



**First Tier, Downstream,
and Related (FDR) Entity
Compliance Program Guide**



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Care N’ Care Insurance Company of North Carolina, Inc. (CNC-NC) is committed to conducting business with the highest ethical standards and in compliance with all applicable federal and state laws and regulations.

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I. Introduction—Care N’ Care Insurance Company of North Carolina, Inc.’s Commitment to Compliance

Care N’ Care Insurance Company of North Carolina, Inc. (CNC-NC) is committed to conducting business with the highest ethical standards and in compliance with all applicable federal and state laws and regulations. CNC-NC strives to effectively prevent, detect, and correct non-compliance with laws and regulations, including at the vendor level. CNC-NC’s promise is to demonstrate continued commitment to compliance and a sustainable and operational delegation oversight program.

Requirements for a Compliance Program

CNC-NC contracts with the Centers for Medicare & Medicaid Services (CMS) as a Medicare Advantage Organization (MAO) to provide coverage to Medicare beneficiaries for Medicare Part C medical and Part D prescription drug coverage.

Our contracts with CMS require that we maintain an effective Compliance Program as stated in the following CMS guidance:

- Title 42 of the Code of Federal Regulations (CFR), Parts 422 and 423 (referred to as Parts C & D)
- Medicare Managed Care Manual, Chapter 21—Compliance Program Guidelines and the Prescription Drug Benefit Manual, Chapter 9—Compliance Program Guidelines (both manuals contain identical guidance located at: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter9.pdf>)

Vendors Providing Cost-Effective Solutions

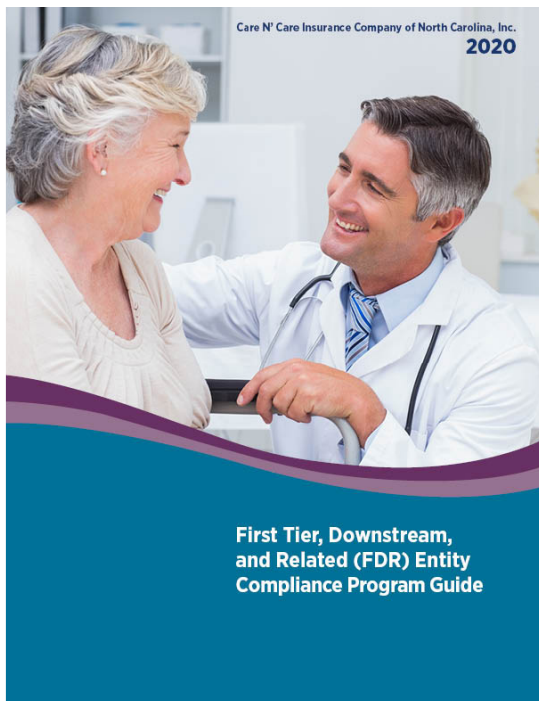
CNC-NC contracts with individuals and entities (vendors) who possess expertise, skill, and knowledge of their respective industries, trades, or professions and who can provide efficient and cost-effective healthcare and/or administrative services. When a vendor provides a core healthcare and/or administrative service on behalf of CNC-NC that is required of CNC-NC under its contract with CMS, the vendor meets the definition of a First Tier, Downstream, or Related (FDR) Entity.



II. What is an FDR?

CMS Definitions

- A. First Tier Entity**—is any party that enters into a written arrangement, acceptable to CMS, with a Medicare Advantage Organization (MAO) to provide administrative services and/or healthcare services to a Medicare-eligible individual under the Medicare Advantage Part C and/or Part D Program (e.g., vendors contracted with CNC-NC to provide claim processing, utilization management, transportation, or other core healthcare and/or administrative functions).
- B. Downstream Entity**—is a party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the Medicare Advantage benefit or Part D benefit, below the level of the arrangement between an MAO and a First Tier Entity (e.g., vendors contracted with an FDR to help fulfill its contractual obligations to CNC-NC). The written arrangements continue down to the level of the ultimate provider of services for both health and administrative functions.
- C. Related Entity**—any entity that is related to an MAO by common ownership or control and: Performs some MAO management functions under contract or delegation; furnishes services to Medicare enrollees under an oral or written agreement; or leases real property or sells materials to the MAO at a cost of more than \$2,500 during a contract period. CMS does allow sponsors (plans) some flexibility in their classification of a vendor as an FDR.



III. What is the Purpose of this FDR Compliance Guide?

This FDR Compliance Guide is provided because your organization has been identified as an FDR by CNC-NC. CMS requires FDRs to fulfill the same Compliance Program requirements that apply to CNC-NC. This guide also contains additional expectations CNC-NC requires of all FDRs.

You'll find a summary of requirements in this guide. Please use this as a quick reference to understand the CMS Compliance Program requirements and to ensure that you have internal processes to support your Compliance Program.

NOTE: Section I of this guide provides information where you can obtain more detailed guidance on the CMS Compliance Program requirements.

IV. FDR Compliance Delegation Oversight Program Requirements

CNC-NC is committed to ensuring that our FDRs are compliant with applicable laws, rules, and regulations. It is important that you follow these requirements. FDRs are expected to adhere to CMS Compliance Program requirements and CNC-NC's standards when conducting business on CNC-NC's behalf.

Compliance Program Elements

Your organization and your Downstream Entities (if any) must comply with CMS Compliance Program requirements. There are seven elements to ensure that your Compliance Program meets CMS' standards:

- **Element 1:** Written Policies, Procedures and Standards of Conduct
- **Element 2:** Designating a Compliance Officer and Oversight of Compliance Program
- **Element 3:** Effective Training and Education
- **Element 4:** Effective Lines of Communication
- **Element 5:** Well-Publicized Disciplinary Standards
- **Element 6:** Effective System for Routine Monitoring and Identification of Compliance Risks
- **Element 7:** Prompt Response to Compliance Issues



ELEMENT ONE: Written Policies, Procedures and Standards of Conduct

FDRs must provide written policies and procedures and Standards of Conduct to all employees providing administrative and/or healthcare services on behalf of CNC-NC. FDRs must also ensure their Downstream Entities distribute appropriate policies and procedures and Standards of Conduct to their employees that support similar requirements.

These policies and procedures and Standards of Conduct should include the following information:

1. FDR's commitment to comply with all applicable federal and state standards
2. FDR's expectations of its employees to comply with the policies and Standards of Conduct
3. FDR's Compliance Program operation
4. Appropriate guidance for employees and others on dealing with suspected, detected, or reported compliance issues
5. Details on how employees should communicate compliance issues to appropriate compliance personnel
6. Description of how suspected, detected, or reported compliance issues are investigated/resolved
7. Non-intimidation and non-retaliation protections for individuals who make good faith reports of non-compliance activity to its Compliance Program

Such information must be distributed to FDR employees and contractors:

1. Within 90 days of hire/contract; and
2. When updated or annually thereafter

FDRs can determine the most effective method to distribute the policies and procedures and Standards of Conduct (e.g., via hardcopy at the time of hire/contract, via electronic copy, posting a copy to the FDR's intranet, etc.). FDRs must maintain documentation that demonstrates the information was distributed.

Feel free to distribute CNC-NC's Code of Conduct to your employees.

ELEMENT TWO: Designating a Compliance Officer and Oversight of Compliance Program

Each FDR must designate a senior level employee to act as the Compliance Officer for its organization. The Compliance Officer must maintain responsibility for the implementation of the FDR's Compliance Program, including responding to reports of potential fraud, waste, and abuse (FWA) and non-compliance. The Compliance Officer maintains documentation on the Compliance Program and is responsible to oversee, develop, and monitor corrective action plans.

The Compliance Officer must have direct access to the FDR's senior-most leader (e.g., the CEO or president/owner) and/or the FDR's governing body (if applicable).

ELEMENT THREE: Effective Training and Education

As of January 1, 2019, Final Rule CMS-4182-F, eliminated Part C and Part D compliance program and FWA training requirements for FDRs. CNC-NC decided not to require our FDRs to provide us with this training completion attestation process. While we encourage all appropriate FDR personnel to complete the annual FWA and general compliance trainings, we will no longer require our FDRs to acknowledge this training completion with an attestation. FDRs should include privacy and security training for appropriate staff.

Privacy and Security Training

FDRs are required to protect all of CNC-NC's member information, including Protected Health Information (PHI), and Personally Identifiable Information (PII). Employees who have access to PHI and/or PII must receive Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security training within 90 days from the date of hire and annually thereafter.

Privacy and Security training should address topics such as:

1. Federal and state laws governing the confidentiality of PHI and PII
2. When PHI and PII may be accessed, used, and disclosed
3. Safeguards to protect the integrity, confidentiality, and availability of PHI and PII

Validation of Training Completion

FDRs must retain records of training completion on the topics listed previously. Evidence may include sign-in sheets/training logs (if classroom training is provided), electronic certificates/reports generated from the FDR's training system.

ELEMENT FOUR: Effective Lines of Communication

An FDR must maintain effective communication between its employees and its Downstream Entities. This should include providing the name, contact, and location information of its Compliance Officer to both its employees and any Downstream Entities.

FDRs must adopt a policy of non-intimidation and non-retaliation against employees for good faith reports of non-compliance or FWA. FDRs must advertise to their employees the policy of non-intimidation and non-retaliation.

How to Report Suspected Compliance Issues

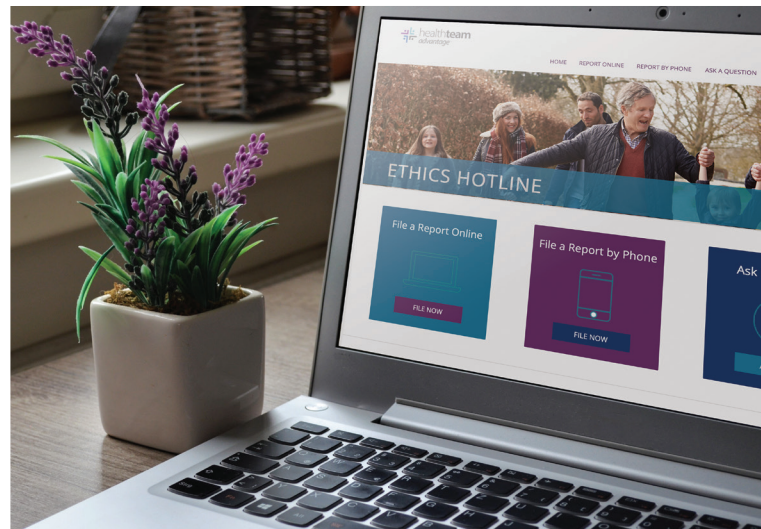
FDR employees are expected to report any suspected issues of non-compliance or FWA to the FDR's Compliance Officer. Alternative reporting mechanisms include anonymous reporting via the FDR's website, or compliance hotline.

CNC-NC provides additional reporting mechanisms for an FDR's employees via its web portals <https://hta.ethicspoint.com>, or <https://tealpremier.ethicspoint.com>. Please feel free to share these links with your employees.

ELEMENT FIVE: Well-Publicized Disciplinary Standards

FDRs must require their employees to adhere to the requirements of their Compliance Program. FDRs should provide employees examples of what constitutes non-compliant, unethical, and/or illegal behavior that is in violation of the Compliance Program, as well as publicize disciplinary standards that will be enforced when non-compliance is identified. Some examples of the types of publication methods include:

1. FDR's intranet site
2. General compliance training
3. Posters prominently displayed throughout employee work and break areas



Enforcement of Disciplinary Standards

FDRs must be able to demonstrate that disciplinary standards are enforced timely, consistently, and in an effective manner. Records pertaining to any disciplinary action in response to a compliance violation should be maintained for a period of 10 years.

*FDRs must report any issue of non-compliance or FWA to CNC-NC if the issue is associated with the services performed on CNC-NC's behalf.

ELEMENT SIX: Effective System for Routine Monitoring and Identification of Compliance Risks

CNC-NC is ultimately responsible for fulfilling the terms and conditions of its contract with CMS. If any function is performed by an FDR, CMS requires monitoring and auditing to ensure such functions are performed in accordance with applicable laws and regulations.

FDRs must perform Debarment and Exclusion Screenings

Federal law prohibits Medicare, Medicaid, and other federal healthcare programs from paying for items or services provided by debarred or excluded individuals and entities from participation in any federal healthcare programs.

FDRs must screen employees, temporary employees, volunteers, consultants, governing body members, contractors and Downstream Entities against the following debarment and exclusion sites prior to employing or contracting with the employee/contractor and then monthly thereafter:

1. Office of Inspector General (OIG): <https://exclusions.oig.hhs.gov/>
2. System for Award Management (SAM): <https://www.sam.gov/SAM>

FDRs must maintain the records of evidence that they checked these sources for a minimum of 10 years.

Required Action

If any individual or entity performing services for CNC-NC is on the OIG or SAM exclusion list, you must verify that the exclusion match is valid. Upon confirmation, the individual or entity shall not work on any CNC-NC business, and CNC-NC must be notified immediately.

Preclusion List Screening

As of 2019, CMS publishes a Preclusion List of providers and pharmacies that CMS has identified as being excluded from receiving payment from a Medicare plan for healthcare items, services and Part D drugs. CMS publishes the Preclusion List monthly and CNC-NC is responsible to send it to FDRs to ensure the requirements, notifications, and timeframes are met. For more information: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/PreclusionList>

Your organization may be identified as an entity required to run checks of providers and pharmacies against the Preclusion List. CNC-NC may require your organization to submit a monthly Preclusion List attestation. By completing this monthly attestation, your organization attests that it meets the CMS requirements and will report any findings to CNC-NC.

1. Complete a review to determine if the organization has any providers or pharmacies on the Preclusion List.
2. If none, return the Preclusion List attestation to CNC-NC by the end of each month.

Required Action

If yes, remove the provider or pharmacy. Also, notify all affected enrollees who have received care from the provider or pharmacy within the last 12 months.

1. If you do not already have the plan's enrollee notification letter, please let CNC-NC know and a copy will be forwarded.
2. CNC-NC will need confirmation from the FDR that the Preclusion steps have been taken via the monthly attestation, due on the last day of each month.



Avoiding a Conflict of Interest

A Conflict of Interest (COI) exists when the interests of an FDR or its employees influence, or has the appearance to influence, their ability to make objective decisions in the course of the FDR job duties and responsibilities. A COI may also exist if the demands of any outside activities hinder or distract an employee from the performance of job duties or responsibilities or result in use of company resources for other than company purposes. FDRs and their employees must avoid a COI at all times.

If a potential COI arises, the activity must be reported to the FDR's Compliance Officer. If a COI relates to CNC-NC's business, this must be reported immediately to CNC-NC's Compliance and Integrity Department at 855-741-4518, <https://hta.ethicspoint.com>, or <https://tealpremier.ethicspoint.com>.

ELEMENT SEVEN: Prompt Response to Compliance Issues Reporting Compliance Concerns

There are confidential ways to report suspected or detected non-compliance or potential FWA to CNC-NC. Reporting mechanisms are on our websites at <https://hta.ethicspoint.com>, <https://tealpremier.ethicspoint.com> or, call the Helpline at 855-741-4518.

You can share these links with your employees or Downstream Entities. You can also keep them as a reference tool and use your own internal processes for reporting and collecting these issues. If you choose to use your own processes, make sure that any issues of non-compliance and/or FWA are reported in a timely manner to CNC-NC's Compliance and Integrity Department. Any issues of detected non-compliance or potential FWA must be investigated in a timely manner and reported to the appropriate parties.

Reporting Non-Permitted Disclosures and Breaches

FDRs are required to protect CNC-NC's member information, including PHI and PII. If an FDR detects or is made aware of a non-permitted disclosure (breach) of PHI or PII affecting CNC-NC members or its employee data, they are to report it immediately to CNC-NC's Compliance and Integrity Department.

Reporting

FDRs use their own system of non-permitted disclosure (breach) reporting and forward a copy of it to CNC-NC's Compliance and Integrity Department at: privacyissues@healthteamadvantage.com.

Use the CNC-NC's Compliance and Integrity Department's Issue Reporting Document (provided upon request) and forward a copy of it to CNC-NC at: privacyissues@healthteamadvantage.com.

Corrective Action Plans

You must notify CNC-NC's Compliance and Integrity Department immediately if non-compliance is identified related to the functions provided for CNC-NC. CNC-NC may require you to conduct a root cause analysis and implement a Corrective Action Plan (CAP). The CAP must contain the following:

1. Date identified
2. Root cause
3. Period of time
4. How it was identified
5. Summary of issue
6. Corrective action

CNC-NC expects FDRs to take timely action on all issues of non-compliance and FWA. This includes timely implementation of disciplinary actions, when applicable, to prevent a recurrence of non-compliance.

V. Routine Monitoring and Auditing

CNC-NC monitors and audits all First Tier Entities. This promotes compliant administration of its contracts with CMS and ensures compliance with applicable laws and regulations. FDRs must cooperate and participate in any monitoring and auditing activities. CNC-NC monitoring and auditing is reported on the annual Compliance Program Effectiveness self-assessment audit, as well as any CMS program audits.

First Tier Entities are also responsible to monitor and audit functions provided to CNC-NC. If a First Tier Entity contracts with other individuals or entities to provide administrative and/or healthcare services to fulfill its obligations to CNC-NC, the First Tier Entity must monitor and audit the Downstream Entity to ensure it performs such functions in accordance with all applicable laws and regulations and in accordance with the First Tier Entity's contract with CNC-NC. The First Tier Entity must also ensure its contracts with Downstream Entities contain CMS-required provisions.

If FDR functions are not in compliance with applicable laws and regulations, or meet the terms of its contract with CNC-NC, CNC-NC will require the FDR to develop and submit a CAP.

VI. Offshore Operations and CMS Reporting

All work performed by FDRs on CNC-NC's behalf is usually performed within the United States and its territories. An FDR may request approval in advance from CNC-NC to utilize employees or vendors outside the United States. This work is considered offshoring and the FDR must notify CNC-NC's Compliance and Integrity Department if it does, or plans to, directly contract with an entity that offshores.

If CNC-NC approves the offshore proposal, CNC-NC must report the offshore arrangement to CMS. FDRs must also sign an attestation annually as to how they will oversee the offshore functions.

VII. FDR Attestation Requirements

CNC-NC further requires the following:

1. A monthly attestation that all employees and vendors are being appropriately screened against the exclusion and debarment lists, and, if appropriate, their provider network has been screened against the CMS Preclusion list.
2. A quarterly report of exclusion and debarment results.
3. An annual attestation that all employees and vendors were appropriately screened against the exclusion and debarment lists, and, if applicable, their provider network has been screened against the CMS Preclusion list.

An Authorized Representative from the FDR must attest to its compliance with these requirements. An Authorized Representative may be the Compliance Officer, Chief Executive Officer, Chief Operations Officer, Chief Financial Officer, or an individual of similar title and authority.

VIII. What if an FDR Fails to Comply?

If an FDR fails to meet any of these Compliance Program requirements, this puts CNC-NC and its members at risk and may lead to:

1. Development of a CAP
2. Additional monitoring or auditing
3. Monetary penalties
4. Possible contract termination

CNC-NC's response to issues of non-compliance will depend on the severity of the compliance issue. If an FDR, CNC-NC, federal, or state agency identifies areas of non-compliance by an FDR, the FDR must take prompt action to correct the issue and prevent a recurrence.

IX. Questions or Comments?

If you have any questions regarding this guide or the CMS Compliance Program requirements, please contact:

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