Moda Medicare Advantage

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

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Why this compliance guide?

As a Medicare Advantage plan sponsor, Moda Health must have a compliance program that satisfies requirements outlined in Chapter 21 of the *Medicare Managed Care Manual* and Chapter 9 of the *Medicare Prescription Drug Manual*.

Each First Tier, Downstream, and Related Entity (FDR) we contract with to assist in administration of the Medicare Advantage and prescription drug program must have a compliance program that meets requirements of the Center for Medicare & Medicaid Services (CMS).

CMS' compliance program requirements include, but are not limited to, the following:

- A distribution policy for Standards of Conduct/compliance policy
- Conducting Office of Inspector General (OIG)/System for Award Management (SAM) exclusion checks
- A reporting policy for suspected Fraud, Waste, and Abuse (FWA) or non-compliance concerns
- Reporting of offshore contracting to CMS
- FWA and Compliance training for employees involved in administering Medicare Advantage and the prescription drug plans
- Monitoring and auditing of FDRs

A compliance tool

This guide is a tool to assist an FDR in developing a compliance program that meets CMS requirements for Medicare Advantage plans. It provides general information about compliance requirements and advises where more extensive information can be found. It also includes references to regulations related to the requirements.

Expectations

Moda has a responsibility to ensure our FDRs have a compliance program in place and that compliance policies are being followed. An FDR can expect Moda to annually request completion of an attestation on Medicare Advantage compliance. An authorized representative of the FDR will need to sign the attestation. Moda may periodically audit an FDR to ensure a compliance program and policies are in place.

Failing to complete the attestation or failing an audit may result in the following: corrective training, a corrective action plan, or in extreme circumstances, contract termination.

Contact us

If you have any questions about this guide, you can contact Moda at medicarecompliance@modahealth.com

FDRs subject to this compliance guide

How is it determined if an FDR needs to comply with CMS compliance requirements?

When a plan sponsor has delegated administrative or healthcare service functions to another entity, and those functions relate to the sponsor's Medicare Advantage or prescription drug program, the entity is considered an FDR for CMS compliance purposes and is subject to CMS compliance requirements.

Examples of functions that a plan sponsor may delegate to another party include:

- Sales and marketing
- Utilization management
- Applications processing
- Enrollment, disenrollment, membership functions
- Claims administration, processing and coverage adjudication
- Appeals and grievances
- Licensing and credentialing
- Pharmacy benefit management
- Hotline operations
- Customer service
- Bid preparation
- Outbound enrollment verification
- Provider network management
- Pharmacy claims processing at point of sale
- Negotiation with prescription drug manufacturers and others for rebates, discounts or other price concessions on prescription drugs
- Administration and tracking of enrollees' drug benefits, including TrOOP balance processing
- Coordination with other benefit programs, such as Medicaid, state pharmaceutical assistance or other insurance programs
- Claims data generation
- Healthcare services

Note: Through risk analysis, Moda may determine that an entity providing a service not listed above is subject to this compliance guidance.

Definitions

CMS	**CMS** means the Centers for Medicare & Medicaid Services.
DHHS	**DHHS** is the Department of Health and Human Services. CMS is the agency within DHHS that administers the Medicare program.
Downstream entity	**Downstream entity** is any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the Medicare Advantage (MA) benefit or Part D benefit, below the level of the arrangement between a Medicare Advantage Organization (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. (See 42 CFR §§ 422.500 and 423.501.)
FDR	**FDR** means First Tier, Downstream, or Related Entity. Moda may refer to these entities as delegates.
First tier entity	**First tier entity** is any party that enters into a written arrangement, acceptable to CMS, with an MAO or Part D plan sponsor or applicant to provide administrative services or healthcare services to a Medicare eligible individual under the MA program or Part D program. (See 42 CFR §§ 422.500 and 423.501.)

GSA	**GSA** means General Services Administration. The GSA maintains the Excluded Parties Lists System (EPLS) found on SAM. Providers, suppliers, employees, and FDRs on the EPLS cannot receive Medicare payment for items or services they furnish or prescribe.
OIG	**OIG** is the Office of the Inspector General within DHHS. The Inspector General is responsible for audits, evaluations, investigations, and law enforcement efforts relating to DHHS programs and operations, including the Medicare program. The OIG maintains the List of Excluded Individuals and Entities (LEIE). Providers, suppliers, employees, and FDRs on the LEIE cannot receive Medicare payment for items or services they furnish or prescribe.
Plan sponser	**Plan sponsor** refers to an organization that has an approved contract with the federal government to offer Medicare Advantage and prescription drug plans. Moda Health is a Plan sponsor.
Related entity	**Related entity** means 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. (See 42 CFR §§ 422.500 and 423.501.)
SAM	**SAM** is the System for Award Management, an official website of the US government. See GSA for more information.

What are the compliance program requirements?

The following is a description of the compliance program requirements an FDR is expected to have. This section also has information about Moda's annual compliance attestation and audit process.

Standards of Conduct/compliance policies distribution

(42 CFR §§ 422.503(b)(4)(vi)(A) and 423.504(b)(4)(vi)(A))

Standards of Conduct (also known as a Code of Conduct) state the principles and values under which a company operates and the way it communicates to employees that compliance is everyone's responsibility. Compliance policies describe the details of a compliance program. Examples include a company's compliance structure, how fraud, waste and abuse are investigated, and compliance training requirements.

Standards of Conduct and compliance policies must be distributed to employees within 90 days of hire, when there are updates, and annually, thereafter.

Additional details about the content of Standards of Conduct, as well as compliance policies, can be found in Chapter 21 of the Medicare Managed Care Manual and Chapter 9 of the Medicare Prescription Drug Manual. In particular, the documents must contain the elements mentioned in section 50.1 of the manual. A link can be found in the "Toolbox of resources" section.

If you do not have Standards of Conduct or written compliance policies, you can download Moda's Compliance Plan and distribute it to your employees.

Conducting OIG/GSA exclusion check

(42 CFR § 1001.1901)

Plan Sponsors cannot use federal funds to pay for services provided by a person or entity excluded under the Department of Health and Human Services (DHHS) OIG List of Excluded Individuals and Entities (LEIE list) or the GSA Excluded Parties Lists System (EPLS). Before hiring and monthly, thereafter, an FDR must check that each potential hire or current employee is not listed on the OIG or GSA exclusion lists.

This requirement applies to any new employee, temporary employee, volunteer, consultant, governing body member, or FDR for your company if the individual or entity is assigned to work on the Medicare Advantage or prescription drug plan. If a person or entity is found to be on one of the lists, they must be removed from working on Moda's plan.

Records verifying the exclusion checks prior to hire/contracting and monthly, thereafter, must be maintained for 10 years and be available upon request.

Links to the OIG and GSA lists can be found in the "Toolbox of resources" section of this guide.

Communication and reporting mechanisms

(42 CFR §§ 422.503(b)(4)(vi)(D) and 423.504(b)(4)(vi)(D))
(42 CFR §§ 422.503(b)(4)(vi)(E)(1-3 and 423.504(b)(4)(vi)(E)(1-3))

An FDR must have a process for employees, members of the governing body, and their own FDRs to report compliance concerns. A process needs to be in place to receive, record, respond, and track compliance questions or reports of potential noncompliance. The process needs to be described in the Standards of Conduct or in a compliance policy.

The reporting process must maintain confidentiality for the individual reporting. It also must emphasize a policy of non-intimidation and non-retaliation for reporting in good faith. The reporting mechanism(s) must be easy to access and navigate and be available 24 hours a day.

The reporting process must be prominently publicized throughout company facilities. Posters or prominent website displays are examples of how the process can be publicized.

A compliance audit conducted by Moda will require a copy of the means your company has of publicizing the reporting process (e.g., a screenshot of the website, a copy of the poster).

Employees, members of the governing body, and FDRs may also report compliance concerns directly to Moda. Contact information is found in the "Toolbox of resources" section of this guide.

Fraud, Waste and Abuse (FWA) and General Compliance training

(42 CFR §§ 422.503(b)(4)(vi)(C)(1-2) and 423.504(b)(4)(vi)(C)(1-2))

FDRs who provide administrative services for our Medicare Advantage and prescription drug plans are subject to the training requirement. Providers of healthcare services are not subject to annual FWA and General Compliance training per CMS regulations.

FWA and General Compliance training must be provided to new employees within 90 days of hire and annually to employees. Training must also be provided to the CEO, senior administrators or managers, the governing body, and to FDRs (if contracted to provide administrative services for our plans).

Training requirements may be satisfied through classroom training, online training or attestations that employees have read and received the Standards of Conduct and/or compliance policies and procedures. A record of training for each employee must include the date of training. Records must be maintained for 10 years.

A copy of CMS' last training modules for FWA and Compliance is available at **modahealth.com/compliance**. These modules can be used for training if you have not developed your own training.

Details on effective training and education can be found in section 50.3 of Chapter 21 of the Medicare Managed Care Manual and Chapter 9 of the Medicare Prescription Drug Manual.

Notifying Moda of offshore contracting

The term "offshore" refers to any country that is not the United States or its territories (i.e., American Samoa, Guam, Northern Mariana Islands, Puerto Rico and U.S. Virgin Islands). Entities that are considered offshore can be either American-owned companies with portions of their operations performed outside the United States or foreign-owned companies with operations performed outside the United States. Offshore contracting occurs when services are performed by workers located in a country that is not the United States or its territories, regardless of whether the workers are employees of American or foreign companies.

Moda is required to inform CMS of offshore contracting related to its Medicare Advantage plans. As a result, FDRs must inform Moda if they contract with an offshore individual or entity who may receive, process, transfer, handle, store or access beneficiary protected health information (PHI) in oral, written or electronic form.

Part of the annual attestation process includes completion of an offshore attestation, if applicable.

Monitoring and auditing of FDRs

(42 CFR §§ 422.503(b)(4)(vii)(F) and 423.504(b)(4)(vi)(F))

It is Moda's responsibility to be compliant with CMS requirements for administration of its Medicare Advantage and prescription drug plans. When Moda delegates administrative services, it is Moda's responsibility to ensure that the first tier entity is meeting CMS compliance requirements. Moda uses attestations and audits as part of its process of monitoring first tier entities.

When a first tier entity contracts responsibility downstream, they are responsible for monitoring and auditing the downstream entity. A first tier entity may develop its own strategy for monitoring, but the strategy needs to include a means to determine if the downstream entity has a compliance program and policies as required by CMS.

Below is information about Moda's annual attestation and audit expectation. It is provided as a tool for your compliance program.

Our annual attestation

On an annual basis, you can expect Moda to ask you about the following compliance activities:

- Do you distribute Standards of Conduct and compliance policies to your employees, contractors and board members within 90 days of hire, when there are updates, and annually, thereafter?
- Are employees, contractors, board members and downstream entities screened against the OIG and GSA exclusion list prior to employment or contracting and monthly, thereafter?
- If an employee, board member or contractor is found on an exclusion list, is that person immediately removed from work related to a federal healthcare program?
- Are notices of how employees can report noncompliance or fraud, waste and abuse publicized throughout your facility?
- Do you have a non-retaliation policy that allows employees and contractors to report instances of fraud, waste and abuse or noncompliance when reporting in good faith?
- Is the non-retaliation policy communicated to all employees and contractors?
- Do you inform Moda prior to entering into a contract that transfers (sub-delegates) an obligation under your contract with Moda to a third party (a sub-delegate)?
- Do you monitor subcontractors to ensure they are compliant with the same Medicare regulations and requirements that apply to your contract with Moda?
- Does your company utilize any offshore services or sub-delegate to any offshore entity that involves processing, transferring, handling, storing or accessing protected health information (PHI)?
- Do employees who are subject to Fraud, Waste and Abuse (FWA) and General Compliance training requirements receive training within 90 days of hire and annually, thereafter?

Our audit requests

During a Compliance program audit, you will be asked to provide at least the following information:

- A copy of your Standards of Conduct.
- A copy of compliance policies that include information about your company's FWA reporting and investigation process, your FWA and General Compliance training requirements, your process for OIG/GSA exclusion checks, and a description of your company's Compliance structure.
- Verification of publicizing FWA reporting procedures.
- A copy of FWA and General Compliance training.
- A list of employees who work on the Medicare Advantage and prescription drug plans. This list needs to include the date of hire. Employees will be selected from the list to confirm training and OIG/GSA exclusion checks.
- Verification employees have taken FWA and General Compliance training.
- Verification of OIG/GSA exclusion checks.

Audits are conducted via email or online presentation. Timelines for submitting information follow CMS guidelines.

Contact us

If you have questions or concerns about creating a compliance program, you can contact us at: medicarecompliance@modahealth.com

Toolbox of resources

These resources can assist you when creating a compliance program.

CMS Compliance Program Guidelines	Manual and Chapter 9 of the Medicare Prescription Drug Manual are found at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf These documents provide details for creating a compliance program.
Moda Health's Medicare Compliance webpage	Here you will find links to: • Moda's Medicare Compliance Program, Code of Conduct and compliance policies • Fraud, Waste and Abuse (FWA) and General Compliance training • Moda's FWA reporting poster • A copy of an annual attestation for FDRs, including an offshore attestation • A description of regulatory requirements related to the annual attestation • A FAQ related to the attestation
Exclusion list screening	• OIG report: the Office of Inspector General's LEIE downloadable database is found at: https://oig.hhs.gov/exclusions/exclusions_list.asp • GSA report: the Exclusions Extract Data Package is found at: https://www.sam.gov/SAM/pages/public/extracts/samPublicAccessData.jsf
Direct reporting of noncompliance to Moda Health	**Medicare Compliance Department** Email: medicarecompliance@modahealth.com Phone: 855-801-2991 **Special Investigations Unit (SIU)** Email: stopfraud@modahealth.com Phone: 855-801-2991 **Anonymous hotline and website administered by EthicsPoint, a confidential third party** Website: www.ethicspoint.com Hotline phone: 866-294-5591

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