

2024 GUIDE FDR COMPLIANCE

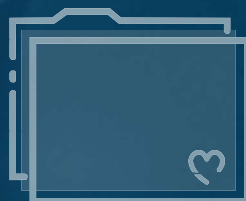


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INTRODUCTION

The CareMax ***First-Tier, Downstream, and Related Entity (FDR) Compliance Guide*** is a resource designed to assist CareMax FDRs with understanding and complying with the CareMax Compliance Program and its requirements. This guide will:

- Demonstrate CareMax’s commitment to responsible corporate conduct.
- Set forth FDR compliance requirements.
- Publicize mechanisms for reporting fraud, waste, abuse, and compliance issues.
- Communicate information about the CareMax Code of Business Conduct & Ethics and the compliance policies in place to detect, prevent, correct, and monitor fraud, waste, abuse, and inefficiencies.
- Define and provide examples of fraud, waste, and abuse.
- Provide information about relevant laws and regulations.

SECTION 1: CAREMAX COMPLIANCE PROGRAM

CareMax, Inc., its subsidiaries, and affiliates (“CareMax”) is committed to practicing business in an ethical manner. CareMax’s Compliance Program is designed to reduce or eliminate fraud, waste, abuse, and inefficiencies, ensure CareMax’s compliance with applicable regulations, and reinforce CareMax’s commitment to zero tolerance for such activities.

The CareMax Compliance Program Description is based on, but not limited to, the Office of the Inspector General’s (OIG’s) Seven Elements of an Effective Compliance Program (specified in 42 C.F.R. §§ 422.503(b)(vi) and 423.504(b)(4)(vi)) as listed below:

- **Element 1** Written Policies, Procedures, and Standards of Conduct
- **Element 2** Designated Compliance Officer, Compliance Committee, and High-Level Oversight
- **Element 3** Effective Training and Education
- **Element 4** Effective Lines of Communication
- **Element 5** Effective System for Routine Monitoring, Auditing, and Identification of Compliance Risks
- **Element 6** Well-Publicized Disciplinary Standards and Enforcement
- **Element 7** Prompt Responses to Detected Offenses and Corrective Actions

In addition to the CareMax Compliance Program Description, CareMax also maintains a **Fraud, Waste, & Abuse (FWA) Program**, a **HIPAA Privacy Program**, and a **HIPAA Security Program** that support the overall CareMax Compliance Program. Using this structure, the overall CareMax Compliance Program closely aligns to the following goals:

- Ensures adequate processes are in place to facilitate ethical conduct through policy development and education.
- Serves as an internal control to potential FWA-prone business areas.
- Minimizes loss and disciplinary action (financial, criminal, etc.) through early detection and

reporting (i.e., OIG List of Excluded Individuals/Entities (LEIE)/General Services Administration (GSA) System for Award Management (SAM) exclusion screening).

- Provides central contact for team members to receive information and guidance on applicable federal and state statutes, regulations, and other requirements.
- Ensures timely and thorough investigation of alleged misconduct and initiation of immediate and appropriate corrective action.

The CareMax Compliance Program applies to all CareMax workforce members, which include team members, officers, managers, volunteers, interns, governing body members (Board of Directors), vendors (i.e., contractors, subcontractors), and employees of any contractor/subcontractor or related entity that is acting on behalf of CareMax.

CareMax policy is to provide information on its Compliance Program to individuals, entities, businesses, and providers with whom we work. The Centers for Medicare & Medicaid Services (CMS) and various other agencies provide guidance and regulatory oversight of our Compliance Program.

SECTION 2: CAREMAX CODE OF BUSINESS CONDUCT & ETHICS

The CareMax Code of Business Conduct & Ethics provides guidance to CareMax workforce members regarding the ethical and legal standards of our Compliance Program. CareMax expects every workforce member to respect these principles and to conduct business with CareMax in accordance with the Code. You can find the CareMax Code of Business Conduct & Ethics here:

<https://ir.caremax.com/governance/governance-documents/default.aspx>

SECTION 3: WHAT IS AN FDR?

CareMax has contracts with Medicare Advantage plans to provide healthcare and administrative services to their members. CareMax then subcontracts with several external individuals and entities as a cost-effective and efficient way of providing some of those services. CMS refers to the various levels of contractors under Medicare Advantage contracts as First-Tier, Downstream, and Related Entities (FDRs):

A **First-Tier Entity** (such as CareMax in this case) means any party that enters an acceptable written arrangement with a Medicare Advantage organization (or contract applicant) to provide administrative services or health care services for Medicare-eligible individuals.

A **Downstream Entity** (such as your organization in this case) means any party that enters an acceptable written arrangement below the level of the arrangement between a Medicare Advantage organization (or contract applicant) and a First-Tier Entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

A **Related Entity** means any entity that is related to the Medicare Advantage organizations by common ownership or control and:

- (1) Performs some of the Medicare Advantage organization's management functions under contract or delegation

- (2)** Furnishes services to Medicare enrollees under an oral or written agreement; or
- (3)** Leases real property or sells materials to the Medicare Advantage organization at a cost of more than \$2,500 during a contract period.

CMS requires that any of the compliance obligations that CareMax (a First-Tier Entity) has under its Medicare Advantage contracts flow down to any CareMax contractor or vendor that meets the CMS definition of a Downstream or Related Entity. Under your organization's contract with CareMax, your organization is considered a Downstream Entity to CareMax. Therefore, CMS holds you subject to the requirements discussed in this guide.

SECTION 4: FDR REQUIREMENTS

i. FDR Attestation

Upon contract and annually thereafter, an authorized representative of the FDR entity must complete the CareMax FDR Attestation. This authorized representative must be an individual who has responsibility directly or indirectly for all:

- Employees, board members, and volunteers;
- Contractors and vendors; and
- Providers/practitioners.

The CareMax FDR Attestation is your organization's affirmation of compliance with requirements discussed in this guide, including compliance with the CareMax Code of Business Conduct & Ethics, the establishment of compliance policies, the performance of monthly OIG LEIE and GSA SAM exclusion screenings, and the use of an anonymous reporting mechanism. Upon submission of the attestation, you may be asked to provide evidence of your organization's compliance with these requirements. Failure to produce evidence of compliance with the requirements may result in a corrective action plan request from CareMax or other contractual remedies, up to and including contract termination. CareMax will send a notification to each FDR to communicate the deadline for completion of the annual attestation. All CareMax FDRs must complete the attestation within the designated timeframe.

ii. Standards of Conduct and Compliance Program Policies

Your organization must provide its employees, board members, contractors, vendors, and volunteers with standards of conduct (or, a Code of Conduct) and compliance program policies that meet federal requirements outlined in this guide. In addition, you must ensure that any FDRs that you use to fulfill your contractual obligations under your agreement with CareMax also provide a compliant Code of Conduct and compliance program policies to their employees.

Your organization's Code of Conduct and compliance program policies must be distributed to staff:

- Within 90 days of hire/start or the FDR's contract effective date
- Annually thereafter; and
- Whenever there are updates to the Code of Conduct and policies.

Distribution of this guide can be utilized to satisfy the Standards of Conduct and Compliance Program Policies requirement; however, if a Downstream Entity opts to use its own materials, its Compliance Program policies must include, at minimum:

- A description of your organization's Compliance Program
- Instructions on how to report suspected noncompliance
- The requirement to report potential noncompliance and FWA
- Requirements to report potential noncompliance and FWA
- Disciplinary guidelines for noncompliance behavior
- A non-retaliation provision (i.e., non-retaliation for staff who make reports of noncompliance in good faith)
- An FWA training requirement
- An overview of relevant laws and regulations (such as the Deficit Reduction Act of 2005, False Claims Act, and HIPAA)

Evidence of the distribution of a Code of Conduct and compliance program policies to individuals and contractors must be retained for at least ten (10) years.

iii. Reporting FWA and Compliance Concerns

FDRs have a responsibility to report any alleged compliance violations that may impact CareMax, including FWA and/or conflict of interest issues. CareMax requires its FDRs to establish and publicize a confidential reporting mechanism for its employees and contractors to report potential noncompliance. Mechanisms may include use of a confidential reporting website or phone number.

FDRs and other vendors or subcontractors may use the following methods to confidentially report a potential violation of our compliance policies or of any applicable regulation without fear of retaliation:

CareMax Reporting

- Email or call Teresa McMeans, CareMax Chief Compliance Officer at Teresa.McMeans@caremax.com or (786) 206-8721
- Email Kim Anderson, CareMax Director of Compliance at Kimberly.Anderson@caremax.com
- Anonymously, via the CareMax toll-free Compliance Hotline at 1-800-672-3039 or online at <https://reportanissue.com/caremax>
- Office of Inspector General (OIG) at 1-800-HHS-TIPS (1-800-447-8477), TTY 1-800-377-4950
- Centers for Medicare & Medicaid Services (CMS) at 1-800-MEDICARE (1-877-486-2048)

In addition to reporting issues of noncompliance and establishing an anonymous reporting mechanism, your organization must adopt and enforce a non-retaliation policy that prohibits retaliation or intimidation against anyone that reports suspected misconduct or FWA in good faith. Evidence of confidential reporting mechanisms and the establishment of a non-retaliation policy must be made available to CareMax upon request.

iv. Exclusion List Screening

Federal law prohibits federal/state health care programs such as Medicare, Medicaid, TRICARE, etc., from paying for services or items provided by a person or entity who has been excluded from participation in those programs. Therefore, prior to hiring an employee or contracting with an individual or an entity—and monthly thereafter—your organization must check the required exclusion lists to confirm that your permanent and temporary employees, volunteers, board members, leadership, owners, and FDRs/contractors that provide services under the CareMax contract are not excluded from participating in federal/state health care programs.

Your organization (or, its screening vendor) must use the following websites to perform the required exclusion list screenings:

- OIG List of Excluded Individuals and Entities (LEIE): <https://exclusions.oig.hhs.gov>
- GSA's System for Award Management (SAM): <https://sam.gov/content/exclusions>

In the event an employee, contractor, or Downstream Entity used by your organization is found in the LEIE or SAM exclusion lists, you must take the following actions:

1. Immediately remove the person or entity from work that is directly or indirectly related to CareMax's contract,
2. Determine whether the person or entity is indeed excluded and,
3. If they are excluded or you cannot determine their status, immediately notify CareMax.
4. FDRs must maintain evidence of exclusionary checks (i.e., logs or other records) to document that each employee and contractor has been screened in accordance with current regulations and requirements. Evidence of the pre-hire and monthly exclusionary checks for each individual or contractor must be maintained for at least ten (10) years.

v. Monitoring and Auditing

CMS requires that First-Tier Entities, such as CareMax, monitor the compliance of any FDRs to assure that they comply with all applicable laws, rules, and regulations including CMS regulatory/sub-regulatory guidance. As a result of this obligation, CareMax periodically audits its FDRs to ensure that all the applicable laws, rules, and regulations are being met. Your organization, as a Downstream Entity, must cooperate and participate in these activities. If you perform your own audits, we may ask for those audit results that affect CareMax's contract. If we determine that a Downstream Entity is noncompliant with any of the requirements, we will require the Downstream Entity to develop and submit a corrective action plan to address the identified issues. A failure to correct these issues can lead to additional progressive consequences, leading up to termination of the contract.

CMS requires that compliance obligations flow down through all levels of contractors who provide services that are part of performing healthcare and administrative activities under Medicare Advantage contracts. So, if you choose to subcontract with other individuals/entities to meet your obligations under your contract with CareMax, you must also make sure that your subcontractors abide by all laws, rules, and regulations applicable to CareMax and you. These include Medicare compliance programs (as described in this guide) and contractual agreements that contain all CMS-required provisions.

If you choose to use subcontractors, you must conduct sufficient oversight to evaluate and ensure that your subcontractors:

- Comply with applicable laws, rules, and regulations
- Maintain policies and procedures that protect beneficiary protected health information (PHI)
- Conduct analyses for problems and implement corrective action plans (CAPs)
- Take disciplinary actions to prevent recurrence of noncompliance
- Retain evidence of your organization's performance of monitoring, auditing, and oversight of your subcontractors' compliance.

vi. Offshore Activities and CMS Reporting

To ensure that CareMax meets the applicable federal and state laws, rules, and regulations including CMS regulatory/sub-regulatory guidance, you are prohibited from using any individual or entity that performs services under the CareMax contract that is physically outside of the United States or one of its territories. The only exception is if an authorized CareMax representative has expressly allowed the use of offshore services in advance and in writing.

If you perform services offshore or use an offshore entity to perform services involving the receipt, processing, transferring, handling, storing, creating, or otherwise accessing of PHI, and CareMax approves the arrangement, CareMax must submit an attestation to its contracted Medicare Advantage plans. Those plans in turn must report the arrangement to CMS. Therefore, you will need to provide the necessary information to CareMax in advance to meet these reporting requirements.

One example provided by CMS that triggers this requirement is “offshore subcontractors that receive radiological images for reading, because beneficiary PHI is included with the radiological image and the diagnosis is transmitted back to the U.S.” Another example is any coding or billing that is conducted outside of the United States or its territories.

FDRs with offshore subcontractors must:

- Receive written approval from CareMax prior to contracting
- Maintain contractual agreements with the offshore subcontractor that include all applicable Medicare requirements, HIPAA privacy and security regulations, and name the vendor as a Business Associate
- Ensure that each offshore subcontractor maintains policies and procedures that protect PHI
- Conduct annual audits of offshore subcontractors and make audit results available upon request

Note: Pursuant to Section 408.051 of the Florida Statutes, effective July 1, 2023, the storage of patient information in an offshore location is strictly prohibited.

SECTION 5: FRAUD, WASTE, ABUSE

i. What is Fraud, Waste, Abuse?

Fraud: An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to themselves or another person. It includes any act that constitutes fraud under applicable federal or state law.

Waste: The extravagant, careless, or needless expenditure of funds resulting from deficient practices, systems, controls, or decisions.

Abuse: Practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards of care. It includes enrollee practices that result in unnecessary cost.

Common methods of fraud, waste, abuse include:

- Fabrication of claims: In the outright fabrication of claims or portions of claims for treatments or services that were never provided or performed to otherwise legitimate claims.
- Falsification of claims: In the falsification of claims, the perpetrator makes a material and intentional misrepresentation of one or more elements of information in the claim, for the purpose of obtaining a payment to which they are not entitled.
- Duplicate claim submissions: submitting claims for the same services and beneficiary under two Tax Identification Numbers to bypass duplicate claim edits in the claims-processing system.

ii. Relevant Laws and Regulations

False Claims Act (FCA)

The civil False Claims Act (FCA), 31 United States Code (U.S.C.) §§ 3729–3733, protects the Federal Government from being overcharged or sold substandard goods or services. The civil FCA imposes civil liability on any person who knowingly submits, or causes the submission of, a false or fraudulent claim to the federal government. The terms “knowing” and “knowingly” mean a person has actual knowledge of the information or acts in deliberate ignorance or reckless disregard of the truth or falsity of the information related to the claim. No specific intent to defraud is required to violate the civil FCA. Example: A physician knowingly submits claims to Medicare for medical services not provided or for a higher level of medical services than actually provided.

Filing false claims may result in fines of up to three times the program’s loss plus \$11,000 per claim filed. Additionally, under the criminal FCA, [18 U.S.C. Section 287](#), individuals or entities may face criminal penalties for submitting false, fictitious, or fraudulent claims, including fines, imprisonment, or both.

Anti-Kickback Statute (AKS)

AKS, [42 U.S.C. Section 1320a-7b\(b\)](#), makes it a crime to knowingly and willfully offer, pay, solicit, or receive any remuneration directly or indirectly to induce or reward patient referrals or the generation of business involving any item or service reimbursable by a federal health care program. When a provider offers, pays, solicits, or receives unlawful remuneration, the provider violates the AKS. NOTE: Remuneration includes anything of value, such as cash, free rent, expensive hotel stays and meals, and excessive compensation for medical directorships or consultancies. For example, a provider receives cash or below-fair-market-value rent for medical office space in exchange for referrals.

Criminal penalties and administrative sanctions for violating the AKS may include fines, imprisonment, and exclusion from participation in the federal health care program. Under the CMPL, physicians who pay or accept kickbacks also face penalties of up to \$50,000 per kickback plus three times the amount of the remuneration.

The “safe harbor” regulations, as defined in 42 Code of Federal Regulations (C.F.R.) Section 1001.952, describe various payment and business practices that, although they potentially implicate the AKS, are not treated as offenses under the AKS if they meet certain requirements specified in the regulations. Individuals and entities remain responsible for complying with all other laws, regulations, and guidance that apply to their businesses.

Civil Monetary Penalties Law (CMPL)

The CMPL, [42 U.S.C. Section 1320a-7a](#), authorizes the OIG to seek civil monetary penalties and sometimes exclusion for a variety of health care fraud violations. Different amounts of penalties and assessments apply based on the type of violation. CMPs also may include an assessment of up to three times the amount claimed for each item or service, or up to three times the amount of remuneration offered, paid, solicited, or received. Violations that may justify CMPs include:

- Presenting a claim you know, or should know, is for an item or service not provided as claimed or that is false and fraudulent
- Violating the AKS
- Making false statements or misrepresentations on applications or contracts to participate in federal health care programs

SECTION 6: HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

i. HIPAA Privacy

The HIPAA Privacy Rule requires covered entities and their business associates to take reasonable steps to protect and safeguard PHI. An individual’s PHI is subject to the protections established by the Privacy Rule and under the relationship between CareMax and the individual, and between CareMax and a covered entity, business associate, or FDR. PHI includes information regarding health plan enrollment, medical records, claims submitted for payment, etc. Such PHI must be safeguarded and held in strict confidence, so as to comply with applicable privacy provisions of state and federal laws, including HIPAA.

ii. HIPAA Security

The HIPAA Security Rule requires covered entities and their business associates to adopt national standards for safeguards to protect the confidentiality, integrity, and availability of electronic PHI that is collected, maintained, used, or transmitted by a covered entities and their business associates. Since you are contracted with a covered entity (CareMax), you must ensure that you have the appropriate administrative, technical, and physical safeguards in place to protect any data that is being electronically accessed by your workforce. You must (a) ensure the integrity and confidentiality of the information; and (b) protect against any reasonably anticipated (i) threats or hazards to the security or integrity of the information; and (ii) unauthorized uses or disclosures of the information. This can be accomplished by establishing appropriate policies and procedures that outline your compliance with the Rule and your expectations of your workforce in complying with the HIPAA Security Rule.

SECTION 7: OTHER FEDERAL AND STATE COMPLIANCE OBLIGATIONS

Based on the services that you provide under this contract, there may be other compliance obligations that you are subject to at the federal or state level, such as the Payment Card Industry Data Security Standard (PCI). Even if it is not discussed here, CareMax expects you and your organization to be compliant with all applicable federal and state laws, rules, and regulations including CMS regulatory/sub-regulatory guidance as part of your contractual obligations and to have a mechanism to assure your employees are aware of the applicable requirements.

Additional resources applicable to the compliance program requirements explained in this guide are listed below:

- Medicare Managed Care Manual Chapter 21 – Compliance Program Guidelines
- Prescription Drug Benefit Manual Chapter 9 - Compliance Program Guidelines
- U.S. Department of Health and Human Services: www.hhs.gov

SECTION 8: CORRECTIVE ACTION FOR NONCOMPLIANCE

If CareMax's FDRs fail to comply with the requirements directed in this guide, CareMax may be found by the Medicare Advantage plans to not meet its contractual obligations. This may lead to:

- CareMax requesting your organization complete a CAP to help your organization resolve gaps;
- Training or retraining to prevent future noncompliance; and/or
- Contractual modification or termination of the contract by CareMax.

CareMax's actions in response to noncompliance will depend on the severity of the issue(s) and your response(s). If you identify an area of noncompliance (such as failing to screen your employees against the required exclusion lists), you must take prompt action to correct the situation and prevent it from happening again.

ADDITIONAL REFERENCES

CareMax

<https://www.caremax.com>

Centers for Medicare & Medicaid Services

<https://cms.gov>

OIG Exclusion Database and Information

<https://oig.hhs.gov/exclusions/index.asp>

System for Award Management (SAM) Database and Information

<https://sam.gov/content/exclusions>