First-Tier, Downstream, and Related Entities (FDRs) Medicare Compliance Program Guide

MARCH 2019

www.communitycareinc.org
First-Tier, Downstream and Related Entities (FDRs)

FDR Compliance Program Requirements

Introduction

Community Care contracts with the Centers for Medicare & Medicaid Services (CMS) to provide services under Medicare Parts C and D. To help fulfill its obligations to CMS, Community Care enters into contracts with external vendors and providers to provide administrative or health care services to its members. CMS refers to these subcontractors as First-Tier, Downstream, and Related Entities (FDRs).

Although these services are delegated, Community Care is ultimately responsible for ensuring services are performed according to all applicable laws and regulations. Therefore, CMS requires FDRs fulfill specific Medicare compliance program requirements.

The Code of Federal Regulations (C.F.R.) Title 42 §§ 422 and 423 explain in detail the Medicare compliance program requirements; these requirements can also be found in the Medicare Managed Care Manual, Chapters 9 and 21, Compliance Program Guidelines. We are providing you this guide because we have identified you as a FDR expected to adhere to the standards contained in this guide.

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 (42 C.F.R. §§ 422.500 and 423.501).

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 (42 C.F.R. §§ 422.500 and 423.501).

Related Entity means any entity that is related to an 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; or

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 (42 C.F.R. §§ 422.500 and 423.501).
Health Services

The requirements outlined in this guide apply to health care providers contracted with Community Care to participate in our Medicare network. This includes physicians, hospitals and other provider types. The reason these health care providers are included as FDRs is that:

- Medicare Advantage (MA) regulations and Centers for Medicare and Medicaid Services (CMS) rules indicate providers contracted with Community Care to provide services to our Medicare members are “First-Tier Entities.”

- Chapter 21 of the Medicare Managed Care Manual lists “health services” as an example of the types of functions that a third party can perform that relate to an MA organization’s contract with CMS (Medicare Managed Care Manual Chapter 21 § 40.)

- CMS provides a chart in the manual, Chapter 21 § 40, showing that health services and hospital groups are first-tier entities. Thus, if Community Care contracts with a hospital group and does not have a direct relationship with the group’s hospitals and other providers, the hospitals and providers are Downstream Entities. This means the hospital group is a First-Tier Entity and must comply with the provisions of this guidance. As a result, the hospital group must ensure its Downstream Entities comply with CMS compliance program requirements.

Administrative Services

The Medicare compliance program requirements described in this guidance also apply to entities that Community Care contracts to perform administrative service functions relating to our MA or Part D contracts with CMS. Examples of administrative service functions include:

- Pharmacy benefit management (PBMs)
- Hotline Operations
- Credentialing

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

CMS requires that Medicare Advantage organizations’ FDRs comply with all applicable laws, rules, and regulations. Likewise, FDRs must also ensure that their Downstream Entities comply with Medicare compliance program requirements including the requirements outlined in this guide.

Compliance Program Requirements

Medicare compliance program requirements are as follows:
- 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 Code of Conduct/compliance program policies and procedures (ie. Community Care’s 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

Failure of a FDR to meet the CMS compliance requirements outlined in this guide, could result in one of the following actions:
- Development of a corrective action plan (CAP)
- Retraining
- Termination of your contract with Community Care

The extent of our corrective action depends on the severity of the noncompliant behavior.

Attestation

FDRs must maintain evidence of compliance with Medicare compliance program requirements for no less than 10 years. Each year an authorized representative from your organization will attest to your 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. This is generally a practice manager/administrator, an executive officer, or a similar position.

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 on Community Care’s contract. This training must be formally 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. Each FDR is responsible for designing and conducting their own FWA and General compliance training.
**Code of Conduct**

Your organization must provide either Community Care’s Code of Conduct or your own comparable Code of Conduct to all applicable employees and Downstream Entities who provide administrative and/or health care services for Community Care’s Medicare lines of business. The Code of Conduct must contain all the elements set forth in Section 50.1 and subsections of Medicare Managed Care Manual, Chapter 21. You must distribute the Code of Conduct:

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

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

You can find the Code 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 § 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. Therefore, before hiring or contracting, and monthly thereafter, each FDR must check exclusion lists from the Office of Inspector General (OIG) and the General Administration Services (GSA). These exclusions lists are at the following websites:

- [https://exclusions.oig.hhs.gov](https://exclusions.oig.hhs.gov)
- [https://www.sam.gov](https://www.sam.gov)

You must maintain evidence that you have checked these lists. You can use logs or other records to document your compliance with this requirement. 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 Community Care’s Medicare lines of business 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 § 50.6.8.
Communications and Reporting Mechanisms

If any FDR knows of, or suspects, an issue of potential noncompliance or FWA, they must report it to Community Care. You can report compliance concerns and FWA by:

• Contacting Community Care’s Compliance Department at 866-992-6600;
  
  • Calling the Ethics and Compliance Hotline anonymously 24 hours a day at 800-826-6762;
  
  • Completing the Compliance Inquiry form online at www.communitycareinc.org; or
  
  • Emailing the Compliance Department at compliancehotline@communitycare.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 § 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 Mariana Islands, Puerto Rico and Virgin Islands), CMS requires Medicare Advantage Organizations (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 members’ PHI. If a first-tier entity contracts with an offshore subcontractor, and provides that subcontractor with members’ PHI, the first-tier entity must report it to Community Care immediately.

Record Retention and Record Availability

FDRs must agree to audits and inspections by CMS, Community Care 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

Community Care monitors and audits the activities of 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

These 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 § 50.6.6.