



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

## Section I: Introduction

FirstCarolinaCare Insurance Company (FCC) relies on contracted vendors and providers to help us meet the needs of our membership according to Medicare Advantage and Medicare Prescription Part D program requirements. These individuals and organizations are called First Tier, Downstream and Related Entities (“FDRs”). FDRs are individuals or entities to which FCC has delegated administrative or health care service functions related to its contract with the Center for Medicare and Medicaid Services (CMS). FDRs are a vital part of the FCC Medicare Advantage program and have specific responsibilities under Medicare guidelines. The goal of this Compliance Program Guide is to assist our FDRs with understanding and meeting their compliance obligations under Medicare guidelines.

### Definitions

- **First Tier Entity**- any party that enters into a written agreement, acceptable to CMS, with a Medicare Advantage organization or Part D plan sponsor or applicant to provide administrative or health care services to a Medicare-eligible individual under the MA or Part D program.
- **Downstream Entity**- any party that enters into a written agreement, acceptable with CMS, with persons or entities involved with the MA or Part D benefit, below the level of the arrangement between an MA 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**- any entity that is related to an MA organization or Part D sponsor by common ownership or control and:
  1. Performs some of the MA organization or Part D plan sponsor’s management functions under contract or delegation
  2. Furnishes services to Medicare enrollees under an oral or written agreement
  3. Leases real property or sells materials to the MA organization or Part D plan sponsor at a cost of more than \$2,500 during a contract period.
- **Health Care Services**- The Medicare Compliance Program requirements described in this guide apply to health care providers contracted with FCC to participate in our Medicare network.
- **Administrative Services**- The Medicare Compliance Program requirements also apply to entities with which we contract to perform administrative service functions relating to our MA or Part D contracts with CMS. Examples of these functions include: claims administration, processing and coverage adjudication, utilization management, licensing and credentialing, sales and marketing, quality improvement, application processing, enrollment, disenrollment and membership functions, appeals and grievances, pharmacy benefit management, hotline operations, customer service, bid preparation, outbound enrollment verification, provider network management, health care services, etc.

## Section II: FirstCarolinaCare Medicare Compliance Program

As a Medicare Advantage Prescription Drug Plan with a CMS contract, we are committed to operating a health plan that meets the requirements of all applicable state, federal and Medicare laws. According to CMS, each Medicare Advantage Organization must implement a compliance program that is effective in preventing, detecting and correcting noncompliance and fraud, waste and abuse. The elements of an effective compliance program include:

- Written Policies, Procedures and Standards of Conduct
- Designation of a Compliance Officer, Compliance Committee and Governing Body
- Effective Training and Education
- Effective Lines of Communication
- Well-Publicized Disciplinary Standards
- Effective System for Routine Monitoring, Auditing and Identification of Compliance Risks
- Procedures and System for Prompt Response to Compliance Issues

### **Section III: FDR Compliance Requirements and How to Meet Them**

The key compliance requirements for FDRs and recommendations for meeting them are outlined below. FCC also requires all of its FDRs to complete and submit the **Medicare Program Requirements Attestation** document located on our website annually to provide us with evidence of compliance with these requirements.

#### *A. Written Policies and Procedures and Standard of Conduct*

1. **CMS Requirement:** Plan Sponsors are expected to distribute its Standards of Conduct and any applicable policies and procedures to all of its FDRs in order to communicate the plan's compliance expectations. Alternatively, the plan sponsor may ensure that the FDR has comparable policies and procedures or Standards of Conduct that are similar to its own that are distributed to all FDR employees and downstream entities within 90 days of hire and annually thereafter. (*Medicare Managed Care Manual Chapter 21, Section 50.1.3*)
2. **How To Comply:** As an FCC FDR, you must either:
  - Distribute FCC's Code of Conduct and applicable policies and procedures to all your employees and downstream entities within 90 days of hire and annually thereafter OR
  - Distribute Standards of Conduct or policies and procedures that are similar to FCC's to all your employees and downstream entities within 90 days of hire and annually thereafter

**NOTE:** FCC's most current Standard of Conduct ("Code of Ethical Conduct") document and policies and procedures can be located on our website at- <http://www.firstcarolinacare.com/medicare/Compliance/index>

#### *B. General Compliance And Fraud, Waste and Abuse (FWA) Training*

1. **General Compliance Education-** Plan Sponsors must ensure that general compliance education information is communicated to their FDRs. The plan sponsor's expectations can be communicated through distribution of its Standards and/or compliance policies to FDR's employees.
2. **Fraud, Waste and Abuse Training-** FCC's employees, governing body members and FDR employees who are involved in the administration or delivery of Parts C & D benefit must at a minimum, receive general Medicare and FWA training within 90 days of initial hiring or contracting and annually thereafter. Plans must be able to show that their employees and FDRs have fulfilled these training requirements. Examples of proof of training may include copies of sign-in sheets, employee attestations and electronic certifications, from the

employees taking and completing the training. (*Medicare Managed Care Manual Chapter 21, Section 50.3.2*)

3. **How To Comply:**

- Take the CMS Standardized General Compliance and FWA Training Modules available on CMS' Medicare Learning Network (MLN) webpage at: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/WebBasedTraining.html>.
- FCC Agents and/or Brokers must comply with this requirement by completing the Medicare and Fraud, Waste and Abuse training administered by America's Health Insurance Plans (AHIP) and provide evidence of completion to FCC annually.

**NOTE:** If you are “**deemed**” (applies only to FDRs or physicians who have met the FWA certification requirements through enrolment into Parts A and B of the Medicare Program or through accreditation as a supplier of DMEPOS), then your organization is exempt from completing the FWA training requirement. Your organization must still complete the General Medicare Training.

C. *Reporting Mechanisms*

1. **CMS Requirement:** Plan Sponsors must have a system in place to receive, record, respond to and track compliance questions or reports of suspected or detected noncompliance or potential FWA from employees, governing body members, members, FDRs or their employees. Reporting systems must maintain confidentiality, allow anonymity (e.g. through telephone hotlines or mail drops) and emphasize the plan sponsor's /FDR's policy of non-intimidation and non-retaliation for good faith reporting of compliance concerns and participation in the compliance program.

The methods available for reporting compliance or FWA concerns and the non-retaliation policy must be publicized throughout the sponsor's or FDR's facilities. Plan sponsors must make the reporting mechanisms user friendly, easy to access and navigate and available 24 hours a day for employees, governing body members, enrollees and FDRs.

2. **How To Comply:** Distribute FCC's Compliance Helpline Poster or post it in a visible area in your facility. This poster provides the required notifications regarding the availability of an anonymous reporting method and FCC's policy prohibiting retaliation or retribution against anyone who reports suspected violations in good faith. The Helpline Poster is in Appendix A of this guide and is also available on FCC's website at: [www.firstmedicare.com/medicare/Compliance](http://www.firstmedicare.com/medicare/Compliance).

If you partner with multiple Medicare Advantage plan sponsors, train your employees on your organization's reporting processes, including an emphasis that reports must be made to the appropriate plan sponsor. Notify your employees that they are protected from retaliation for False Claims Act complaints and any other applicable anti-retaliation protections that your organization has.

D. *OIG and GSA Exclusion Screening*

1. **CMS Requirement:** Plan Sponsors must review the Department of Health and Human Services OIG List of Excluded Individuals and Entities (LEIE) and the GSA Excluded Parties Lists System (EPLS) prior to the hiring and contracting of any new employee, temporary employee, volunteer, consultant, governing body member, or FDR and monthly thereafter to ensure that none of these persons or entities are excluded or become excluded from participation in state or federal programs. Monthly screening is essential to prevent inappropriate payment to providers, pharmacies and other entities. (*Medicare Managed Care Manual Chapter 21, Section 50.6.8*).
2. **How To Comply:** Review the LEIE and EPLS prior to hiring and contracting and monthly thereafter. Be prepared to produce evidence that your employees and any entities with whom you contract have been timely checked against the exclusion lists.

**LEIE:** <http://www.oig.hhs.gov/exclusions/index.asp>

**EPLS:** <http://www.sam.gov>

#### E. *Offshore Subcontractors*

1. **CMS Requirement:** Medicare Advantage Organizations who contract with FDRs that work with offshore contractors (FDRs) to perform Medicare-related work that uses beneficiary protected health information (PHI) must provide CMS with specific offshore subcontractor information and complete an attestation regarding protection of beneficiary PHI. (*CMS memo dated 08/28/08 re: Offshore Subcontractor Data Module in HPMS*).
2. **How To Comply:**
  - Notify FCC if your organization or if any of your organization's subcontractors (downstream entities) perform contractually delegated services offshore that require the sharing of member protected health information (PHI). FCC will request the information necessary to complete the Offshore Subcontractor Data Module in HPMS.
  - Verify that any contractual agreements with those entities include all Medicare Part C and D language.
  - Conduct annual audits of offshore subcontractors and make audit results available upon request from CMS.
  - Download, complete and submit FCC's Offshore Services\_Attestation form.

#### F. *Record Retention and Availability*

1. **CMS Requirements:**
  - All FDRs and their downstream entities must comply with Medicare laws, regulations and CMS instructions and agree to audits, inspections by CMS and to cooperate, assist and provide information as requested, and maintain records for a minimum of ten (10) years. (*Medicare Managed Care Manual Chapter 11, Section 100.4*)
  - Plan Sponsors are accountable for maintain records for a period of 10 years of the time, attendance, topic, certificates of completion (if applicable) and test scores of any tests

administered to their employees and must require FDRs to maintain records of their employee training. (Medicare Managed Care Manual Chapter 21, Section 50.3.2)

2. **How To Comply:**

- Maintain all records, reports and supporting documentation that relate to the functions your organization is performing or providing under the FCC's for at least ten (10) years.
- Maintain records of any Medicare general compliance and fraud, waste and abuse training and education taken by your employees for 10 years. The records must demonstrate the date of the training, the topic, attendance and certificate of completion and/or test scores, if applicable. Examples of proof of training may include copies of sign-in sheets, employee attestations and electronic certifications from employees.
- Be prepared to make your records available to FCC as part of an audit or monitoring activity and to CMS or a CMS designee in the event of a program audit.

IV. **What May happen if you do not comply**

Failure to comply with any of these requirements or non-submission of the annual attestation within the requested deadline may lead to:

- Issuance of a Notice of Non Compliance (NONC) from the Compliance, development and completion of a root cause analysis (RCA) and Corrective Action Plan (CAP).
- Retraining, Monitoring and Auditing to ensure compliance.
- Termination of your contract with FCC.