



CARE1ST HEALTH PLAN

POLICY & PROCEDURE

Corporate Compliance Department

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| Policy Title: Compliance Expectations for Care1st's First-Tier, Downstream, and Other Related Entities (FDRs) | | |
| Policy No: 50.17.21 | Orig. Date: 11/2012 | |
| Effective Date: 11/2012 | Revision Date: | Revision No: |
| P&P Subcommittee Approval:  | Date: 12/13/12 | Scope of Coverage: Medicare |
| Board Approval:  | Date: 12-13-12 | |

PURPOSE:

To document and formalize Care1st Health Plan's ("Care1st") compliance expectations from its delegated and/or contracted FDRs who are contracted to perform services or administer the Medicare Part C and Part D programs on behalf of Care1st Health Plan.

POLICY:

As part of Care1st's compliance strategy in achieving an effective compliance program, Care1st distributes and communicates its policies and procedures and Standards of Conduct (SoC) for vendors/FDRs to its FDRs. The distribution / communication is conducted annually (for existing contracted FDRs) and within 90 calendar days of contract for new FDRs.

Care1st's delegated and/or contracted FDRs must also adhere to the following compliance requirements below. **This is not an exhaustive list;** this list does not replace existing contractual, State, Federal, and other accreditation and regulatory requirements that the Care1st's delegated or contracted FDRs are required to comply with in carrying out their duties and responsibilities under the Medicare Part C and Part D programs.

ATTESTATION: The FDRs must complete, sign, and send/mail the attestation at the end of this policy and procedure to Care1st Health Plan, at ComplianceDepartment@care1st.com. Attestation must be conducted within 90 calendar days from the effective date of the contract and annually thereafter.

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Note: Care1st Health Plan may, on special circumstances and/or as deemed appropriate by Care1st's Management, use a calendar basis (rather than on a fiscal basis) with regards to the distribution of Compliance P&Ps, the Standards of Conduct for Vendors and FDRs, and the Anti-Fraud Plan (AFP) and request for complete attestations.

PROCEDURES:

- A. Excluded Listings:** All Care1st's delegated and/or contracted FDRs must verify or validate their employees and their downstream contracted entities against the Department of Health and Human Services (DHHS) Office of Inspector General (OIG) List of Excluded Individuals and Entities (LEIE list) <http://exclusions.oig.hhs.gov/> and the General Service Administration (GSA) Excluded Parties List System (EPLS) <https://www.epls.gov/> prior to the hiring or contracting of any new employee, temporary employee, volunteer, consultant, governing body member, or FDR, and **monthly thereafter**, to ensure that no persons/individuals or entities are excluded or become excluded from participation in federal programs. **Monthly screening is essential to prevent inappropriate payment to providers, pharmacies, and other entities that have been added to the exclusions lists since the last the list was checked.** After individuals and entities are initially screened against the entire LEIE and EPLS at the time of hire or contracting, FDRs need only review the LEIE supplement file provided each month, which lists the entities added to the list that month, and review the EPLS updates provided during the specified monthly time frame. OIG's LEIE includes all health care providers and suppliers that are excluded from participation in federal health care programs, including those health care providers and suppliers that might also be on the EPLS. In addition to health care providers (that are also included on the OIG LEIE) the EPLS includes non-health care contractors.
- B. Fraud, Waste, and Abuse (FWA) Training:** All Care1st delegated and/or contracted FDRs, and the FDRs' employees and FDRs' downstream contracted entities, who have involvement in the administration or delivery of Parts C and D benefits must, at a minimum, receive FWA training **within 90 calendar days from initial contracting date, and annually thereafter.** Care1st Health

Plan provides or distributes the training materials to its FDRs. Care1st requires its FDRs to submit an attestation that required FWA training has been completed.

a. Topics on FWA include, but are not limited to the following:

- i. Laws and regulations related to Medicare Advantage and Part D FWA (i.e., False Claims Act, Anti-Kickback statute, Health Insurance Portability and Accountability Act (HIPAA)/HITECH, etc.);
- ii. Obligations of FDRs to have appropriate policies and procedures addressing FDRs;
- iii. Processes for FDRs and to report suspected FWA to Care1st Health Plan; or, as to FDR employees, either to report to Care1st directly or to the FDR employees' employer who then must report the incident to Care1st;
- iv. Protection for FDRs and FDR employees who report suspected FWA; and
- v. Types of FWA that can occur in the settings in which Care1st and the FDR employees work.

b. Care1st expects FDRs to maintain records for a period of 10 years of the time, attendance, topic, certificates of completion (if applicable), and test scores of any tests (if applicable) administered by the FDRs to their employees.

c. **FWA Deeming:** FDRs who have met the FWA certification requirements through enrollment into Parts A or B of the Medicare program or through accreditation as a supplier of Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) are deemed to have met the FWA training and education requirements. No additional documentation beyond the **documentation necessary for the proper credentialing is required** that an FDR or an employee of the FDR is deemed.

C. General Compliance Training: All Care1st delegated and/or contracted FDRs, and the FDRs' employees and FDRs' downstream contracted entities, which have involvement in the administration or delivery of Parts C and D benefits, must, at a minimum, receive General Compliance training **within 90 calendar days from initial contracting date, and annually thereafter.** Care1st Health Plan provides or distributes the training materials to its FDRs. Care1st

requires its FDRs to submit an attestation that required FWA training has been completed.

- a. The General Compliance training requirements may be satisfied through:
 - i. Distribution of training materials to the FDRs;
 - ii. Classroom training;
 - iii. Online training modules; or
 - iv. Attestations that FDR employees have read and received Care1st's Standards of Conduct for Vendors and/or compliance policies and procedures.
- b. Proofs of Training Requirements: If FDRs have their own Compliance Training Program, FDRs must maintain copies of sign-in sheets, training materials, employee attestations and electronic certifications from their employees who took and completed the training.
- c. **Topics of the General Compliance Training program may include:**
 - i. General description of Medicare Compliance Program, including a review of compliance policies and procedures, the Standards of Conduct, and Care1st's commitment to business ethics and compliance with all Medicare program requirements. (Source: Seven Elements of A Compliance Program);
 - ii. An overview of how to ask compliance questions, request compliance clarification or report suspected or detected noncompliance. Training emphasizes confidentiality, anonymity, and non-retaliation for compliance related questions or reports of suspected or detected noncompliance or potential FWA; (Source: Standards of Conduct for Vendors).
 - iii. The requirement to report to Care1st actual or suspected Medicare program noncompliance or potential FWA; (Source: Standards of Conduct for Vendors).
 - iv. A review of the Care1st's disciplinary guidelines for non-compliant or fraudulent behavior and communicate how such behavior can result in mandatory retraining and may results in disciplinary action, including termination of contract with Care1st when such behavior is serious or

repeated or when knowledge of a possible violation is not reported; (Source: Standards of Conduct for Vendors).

- v. Attendance and participation in compliance and FWA training program as a condition of continued contractual relationship; (Source: Distribution of FWA Training materials).
- vi. An overview of HIPAA/HITECH and the importance of maintaining the confidentiality of personal health information (PHI);
- vii. An overview of the monitoring and auditing process; (Source: Chapter 21 – Medicare Managed Care Manual, Section 50.6, and Element VI – all sections under 50.6).
- viii. A review of the laws that govern employee conduct in the Medicare Program. Following are examples of these laws and regulations:
 - Medicare Regulations governing Parts C and D found at 42 Code of Federal Regulations §§422 and §§423 respectively.
 - All sub-regulatory guidance produced by CMS and Health and Human Services (HHS) such as manuals, training materials, Health Plan Management System (HPMS) memos, and guides.
 - Fraud Enforcement and Recovery Act of 2009.
 - Prohibitions against employing or contracting with persons or entities that have been excluded from doing business with the Federal Government (42 United States Code (U.S.C) §1395w-27(g) (1) (G)).
 - False Claims Acts (31 U.S.C. §§3729-3733).
 - Federal Criminal False Claims Statutes (18 U.S.C. §§287, 1001).
 - Anti-Kickback Statute (42 U.S.C. §1320a-7b (b)).
 - Fraud Enforcement and Recovery Act of 2009.
 - Physician Self-Referral (“Stark”) Statute (42 U.S.C. §1395nn).
 - Civil Monetary Penalties of the Social Security Act (42 U.S.C. §1395w-27(g)).
 - The Beneficiary Inducement Statute (42 U.S.C. §1320a-7a (a) (b)).

- Title XVIII of the Social Security Act.
- Patient Protection and Affordable Care Act (Pub's. No. 111-148, 124, 124 Stat. 119).

D. Auditing and Monitoring: Care1st's delegated and contracted entities (FDRs) must comply with Care1st's routine audits, monitoring, and identification of compliance risks to determine, test, and confirm if FDRs comply with Medicare regulations, sub-regulatory guidance, and contractual agreements, and all applicable Federal and State laws, as well as Care1st's Policies and Procedures and FDRs' own internal policies and procedures to protect against Medicare program noncompliance and potential FWA.

- a. FDRs must achieve "sustained" audit scores that meet Care1st's established passing threshold or guidelines.
- b. Non-compliant audit scores are subject to corrective action plans (CAPs) to correct identified deficiencies.
- c. Deficiencies identified must be corrected via corrective action plans and must be implemented timely and/or as specified in accordance with the contractual and delegation agreements.
- d. Continued non-compliance with audits and corrective action plans may be subject to de-delegation, termination of contract, and/or other actions as determined by Care1st Management.

E. Written Policies and Procedures (P&Ps): Care1st's delegated and contracted entities or FDRs must establish P&Ps documenting and directing the operations of Care1st's delegated functions (e.g., Claims, Utilization Management (UM), Credentialing, Dental Grievance, Dental Appeals, Administration of Chiropractic benefits, services on mental health benefits, marketing and/or development of marketing materials, scripts, etc.) as specified on the contract and/or delegation agreement(s). The P&Ps must be Medicare-specific stand alone documents. The P&Ps will be reviewed by Care1st's internal auditors assigned to specific delegation area (e.g., UM, Claims, etc.).

F. Participation in Regulatory (Federal, State, or Accrediting Agencies) Audits, Investigations, and Monitoring. Care1st's FDRs and/or contracted entities are required to participate, cooperate, and/or comply with any Federal (e.g., CMS) audits, investigations, and/or monitoring as Care1st's FDRs. Because FDRs perform functions on behalf of Care1st, all and/or any delegated/contracted transactions, procedures, policies, and other administrative requirements, FDRs

must be ready and willing to provide all documentation requested by the regulatory agencies along with other administrative requests like interview with delegated staff, etc.

G. Compliance with Health Insurance Portability and Accountability Act of 1996 (HIPAA) and Privacy Laws:

a. All Care1st's FDRs must comply with the HIPAA and Privacy laws including the Health Information Technology for Economic and Clinical Health Act (HITECH). If/when a potential/suspected/actual breach of protected health information (PHI) or personally identifiable information (PII) has occurred, the FDR must notify Care1st Health Plan using the following guidelines:

i. **The FDR (or contracted entity) must notify Care1st's Health Plan's Corporate Compliance Officer, Brooks Jones, at (323) 889-6638, ext. 6202 or at BJones@care1st.com or at ComplianceDepartment@care1st.com in accordance with the following timelines:**

- Within 24 hours of discovery, in as much as is known.

ii. Timely reporting and coordination with the appropriate regulatory agencies will be determined by Care1st's Senior Management (Compliance, Legal, Administration, and others as required) and/or in accordance with the Office of Civil Rights' (OCR) timelines and/or as defined by Care1st's Policy and Procedures 70.17.6 (*Breach Notification Procedure per HITECH and the American Recovery and Reinvestment Act of 2009 (ARRA)*), the Department of Health Care Services (DHCS – within 72 hours of discovery), the Centers for Medicare & Medicaid Services (CMS), and other regulatory agencies.

iii. Mitigation and corrective actions are coordinated between Care1st and the contracted entity and/or as specified per the Business Associate Agreement (BAA) – if it applies.

Authorities and References:

- Medicare Managed Care Manual (MMCM) Chapter 21 – Compliance Program Guidelines – Sections: 50.3.1, 50.3.2, 50.6.1, 50.6.6, 50.6.8, and 50.6.11.
- Code of Federal Regulations (CFRs): 42 §§ 422.503(b)(4)(vi)(C), 423.504(b)(4)(vi)(C), 422.503(b)(4)(vi)(C), 423.504(b)(4)(vi)(C), 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F), 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F), 423.504(b)(4)(vi)(F), 423.504(b)(4)(vi)(F), 423.752(a)(6), 1001.1901, 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F), 422.504(e)(2), and 423.505(e)(2).
- <http://www.hhs.gov/ocr/privacy/index.html>
- Care1st Policy and Procedure 70.17.6 (*Breach Notification Procedure per HITECH and the American Recovery and Reinvestment Act of 2009 (ARRA)*)

H. ATTESTATION FORM: The following attestation form must be completed, signed, and returned to Care1st's Compliance Department at ComplianceDepartment@care1st.com.

***[Insert Name of Delegated or Contracted Entity]** has distributed Care1st's *Policies and Procedures* of its Compliance Program, its *Anti-Fraud Plan for Vendors/FDRs*, and *Standards of Conduct for Vendors and FDRs* to our employees and our other contracted downstream entities on [insert date MM/DD/YYYY]. We have also instructed our employees and other downstream entities to review these policies and procedures and Care1st's *Standards of Conduct for Vendors*.*

Print Name and Title/Position of Authorized Representative

Signature of Authorized Representative

Date

E-mail Address

Phone Number