

# Medicare Prescription Drug Compliance Regulations and Resources

## Compliance Program Guidelines

[42 CFR §§ 423.504(b)(4)(vi)]

CMS publishes Medicare compliance program requirements in the Prescription Drug Benefit Manual (PDBM), Chapter 9. The Medicare compliance program requirements apply equally to the plan sponsor, Moda Health, and any individual/entity with which Moda Health contracts for services related to the Prescription Drug (Part D) program. These individuals/entities are classified as either a First Tier, Downstream, or Related entity (FDR). Moda Health refers to these entities as “Delegates”. Definitions for First Tier, Downstream, and Related Entities can be found in the above referenced chapters at the following website: <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf>.

## Compliance Program, Compliance Policies, Compliance Information, and Code of Conduct

[42 CFR §§ 423.504(b)(4)(vi)(A)]

All Delegates who contract with Moda Health’s Prescription Drug (Part D) Programs must either (1) abide by Moda Health’s Code of Conduct and policies and procedures, or (2) adopt an internal code of conduct and policies and procedures consistent with the CMS requirements outlined in Section 50.1.1 of the Prescription Drug Benefit Manual (PDBM), Chapter 9.

A code of conduct states over-arching principles and values by which a Delegate operates and defines the underlying framework for compliance policies and procedures. The code of conduct must provide the standards by which individuals must conduct themselves, including the responsibility to perform duties in an ethical manner and in compliance with laws, regulations, and policies and procedures whether or not explicitly addressed in the code of conduct. The code of conduct, or supplemental policies and procedures should include provisions to ensure those responsible for the administration of Medicare benefits are free from conflicts of interest. Conflicts of interest are created when an activity or relationship renders a person unable or potentially unable to provide impartial assistance or advice, impairs his/her objectivity, or provides him/her with an unfair competitive or monetary advantage.

Additionally, the code of conduct or supplemental policies and procedures must include provisions requiring employees (which include temporary, part-time, full-time, and volunteers) and contractors to report issues of non-compliance and potential fraud, waste, and abuse (FWA) to appropriate compliance personnel. The code of conduct and supplemental policies and procedures must be reviewed annually and made available to all employees and contractors. The delegate should ensure that all employees and contractors agree to abide by the code of conduct and keep record of these acknowledgements.

## Reporting Mechanisms and Disciplinary Standards

[42 CFR §§ 423.504(b)(4)(vi)(D)]

[42 CFR §§, 423.504(b)(4)(vi)(E)(1-3)]

A Delegate and its employees (temporary, part-time, full-time, and/or volunteer staff), contractors and/or subcontractors who conduct work with Medicare beneficiaries on behalf of Moda Health must provide notice throughout its facilities of the duty to report any observed or suspected non-compliance or potential fraud, waste, or abuse (FWA). The notice must provide mechanisms to report any observed or suspected non-compliance and/or potential FWA and should include a 24- hour, anonymous reporting option. The Delegate may utilize an independent third-party to provide an anonymous reporting option for employees. Notices should include reference to the Delegate’s non-intimidation and non-retaliation policy for employees, contractors, and/or subcontractors who report compliance and/or FWA concerns in good faith.

If the Delegate does not have reporting mechanisms consistent with CMS requirements, the Delegate should provide Moda Health’s reporting mechanisms, including the following:

- **Medicare Compliance Department**
  - Email: [medicarecompliance@modahealth.com](mailto:medicarecompliance@modahealth.com)
  - 
  - Phone: 855-801-2991
- **Special Investigations Unit (SIU)**
  - Email: [stopfraud@modahealth.com](mailto:stopfraud@modahealth.com)
  - Phone: 855-801-2991
- **Anonymous Hotline and Website administered by EthicsPoint, a confidential third party**
  - Hotline Phone: 866-294-5591
  - Website: [www.ethicspoint.com](http://www.ethicspoint.com)

### **OIG and GSA Screening**

[42 CFR § 1001.1901]

A Delegate and its employees (temporary, part-time, full-time, and/or volunteer staff), contractors and/or subcontractors who provide administrative and/or healthcare support to Medicare beneficiaries on behalf of Moda Health are prohibited from employing or contracting with persons or entities that have been excluded from doing business with the federal government. Upon hiring/contracting and monthly thereafter, Delegates are required to verify that their employees are not excluded by comparing them against the Office of the Inspector General (OIG) List of Excluded Individuals and Entities (LEIE), and the General Services Administration (GSA) and Excluded Parties List System (EPLS).

No payment will be made by Moda Health, Medicare, Medicaid or any other Federal or State health care programs for any item or service furnished on or after the effective date specified in the notice period by an excluded individual or other authorized individual who is excluded when the person furnishing such item or service knew or had reason to know of the exclusion.

To assist you with implementation of your OIG/GSA Exclusion process, links to the OIG and GSA exclusion websites and descriptions of the lists are below.

***Excluded Party List System (EPLS)*** - <https://www.sam.gov/search>

This list is maintained by the General Services Administration (GSA), now a part of the System for Awards Management (SAM). The EPLS is an electronic, web-based system that identifies those parties excluded from receiving Federal contracts, certain subcontracts, and certain types of Federal financial and non-financial assistance and benefits. The EPLS keeps its user community aware of administrative and statutory exclusions across the entire government, and individuals barred from entering the United States.

***List of Excluded Individuals and Entities (LEIE)*** – <http://exclusions.oig.hhs.gov>

This list is maintained by the Office of Inspector General (OIG) and provides information to the health care industry, patients and the public regarding individuals and entities currently excluded from participation in Medicare, Medicaid and all Federal health care programs. Individuals and entities who have been reinstated are removed from the LEIE.

### **Sub-Delegation**

Sub-delegation occurs when a Delegate contracts with a third party to carry out a responsibility delegated by Moda Health to the Delegate to perform. In the event the Delegate sub-delegates any delegated function, the Delegate must obtain advance written approval from Moda Health. Additionally, the contract between Moda Health and the Delegate must be amended to include the sub-delegation. Any updated agreements shall be filed with the appropriate governmental agencies if applicable.

### **Offshore Subcontractors**

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). Subcontractors that are considered offshore can be either American-owned companies with certain portions of their operations performed outside of the United States or foreign-owned companies with their operations performed outside of the United States. Offshore subcontractors provide services that 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.

The Delegate must ensure its employees have read and understand all requirements pertaining to the regulations for services that are performed by workers located in offshore, regardless of whether the workers are employees of American or foreign companies. Consistent with CMS’ direction, this applies to entities the Delegate may contract or sub-contract with to receive process, transfer, handle, store, or access beneficiary protected health information (PHI) in oral, written, or electronic form. In the event the Delegate sub-delegates any Moda Health Medicare activities to an offshore subcontractor, the Delegate will be required to adhere to the approval process outlined for sub-delegation activities and complete and separate offshore attestation.

### **Additional Resources**

For more information on laws governing the Medicare program or for additional healthcare compliance resources please see:

- Title XVIII of the Social Security Act
- Medicare Regulations governing Parts C and D (42 C.F.R. §§ 423)
- Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))
- Exclusion entities instruction (42 U.S.C. § 1395w-27(g)(1)(G))
- The Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Public Law 104-191) (45 CFR Part 160 and Part 164, Subparts A and E)
- OIG Compliance Program Guidance for the Healthcare Industry: <http://oig.hhs.gov/compliance/compliance-guidance/index.asp>