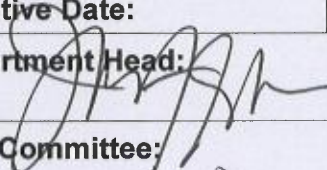
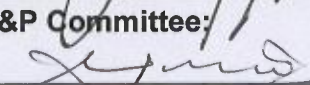




POLICY & PROCEDURE CORPORATE COMPLIANCE

Policy Title: Compliance Expectations for Care1st's First-Tier, Downstream, and Other Related Entities (FDRs)		
Policy No: 70.17.38		Original Date: 5/2013
Effective Date:	Revision Date: 4/2016	Revision No: 1
Department Head: 	Date: 4-11-16	
P&P Committee: 	Date: 4/7/16	Scope of Coverage: All Lines of Business

PURPOSE:

To document and formalize Care1st Health Plan's ("Care1st") compliance expectations from its delegated and/or contracted First-Tier, Downstream, and Related Entities (FDRs) or Sub-Contractors who are contracted to perform services or administer the benefits/services 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) ("SoC for Vendors/Contractors") to its FDRs/Sub-Contractors. The distribution/communication is conducted annually (for existing contracted FDRs) and within 90 calendar days of contract for new FDRs/Sub-Contractors.

Care1st's delegated and/or contracted FDRs/Sub-Contractors 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 Care1st's delegated or contracted FDRs are required to comply with in carrying out their duties and responsibilities.**

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

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.

PROCEDURE:

- A. Excluded Listings:** All Care1st's delegated and/or contracted FDRs must verify or validate their employees and their downstream contracted entities, at a minimum, 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)/System Awards Management (SAM) <https://www.epls.gov/www.sam.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 SAM at the time of hire or contracting, FDRs may only review the LEIE supplement file provided each month, which lists the entities added to the list that month, and review the SAM 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 SAM. In addition to health care providers (that are also included on the OIG LEIE) the SAM includes non-health care contractors.
- B. Fraud, Waste, and Abuse (FWA) Training:** All Care1st delegated and/or contracted FDRs/Sub-Contractors, and the FDRs/Sub-Contractors' employees and FDRs/Sub-Contractors' downstream contracted entities, who are involved in the administration or delivery of Medicaid/Medicare (Parts C and D) and other Medicaid/Medicare related 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/Sub-Contractors. Care1st requires its FDRs/Sub-Contractors 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 FWA (i.e., False Claims Act, Anti-Kickback statute, Health Insurance Portability and Accountability Act (HIPAA)/HITECH, etc.);
 - ii. Obligations of FDRs/Sub-Contractors to have appropriate policies and procedures addressing FWA;
 - iii. Processes for FDRs/Sub-Contractors and to report suspected FWA to Care1st Health Plan; or, as to FDR/Sub-Contractors' employees, either to report to Care1st directly or to the FDR/Sub-Contractors' employees' employer who then must report the incident to Care1st;

- iv. Protection for FDRs/Sub-Contractors and FDR/Sub-Contractors' employees who report suspected FWA; and
 - v. Types of FWA that can occur in the settings in which Care1st and the FDR/Sub-Contractors' employees work.
 - b. Care1st expects its FDRs/Sub-Contractors to maintain records for a period of 10 years (for Medicare) of the time, attendance, topic, certificates of completion (if applicable), and test scores of any tests (if applicable) administered by the FDRs/Sub-Contractors to their employees; and seven (7) years for Medicaid
 - c. **FWA Deeming:** FDRs/Sub-Contractors 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/Sub-Contractor or an employee of the FDR/Sub-contractor is deemed meeting the FWA requirements.
- C. **General Compliance Training:** All Care1st delegated and/or contracted FDRs/Sub-Contractors, and the FDRs/Sub-Contractors' employees and FDRs/Sub-Contractors' downstream contracted entities, which have involvement in the administration or delivery of Medicaid, Medicare (Parts C and D) or Medicaid/Medicare related 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/Sub-Contractors. Care1st requires its FDRs/Sub-Contractors 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/Sub-Contractors;
 - ii. Classroom training;
 - iii. Online training modules; or
 - iv. Attestations that FDR/Sub-Contractor's 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/Sub-Contractor have their own Compliance Training Program, FDRs/Sub-Contractors 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 Care1st's 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 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 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/Omnibus Act and the importance of maintaining the confidentiality of personal/protected 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 and FDRs/Sub-contractors' conduct in the Care1st's Compliance Program. Following are examples of these laws and regulations:
 - Regulations governing the State (Medicaid) and/or Federal (Medicare) program found at 42 Code of Federal Regulations §438.608 and §455.2 and §422 and §423, respectively.
 - California Health and Safety Code §1348.
 - California Welfare & Institution Code §14043.1.
 - Department of Health Care Services (DHCS), Agreement 04-36069, Exhibit E, Attachment 2, Provision 26.
 - PPSA §4.21 "Fraud and Abuse Reporting."
 - L.A. Care Health Plan Policy & Procedure RAC-016.
 - 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/Sub-Contractors) must comply with Care1st’s or Regulatory routine audits, monitoring, and identification of compliance risks to determine, test, and confirm if FDRs/Sub-Contractors comply with State and/or Federal regulations, sub-regulatory guidance, and contractual agreements, and all applicable Federal and State laws, as well as Care1st’s Policies and Procedures and FDRs/Sub-contractors’ own internal policies and procedures to protect against the Care1st’s compliance program noncompliance and potential FWA.

- a. FDRs/Sub-Contractors must achieve “sustained” audit scores that meet Care1st’s or Regulatory established passing threshold or guidelines.
- b. Non-compliant audit scores are subject to corrective action plans (CAPs)/ corrective action requirements (CARs) to correct identified deficiencies.
- c. Deficiencies identified must be corrected via corrective action plans/CARs 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 and its Parent Organization.

E. Written Policies and Procedures (P&Ps): Care1st’s delegated and contracted entities or FDRs/Sub-Contractors 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 (Medicaid or Medicare) specific stand-alone documents. The P&Ps will be reviewed by Care1st’s internal auditors (or Care1st’s designated auditors) assigned to specific delegation area (e.g., UM, Claims, Compliance, etc.).

F. Participation in Regulatory (Federal, State, or Accrediting Agencies) Audits, Investigations, and Monitoring. Care1st's FDRs/Sub-Contractors and/or contracted entities are required to participate, cooperate, and/or comply with any Federal (e.g., CMS/DHCS/DMHC/DOJ) audits, investigations, and/or monitoring.. Because FDRs/Sub-Contractors perform functions on behalf of Care1st, all and/or any delegated/contracted transactions, procedures, policies, and other administrative requirements, FDRs/sub-contractors 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/Sub-Contractors must comply with the HIPAA and Privacy laws including the Health Information Technology for Economic and Clinical Health Act (HITECH)/Omnibus Act. If/when a potential/suspected/actual breach of protected health information (PHI) or personally identifiable information (PII) has occurred, the FDR/Sub-Contractor must notify Care1st Health Plan using the following guidelines:

i. **The FDR/Sub-contractor (or contracted entity) must notify Care1st Health Plan's Corporate Compliance Special Investigation Unit (SIU) at (323) 889-6638. or at ComplianceSIU@care1st.com in accordance with the following timelines:**

• Within required timeframes as indicated on the Business Associate Agreement (BAA), 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, 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), 423.752(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)*)
- 42 Code of Federal Regulations §438.608 and §455.2 respectively.
- California Health and Safety Code §1348.
- California Welfare & Institution Code §14043.1.
- Department of Health Care Services (DHCS), Agreement 04-36069, Exhibit E, Attachment 2, Provision 26.
- PPSA §4.21 "Fraud and Abuse Reporting."
- L.A. Care Health Plan Policy & Procedure RAC-016.

ATTESTATION FORM: The following attestation form (or an updated form similar to the one below) must be completed, signed, and returned to Care1st's Compliance Department at CorpComplianceAudit@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