.F.R. §§ 422.503 (b) (4) (vi) (F), 422.752 (a) (8), 423.50 (b) (4) (vi) (F), 1001.1901, and the Medicare Managed Care Manual Chapter 21 and Prescription Drug Benefit Manual Chapter 9 § 50.6.8.

Communications and Reporting Mechanisms

If you know of, or suspect, an issue of potential noncompliance or FWA, it must be reported to us. There are several ways to report compliance concerns:

- ★ Contacting Ascension Living PACE Compliance Department by:
 - Calling the Ascension FWA hotline anonymously 24 hours a day at 1-844-233-8635;
 - Completing the Compliance FWA Inquiry form online at www.ascensionfwa.ethicspoint.com;
 - Emailing the compliance department at compliance.seniorliving@ascension.org.

You must adopt, maintain and enforce a zero-tolerance policy for retaliation or intimidation against anyone who in good faith reports suspected noncompliance or FWA.

Information on reporting noncompliance and FWA can be found in 42 C.F.R. §§ 422.503 (b) (4) (vi) (D), 42 C.F.R. §§ 423.504 (b) (4) (vi) (D), and the Medicare Managed Care Manual Chapter 21 and Prescription Drug Benefit Manual Chapter 9 § 50.4.

Offshore Subcontracting

Because of the unique risks associated with using contractors operating outside the United States or one of its territories (i.e., American Samoa, Guam, Northern Marianas, Puerto Rico and Virgin Islands), CMS requires Medicare Advantage Organization (MAOs) to take extra measures to ensure offshore contractors protect members' protected health information (PHI). Specifically, CMS is concerned with offshore subcontractors that receive, process, transfer, handle, store, or access participants' PHI. If a first-tier entity contracts with an offshore subcontractor, and provides that subcontractor with participants PHI, then you must report it to us immediately.

Record Retention and Record Availability

FDRs must agree to audits and inspections by CMS, Ascension Living PACE, and/or its designees. They must cooperate, assist, and provide information as requested. Documentation and records needed to meet program requirements (i.e., Medicare Parts C and D) must be maintained for 10 years, including but not limited to attendance records, training certificates, and any other documents that demonstrate compliance with program requirements.

Monitoring and Auditing of FDRs

We monitor and audit the activities of our FDRs to ensure compliance with Medicare Parts C and D program requirements. First-Tier Entities that subcontract with other individuals or entities to provide administrative or health services are responsible for ensuring their downstream entities comply with all Medicare Parts C and D requirements. This includes ensuring:

- Contractual agreements contain all CMS-required provisions
- They comply with the Medicare compliance program requirements described in this guide
- They comply with any applicable Medicare operational requirements

Additionally, your organization must provide sufficient oversight of FDRs, which includes auditing and monitoring to test and ensure your Downstream Entities are compliant with Medicare compliance program requirements. You must retain evidence of your oversight activities, ensure a root cause analysis is conducted for any deficiencies, and implement corrective action as necessary to prevent recurrence of noncompliance.

Routine Monitoring and Auditing

Monitoring and auditing requirements are outlined in 42 C.F.R. §§ 422.503 (b) (4) (vi) (F) and 42 C.F.R. 423.504 (b) (4) (vi) (F), and the Medicare Managed Care Manual Chapter 21 and Prescription Drug Benefit Manual Chapter 9 § 50.6.6.

Fulfill federal and state compliance obligations

You may be subject to other federal and state laws, rules and regulations that you must also fulfill but aren't covered in this guide. We expect your organization to comply with all applicable federal and state laws, rules and regulations.

If you have questions about the compliance obligations for the services your organization performs, please contact the compliance department by emailing: compliance.seniorliving@ascension.org.