

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

**May 2022**



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## Introduction

Medicare Advantage (MA) plans, such as those offered by WellSense Health Plan (WellSense), contract with the Centers for Medicare & Medicaid Services (CMS) to provide services under the Medicare Parts C and D programs. To help fulfill our obligations to CMS, WellSense enters into contracts with individuals/entities to provide or arrange for certain administrative and/or health care services. These contractual arrangements may cause an individual/entity to be identified as a **First-Tier, Downstream and Related Entity** (FDR) if such delegated services meet certain CMS standards.

WellSense is committed to compliance with all applicable laws, regulations and contract requirements set forth by CMS and holds itself to the highest compliance and ethical standards. We expect the same of our FDRs.

WellSense maintains ultimate responsibility for fulfilling the terms and conditions of our contracts with CMS, meeting the Medicare program requirements and delivering service to our members. Although services may be delegated to an FDR, CMS will hold WellSense accountable for the failure of any of its FDRs to comply with applicable Medicare program requirements.

As a WellSense FDR that assists us in providing services related to our MA plans, you are subject to the Compliance Program requirements set forth by CMS under 42 CFR §422.503 and §423.504 as well as those in Compliance Program Guidelines found in Chapter 21 of the Medicare Managed Care Manual and Chapter 9 of the Prescription Drug Benefit Manual.

The purpose of this Medicare Advantage Compliance Guide (Compliance Guide) is to assist our FDRs in fully understanding and meeting their compliance obligations under WellSense's Medicare Compliance Program. Please use it as a "quick reference" guide to understanding our compliance program expectations and ensuring that you have internal processes to support your compliance program.

In the event of any inconsistency between this Compliance Guide and the terms of your agreement with WellSense, the terms of your agreement shall prevail.



Please refer to the **Resources** section of this Compliance Guide for more information on Medicare Compliance Program requirements.

## **Definition of First-Tier, Downstream, and Related Entity (hereafter referred to individually or collectively as FDR)**

**First-Tier Entity:** any party that enters into a written arrangement, acceptable to CMS, with a Medicare Advantage Organization (MAO) or Part D plan sponsor or applicant to provide administrative services or health care services to a Medicare-eligible individual under the MA program or Part D program.

**Downstream Entity:** any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the MA benefit or Part D benefit, below the level of the arrangement between an MAO 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 MAO or Part D sponsor by common ownership or control and:

1. performs some of the MAO or Part D plan sponsor'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 MAO or Part D plan sponsor at a cost of more than \$2,500 during a contract period.

## **How does WellSense identify which third party vendors are FDRs?**

WellSense evaluates the types of functions delegated to the third party and makes a determination, in accordance with CMS standards, whether the performance of those functions cause that individual or entity to be identified as an FDR. The following are a few examples that, if delegated to the third party, presumptively make that third party an FDR:

- Sales and marketing
- Utilization management



- Quality improvement
- Claims administration, processing and coverage adjudication
- Licensing and credentialing
- Hotline operations
- Bid preparation
- Entities that generate claims data
- Enrollment, disenrollment and membership functions
- Appeals and grievances
- Pharmacy benefits management
- Customer Service
- Outbound sales verification
- Health care services

FDRs delegated to perform a core function of WellSense must follow all CMS Medicare program requirements and regulations, just as WellSense is required to do when providing a core function directly. As such, WellSense has developed and implemented clearly defined processes to evaluate and categorize which third parties are FDRs. In addition to the examples listed above, WellSense also utilizes the following factors to determine whether a third party is an FDR:

- The function to be performed by the third party
- Whether the function is something the sponsor must do or provide under its contract with CMS, the applicable federal regulations or CMS guidance or under its contract with the state
- To what extent the function directly impacts enrollees
- To what extent the third party has interaction with enrollees, either orally or in writing
- Whether the third party has access to beneficiary information or protected health information (PHI)
- Whether the third party has decision-making authority (e.g., enrollment third party deciding time frames) or whether the entity strictly takes direction from the sponsor
- The extent to which the function places the delegated entity in a position to commit health care fraud, waste or abuse (FWA).
- The risk that the third party could harm enrollees or otherwise violate Medicare or Medicaid program requirements or commit FWA

## Compliance with state and Federal Requirements

FDRs must operate in accordance with all applicable state and Federal laws, regulations, Medicare program requirements and CMS instructions as applicable including, but not limited to:



**Anti-Kickback Statute** (42 U.S.C. § 1320a-7b(b)) prohibits anyone from knowingly and willfully receiving or paying anything of value to influence the referral of federal health care program business, including Medicare and Medicaid. Kickbacks can take many forms, such as cash payments, entertainment, credits, gifts, free goods or services, the forgiveness of debt or the sale or purchase of items at a price inconsistent with fair market value. Kickbacks may also include the routine waiver of copayments and/or co-insurance. Penalties for Anti-Kickback violations include fines, imprisonment, civil money penalties and exclusion from participation in federal health care programs.

**Beneficiary Inducement Statute** (42 U.S.C. § 1128A(a)(5)) makes it illegal to offer remuneration that a person knows, or should know, is likely to influence a beneficiary to select a particular provider, practitioner or supplier, including a retail, mail order or specialty pharmacy.

**Federal and State False Claims Acts** (31 U.S.C. §§ 3729-3733) prohibits any person from engaging in any of the following activities:

- knowingly submitting a false or fraudulent claim for payment to the United States government;
- knowingly making a false record or statement to get a false or fraudulent claim paid or approved by the government;
- conspiring to defraud the government by getting a false or fraudulent claim paid or approved by the government; and
- knowingly making a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the government.

**Federal Criminal False Claims Statutes** (18 U.S.C. §§ 287, 1001) make it a criminal offense for anyone to make a claim to the United States government knowing that it is false, fictitious or fraudulent.

**Regulations Governing Medicare Parts C and D** including:

- 42 C.F.R. §422: Medicare Advantage program. This regulation implements the Medicare Advantage program under the Social Security Act.
- 42 C.F.R. §423: Prescription drug program. This regulation implements the prescription drug program under the Social Security Act.



**Title XVIII of the Social Security Act** established the Medicare program and which guarantees access to health insurance for all Americans aged 65 and older, younger persons with specific disabilities and individuals with end-stage renal disease.

## Medicare Compliance Program Requirements for FDRs

As an MA plan sponsor, WellSense must comply with applicable CMS Medicare Compliance Program requirements. As a first-tier entity to WellSense, your organization and all of your downstream entities (if applicable) must comply with the same Medicare Compliance Program requirements. First-tier entities are also responsible for ensuring that their downstream entities comply with applicable laws and regulations, including the requirements in this Compliance Guide which summarizes your Medicare Compliance Program responsibilities and which may be shared with downstream entities.

The seven (7) elements of an effective compliance program include:

- 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

You can find these compliance program requirements in:

- Medicare Managed Care Manual Chapter 21
- Prescription Drug Benefit Manual, Chapter 9
- 42 C.F.R. §§422.503(b)(4)(vi), 423.504(b)(4)(vi)



## Written Policies, Procedures and Standards of Conduct

Each FDR is required to establish internal compliance policies and procedures and/or standards of conduct that communicate the organization's compliance expectations and CMS requirements. You may use and provide a copy of WellSense's Code of Conduct if you don't have one of your own. These materials must be provided:

- within 90 days of initial hire or the effective date of contracting,
- whenever there are updates to the documentation and
- annually thereafter.

FDRs can determine the most effective method of distributing the policies and procedures or standards of conduct, including providing a hardcopy or electronic copy at the time of hire/contract or posing a copy on the FDR's intranet site. An FDR must maintain documentation that demonstrates the information was distributed.

You can find these standards of conduct requirements in:

- Medicare Managed Care Manual Chapter 21, §50.1
- Prescription Drug Benefit Manual, Chapter 9, §50.1
- 42 C.F.R. §§422.503(b)(4)(vi)(A), 423.504(b)(4)(vi)(A)

## General Compliance and Fraud, Waste and Abuse (FWA) Training

FDRs are required to develop their own training specific to its organizational needs to train staff on relevant general compliance topics and prevention of FWA.

FDRs are not exempt from general compliance training requirements, but you may be deemed to have met the FWA training and education requirements through enrollment in Parts A or B of the Medicare program or accreditation as a Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) supplier.

General compliance and FWA training must be completed:

- within 90 days of initial hire or the effective date of contracting,





- whenever there are updates to the documentation and
- annually thereafter.

FDRs should keep training logs or other evidence of completion which should include, at a minimum, the employee or contractor name, date(s) of completion and passing score if captured.

You can find these training requirements in:

- Medicare Managed Care Manual Chapter 21, §50.3
- Prescription Drug Benefit Manual, Chapter 9, §50.3
- 42 C.F.R. §§422.503(b)(4)(vi)(C), 423.504(b)(4)(vi)(C)

## Exclusion Screening

Federal law prohibits the payment by Medicare, Medicaid or any other federal health care program for an item or service furnished by a person or entity excluded from participation in these federal programs. WellSense, its FDRs, subcontractors and providers are prohibited from contracting or doing business with any person or entity excluded from participation in these federal programs.

FDRs must perform a check to confirm individuals performing administrative or health care services for WellSense are not excluded from participation in federally funded health care programs according to the Office of Inspector General's List of Excluded Individuals and Entities (OIG LEIE) and the Government Services Administration's System for Award Management's (SAM) exclusion lists. This includes employees, temporary employees, volunteers, consultants, governing body members and FDRs. These screenings must be completed:

- prior to initial date of hire and/or the effective date of contracting and
- monthly thereafter

As part of WellSense's compliance program, WellSense requires its FDRs to screen their employees and downstream entities. In the event any of your employees or downstream entities are found on either exclusion list, you must immediately remove the individual from work related directly or indirectly to WellSense and notify WellSense of your findings.



FDRs must maintain evidence of their exclusion screening queries such as logs or other records for a minimum of 10 years.

You can find these exclusion screening requirements in:

- Medicare Managed Care Manual Chapter 21, §50.6.8
- Prescription Drug Benefit Manual, Chapter 9, §50.6.8
- 42 C.F.R. §§422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)
- OIG LEIE database: <https://exclusions.oig.hhs.gov/>
- SAM database: <https://www.sam.gov/SAM/>

## Reporting FWA and Compliance Issues to WellSense

As an FDR, your organization must have effective lines of communication that foster compliance and the ability for employees and other parties to report suspected or detected non-compliance and FWA concerns. It is the duty of every person who has knowledge of a compliance issue or potential FWA concern to promptly report such issues. This reporting obligation applies even if the individual with the information is not in a position to mitigate or resolve the issue.

If an FDR identifies areas of non-compliance (e.g., failure to conduct monthly exclusion screening), it must report the issue to WellSense and take prompt action to fix the issue and prevent it from happening again. Such reports must be provided to WellSense within 72 hours of discovery unless otherwise defined in your Agreement.

WellSense actions in response to an FDR's non-compliance will depend on the severity of the compliance issue. WellSense maintains oversight policies that outline steps that WellSense would take if an FDR fails to meet either CMS Medicare Compliance Program or WellSense requirements, which may include developing a corrective action plan, retraining or termination of your contract with WellSense.

There are a number of ways to report suspected or detected non-compliance or potential FWA. WellSense has established a confidential compliance hotline for WellSense employees, providers, members, FDRs and other interested persons to report any violations or suspected violations of law and/or WellSense's compliance program.



Reports can be made by contacting the WellSense Compliance Hotline at **888-411-4959**. This toll-free hotline is accessible 24 hours a day, 365 days a year. All callers to the Compliance Hotline can report issues anonymously, and all reports will be referred to WellSense’s Compliance department and investigated. You can also submit reports via email to **[compliance@bmchp-wellsense.org](mailto:compliance@bmchp-wellsense.org)**. Reports of potential FWA issues may also be reported directly to our Special Investigations Unit (SIU) by emailing **[fraudandabuse@bmchp-wellsense.org](mailto:fraudandabuse@bmchp-wellsense.org)**.

FDRs must adopt and enforce a zero-tolerance policy for retaliation or intimidation against anyone who reports suspected misconduct in good faith.

Michael Comerford is WellSense’s dedicated Medicare Compliance Officer. Questions or concerns for Michael or WellSense’s Compliance Department can be directed to **[compliance@bmchp-wellsense.org](mailto:compliance@bmchp-wellsense.org)**.

You can find these reporting requirements in:

- Medicare Managed Care Manual Chapter 21, §50.4
- Prescription Drug Benefit Manual, Chapter 9, §50.4
- 42 C.F.R. §§422.503(b)(4)(vi)(D), 423.504(b)(4)(vi)(D)

## **Record Retention and Record Availability**

FDRs must maintain evidence of compliance with Medicare compliance program requirements for no less than 10 years. FDRs must agree to audits and inspections by CMS, WellSense and/or its designees. FDRs must cooperate, assist and provide information as requested. Documentation and records needed to meet program requirements (i.e., Medicare Parts C and D) must be maintained for no less than 10 years, including, but not limited to, attendance records, training certificates and any other documents that demonstrate compliance with program requirements.

You can find these record retention requirements in:

- Medicare Managed Care Manual Chapter 21, §50.6.11
- Prescription Drug Benefit Manual, Chapter 9, §50.6.11
- 42 C.F.R. §§422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)



## Monitoring and Auditing of FDRs

CMS requires WellSense to develop a process to monitor and audit its FDRs and promote compliance with all applicable laws and regulations and to ensure our FDRs are monitoring their downstream entities for adherence with all applicable laws and regulations pertaining to Medicare Parts C and D program requirements.

WellSense regularly monitors and audits the activities of FDRs to ensure compliance with Medicare Parts C and D program requirements. First-tier entities that subcontract with other individuals or entities to provide administrative or health services are responsible for ensuring any downstream entities comply with all Medicare Parts C and D requirements. This includes ensuring contractual agreements contain all CMS-required provisions, that each downstream entity complies with the Medicare compliance program requirements described in this Compliance Guide and that each downstream entity complies with any applicable Medicare operational requirements.

WellSense will audit a sample of its FDRs on an annual basis, and first-tier entities are required to cooperate fully and participate in WellSense-initiated monitoring and/or auditing activities. If a first-tier entity performs its own audits, WellSense may request a copy of the audit results as part of our overall oversight program.

First-tier entities are also required to cooperate fully and participate in auditing activities conducted by federal, state and local government agencies, including ensuring adherence to any audit timeline.

First-tier entities must apply appropriate compliance program requirements to their downstream entities and provide sufficient oversight of their downstream entities, including auditing and monitoring to test and ensure each downstream entity is compliant with Medicare Parts C and D program requirements (including Medicare compliance program requirements). First-tier entities are required to retain evidence of any oversight activities, ensure a root-cause analysis is conducted for any deficiencies and implement corrective action as necessary to prevent recurrence of noncompliance.

You can find these monitoring and auditing requirements in:

- Medicare Managed Care Manual Chapter 21, §50.6.6



- Prescription Drug Benefit Manual, Chapter 9, §50.6.6
- 42 C.F.R. §§422.503(b)(4)(vi)(F), 422.503(b)(4)(vi)(G), 423.504(b)(4)(vi)(F), 423.503(b)(4)(vi)(G)

## Use of Offshore Operations

Because of the unique risks associated with using contractors operating outside the United States or one of its territories (i.e., American Samoa, Guam, Northern Marianas, Puerto Rico and the Virgin Islands), CMS requires MAOs to take measures to ensure offshore contractors protect members' protected health information (PHI). CMS is specifically concerned with entities that receive, process, transfer, handle, store or access members' PHI. Medicare plan sponsors that work with offshore subcontractors to perform Medicare-related work that uses beneficiary PHI are required to provide CMS with specific offshore subcontractor information and complete an attestation regarding the protection of beneficiary PHI.

Each FDR is required to notify WellSense and obtain WellSense's consent prior to engaging with any potential offshore contractor if it has facilities or employees located outside of the United States and its territories for any work required under your contract with WellSense.

If WellSense consents to any offshore arrangement, FDRs will be required to submit an attestation for any Medicare-related work required under the FDR's contract with WellSense. The required information within the attestation must include, in part:

- the offshore subcontractor's name and functions,
- a description of the PHI provided to the offshore subcontractor,
- a description of safeguards adopted within the offshore subcontracting arrangement to protect beneficiary information and
- the offshore subcontractor audit requirements.

## Annual Attestation

On an annual basis, an authorized representative from each FDR is required to attest to compliance with the Medicare compliance program requirements described in this Compliance Guide. Attestations and responses may be subject to audit.



## Resources

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| Compliance Chapters from the Medicare Managed Care Manual and Prescription Drug Benefit Program Manual | <a href="#">Compliance Program Policy and Guidance</a>  |
| To search Federal regulations cited in this Compliance Guide   | <a href="#">US Code of Federal Regulations</a>  |
| To search the US Office of Inspector General’s List of Excluded Individuals and Entities (LEIE)        | <a href="#">OIG exclusion search</a>  |
| To search the General Service Administration’s System for Award Management (SAM)                       | <a href="#">SAM exclusion search</a>  |
| To report non-compliance or potential FWA  | WellSense Compliance Hotline: 888-411-4959<br><br>WellSense Compliance:<br><a href="mailto:compliance@bmchp-wellsense.org">compliance@bmchp-wellsense.org</a><br><br>WellSense SIU:<br><a href="mailto:fraudandabuse@bmchp-wellsense.org">fraudandabuse@bmchp-wellsense.org</a> |
| Routine questions pertaining to WellSense’s compliance program and/or requirements                     | <a href="mailto:compliance@bmchp-wellsense.org">compliance@bmchp-wellsense.org</a>  |
| Routine questions pertaining to WellSense organizational policies                                      | <a href="mailto:vendormanagement@bmchp-wellsense.org">vendormanagement@bmchp-wellsense.org</a>  |
| Plan mailing address for notices and/or other communications   | 529 Main Street, Suite 500<br>Charlestown, MA 02129   |



# Revision and Approval History

| Review Date | Summary of Revisions | WellSense Compliance Committee Approval Date | Effective Date |
|-------------|----------------------|--|----------------|
| Q1' 2022    | Initial Draft        | April 26, 2022                               | April 26, 2022 |
|             |                      |  |                |

