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

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www.communitycareinc.org

FDR Medicare Compliance Program Requirements

Introduction

Community Care is committed to conducting business with integrity. We believe in being honest, open and fair in our dealings with our clients and their families, other agencies, contractors, volunteers and our employees. We strive for an atmosphere of mutual trust and respect in our work. We do our best to assure that our programs are responsive to the needs of people we serve while providing exceptional outcomes. Our Compliance Program is a key part of maintaining this commitment.

Community Care contracts with the Centers for Medicare & Medicaid Services (CMS) to provide services under Medicare Parts C and D. We are committed to being a good steward of these public resources. 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).

CMS requires FDRs to fulfill specific Medicare compliance program requirements. The Code of Federal Regulations (CFR) 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 to assist you as we have identified you as a FDR. As such, you must follow the standards required by CMS and the Compliance Program created by us for our FDRs.

Please review this guide to make sure you have the internal processes in place to support compliance with the requirements of the program.

What is an FDR?

CMS defines FDRs in 42 CFR §§ 422.500 and 423.501 as follows:

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

Downstream Entity is any party that enters into a written agreement, acceptable to CMS, with persons or entities involved with the MA benefit, below the level of the arrangement between an MAO 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 an MAO or Part D sponsor by common ownership or control and:

1) Performs some of the MAO 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 MAO or Part D plan sponsor at a cost of at least $2,500 during a contract period.

Health Services

The requirements outlined in this guide apply to health care providers contracted with us that participate in our Medicare network. This includes physicians, hospitals and other provider types. Below are the reasons why:

- MA regulations and CMS rules state that providers contracted with Community Care to provide services to our Medicare members are "First-Tier Entities."

- Chapter 21 §40 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 MAO's contract with CMS.

- CMS provides a chart in the manual, Chapter 21 §40, showing that health services and hospital groups are first-tier entities.

Administrative Services

The Medicare compliance program requirements described in this guidance also apply to entities that we contract with 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.

> “A culture of ethical behavior and corporate compliance is essential...”

Medicare Compliance Program and Attestation Requirements

Community Care is committed to conducting business practices that are in compliance with ethical standards, all applicable state and federal laws, regulations and rules, and contractual obligations. A culture of ethical behavior and corporate compliance is essential to meeting this standard. Our Medicare Compliance Program is designed to meet those expectations.

FDR’s must comply with these requirements and follow all applicable laws, rules and regulations. FDRs must also ensure that their Downstream Entities comply with Medicare compliance program requirements including the requirements outlined in this guide.

Compliance Program Requirements

Your organization and all of your downstream entities must comply with the following Medicare compliance program requirements:

- FWA and General Compliance training
- Distribution of the Code of Conduct/compliance program policy
- Screen for excluded individuals and entities
- Maintain record retention
- Make employees aware of reporting mechanisms
- Report FWA and General Compliance concerns to us
- Report offshore subcontracting
- Monitor and audit Downstream and Related Entities

These requirements apply to all employees (including temporary employees and volunteers), governing board members, and contractors providing a health or administrative services relating to Community Care Medicare plans.

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. If areas of noncompliance are found, the FDR must take prompt action to fix the issue and prevent it from happening again.

Attestation Requirements

Each year an authorized representative from your organization will attest to your compliance with the Medicare compliance program requirements described in this guide. This should be someone who is responsible for all employees, contracted personnel, providers/practitioners and vendors who provide health care and/or administrative services for our Medicare plans. This could be your practice manager/administrator, compliance officer, or an executive officer.

The FDR Compliance Attestation will be sent annually. You must keep evidence of your compliance with CMS requirements for no less than 10 years.

General Compliance and FWA Training/Education

As a First Tier Entity, your organization must provide general compliance and FWA training to all employees and downstream entities assigned to provide administrative and/or health care service for Community Care Medicare Parts C and D programs.

CMS no longer requires FDRs to complete its Medicare Parts C and D General Compliance and Combating Medicare Parts C and D Fraud, Waste and Abuse Training. Instead you may complete your own version of general compliance and FWA training. The CMS website is a good source of additional information and includes training options.

Required training/education must be completed:

- Within 90 days of initial hire or effective date of contracting
- When there are updates
- Annually thereafter

Only those employees who provide an administrative or health care service to Community Care Medicare lines of business need to complete the training.

You must retain evidence of training completion for 10 years after conducting the training. Evidence of completion may be in the form of certificates, attestations, training logs or other means that fulfil this requirement. If training logs or standardized reports are used, they should include employee names, date of hire, and name of training and date of completion.

If your organization is enrolled into Medicare Part A or B or is accredited as a supplier of Durable Medical Equipment, Prosthesis, Orthotics, and Supplies (DMEPOS) you are "deemed" to have met the FWA training and education requirements. Those parties deemed to have met the FWA train-

ing will still need to complete the general compliance training. Evidence of your organization's "deemed" status must be made available to Community Care and/or CMS upon request.

You can find the training requirements in Chapter 21 §§ 50.3.1 and 50.3.2 of the Medicare Managed Care Manual.

Code of Conduct

A Code of Conduct is a set of key principles and expectations by which an organization
operates, and defines the compliance policies and procedures. The Code of Conduct defines the
expectations for everyone at Community Care. While leadership at Community Care is responsible for establishing an ethical culture for the whole organization, maintaining an ethical culture is everyone's responsibility.

The Code of Conduct includes the behaviors and actions expected of all representatives of Community Care. Everyone should act ethically. While the Code of Conduct does not explain all expected conduct, you must apply your own good judgment and make ethical decisions.

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.

You must distribute the Code of Conduct:

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

You must retain evidence of your distribution of the Code of Conduct for 10 years.

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. 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:www.sam.gov

You must conduct screenings before hiring or contracting, and monthly thereafter for each:

- Employee (including temporary employee)
- Volunteer
- Consultant
- Governing board member

You must maintain evidence for 10 years 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

Reporting is critical for the prevention, detection and correction of FWA. If any FDR knows of, or suspects, an issue of potential noncompliance or FWA, they must report it to Community Care. Compliance concerns and suspected or actual violations of noncompliance are taken very seriously.
FDRs should train employees on the importance of reporting violations of noncompliance and FWA.

As a FDR that contracts with us, you must ensure all your employees and those of any of your Downstream and Related Entities know how to report compliance concerns and suspected misconduct. We will perform an internal investigation of each concern brought to us after your organization reports an incident.

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 262-207-9440;
- Completing the Compliance Inquiry form online at https://communitycareinc.org/contact-us/compliance-inquiries;
- Emailing the Compliance Department at compliancehotline@communitycare.org.

CMS requires us to have a system in place to receive, record, respond to and track compliance questions or reports of suspected or detected noncompliance or potential FWA. FDRs must create reporting mechanisms for their organization that are anonymous or you can refer your employees and Downstream Entities to report compliance issues to Community Care's Compliance Hotline.

Community Care understands that people might not report suspected violations if they fear retaliation. Community Care does not tolerate retaliation against anyone who in good faith reports suspected violations. You must adopt, maintain, and enforce a zero-tolerance policy for retaliation or intimidation against anyone who in good faith reports suspected misconduct.

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

Due to 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 US Virgin Islands), CMS requires MAOs to take extra measures to ensure offshore contractors protect members' protected health information (PHI). CMS is concerned with offshore subcontractors that receive, process, transfer, handle, store, or access members' PHI. MAOs are required to provide CMS with specific offshore subcontractor information.

Notify us immediately if you plan to use an offshore entity. You must receive written approval from us before you can use an offshore entity. If there are material changes in any offshore services information that you have submitted in the past, tell us right away.

Record Retention and Record Availability

Documentation and records needed to meet program requirements and must be maintained for 10 years. This includes but is not limited to attendance records, training certificates, and any other documents that demonstrate compliance with program requirements.

If you choose to contract with another organization to provide administrative and/or health care services, your Downstream Entities must agree to audits and inspections by CMS, Community Care

and/or its designees. They must cooperate, assist, and provide information as requested.

Monitoring and Auditing of FDRs

Community Care is responsible for the lawful and compliant administration of the Medicare Parts C and D benefits under our contract with CMS. CMS requires that we create a strategy to monitor and audit our First-Tier Entities to ensure they follow all applicable laws and regulations. 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
- Compliance with the Medicare compliance program requirements described in this guide
- Compliance with any applicable Medicare operational requirements

Not every subcontractor is considered a Downstream Entity. Only those entities who provide administrative or health care services for Community Care's Medicare and Prescription Drug Plan products may be Downstream Entities.

FDRs should expect monitoring and audits. We will monitor and periodically audit FDRs for all service or responsibilities delegated to the FDR.

Auditing of First-Tier Entities for compliance program requirements includes an evaluation to confirm that the First-Tier Entities are applying appropriate compliance program requirements to Downstream Entities that they contract with. Your organization must provide sufficient oversight of your own Downstream Entities to ensure they are compliant with Medicare 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.

If Community Care determines that a FDR is noncompliant with any of the requirements in this guide, we'll require the FDR to develop a corrective action plan to correct the deficiencies.

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.

Additional Information

Additional Information on the Community Care FDR Program Requirements can be found on our website at:

https://communitycareinc.org/for-providers/fdr-training-education