This Compliance Attestation is for First Tier, Downstream, and Related Entities (FDRs) that provide services to Medicare and/or Medicare Advantage beneficiaries on behalf of MMS and its Clients.

Per the Centers for Medicare & Medicaid Services (CMS) Chapter 9 of the Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual, the Medicare program requirements apply to FDRs to whom the Plan Sponsor has delegated administrative or health care service functions relating to the Sponsor’s Medicare Parts C and D contracts.

The CMS regulation further requires that Plan Sponsors demonstrate that the FDRs performing services for the Medicare and Medicare Advantage programs are in compliance with all applicable laws, rules, and regulations with respect to Medicare Parts C and D delegated responsibilities.

By submitting this document, the submitter certifies that their entity/organization has met and is in compliance with the requirements referenced below.

DEFINITIONS

**First Tier Entity**: is a 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 health care services to a Medicare eligible individual under the MA program or Part D program (42 C.F.R. §§ 422.2, 423.501)

**Downstream Entity**: is any party that enters into a written agreement, 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 (42 C.F.R. §§ 422.2, 423.501)

**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 (42 C.F.R. §§ 422.2, 423.501)

**Offshore**: refers to any country that is not one of the fifty United States or one of the United States Territories (American Samoa, Guam, Northern Marianas, Puerto Rico, and Virgin Islands). Examples of countries that meet the definition of “offshore” included, Mexico, Canada, India, Germany, and Japan. 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 offshore countries, regardless of whether the workers are employees of American or foreign companies.

**Medicare-related work**: encompasses what offshore subcontractors do when they receive, process, transfer, handle store or access beneficiary Protected Health Information (PHI) while helping sponsors fulfill their Medicare Part C and Part D contract requirements.

REQUIREMENTS

I. **Training and Education**

All persons (including employees, contractors, and subcontractors) involved in administering or delivering Medicare Part D and/or Medicare Advantage benefits within its organization must have completed Compliance and Fraud, Waste, and Abuse (FWA) training, as required by 42 C.F.R. §§ 422.503(b)(4)(vi)(C), 423.504(b)(4)(vi)(C). Regulation further states that employees must be aware of the Medicare requirements related to their job function. MMS reserve the right to request proof of training which may include sign-in sheets, attestations, certifications, training records, and training material samples.

   a. **General Compliance Training**

      Employees (including temporary workers and volunteers) and governing body members must, at a minimum, receive general compliance training within 90 days of initial hiring, and annually thereafter.

      Topics addressed in the general compliance training must include:
A description of the compliance program, including a review of compliance policies and procedures, the Code of Conduct and the commitment to business ethics and compliance with all Medicare program requirements;

An overview of how to ask compliance questions, request compliance clarification or report suspected or detected noncompliance. Training should emphasize a confidentiality, anonymity, and non-retaliation for compliance related questions or reports of suspected or detected noncompliance or potential FWA;

The requirement to report to the sponsor actual or suspected Medicare program noncompliance or potential FWA;

Examples of reportable noncompliance that an employee might observe;

A review of the disciplinary guidelines for noncompliant or fraudulent behavior. The guidelines should communicate how such behavior can result in mandatory retraining and may result in disciplinary action, including possible termination when such behavior is serious or repeated or when knowledge of a possible violation is reports;

Attendance and participation in compliance and FWA training programs as a condition of continued employment and a criterion to be included in employee evaluations;

A review of policies related to contracting with government, such as the laws addressing gifts and gratuities for Government employees;

A review of potential conflicts of interest and the sponsor’s system for disclosure of conflicts of interest;

An overview of HIPAA/HITECH, the CMS Data Use Agreement (if applicable) and the importance of maintaining the confidentiality of protected/personal health information;

An overview of the monitoring and auditing process; and

A review of the laws that govern employee conduct in the Medicare program.

b. Fraud, Waste, and Abuse Training

Employees (including temporary workers and volunteers) and governing body members who have involvement in the administration or delivery of Parts C and D benefits must, at a minimum, receive FWA training within 90 days of initial hiring (or contracting in the case of FDRs) and annually thereafter. Additional specialized or refresher training may be provided on issues posing FWA risks based on the individual’s job function (e.g., pharmacist, statistician, customer service, etc.). Topics that should be addressed in FWA training include, but are not limited to the following:

Laws and regulations related to Medicare Advantage and Part D FWA (e.g., False Claims Act, Anti-Kickback statute, HIPAA/HITECH, etc.);

Obligations of FDRs to have appropriate policies and procedures to address FWA;

Processes for sponsors and FDR employees to report suspected FWA to sponsor (or, as to FDR employees, either to the sponsor directly or to their employers who then report it to the sponsor);

Protections for sponsor and FDR employees who report suspected FWA; and

Types of FWA that can occur in the settings in which sponsor or FDR employees work.

II. OIG/GSA Exclusion

FDRs must review the Department of Health and Human Services (DHHS) Office of Inspector General (OIG) List of Excluded Individuals and Entities (LEIE) and the General Services Administration (GSA) Federal System of Award Management (SAM) 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 none of these persons or entities are excluded or become excluded from participation in federal programs as required by The Act §1862(e)(1)(B), 42 C.F.R. §§422.503(b)(4)(vi)(F), 422.752(a)(8), 423.504(b)(4)(vi)(F), 423.752(a)(6), 1001.1901.

III. Conflict of Interest

Submitter certifies that the entity’s governing body and senior leadership were screened for conflicts of interest through a certification, attestation or other means at the time of hire and annually thereafter.

IV. Standards of Conduct / Code of Conduct and Compliance Policies and Procedures


The Downstream Entity must distribute to its employees, contractors, and subcontractors who support the Medicare business, their own or the MMS Code of Conduct and Compliance Policies and Procedures. The FDR’s Code of Conduct and Compliance Policies and Procedures should be substantively similar to the MMS versions.
Distribution of the Code of Conduct and Compliance Policies and Procedures must occur within 90 days of hire, when there are updates to the policies, and annually thereafter.

V. **Record Retention**
CMS rules and regulations require documents to be retained for the longer of 1) ten (10) years from the termination of the FDRs agreement with MMS, regardless of the reason for termination; 2) completion of any audit; or 3) such other time frame as provided or required by Laws, DHHS, or the Comptroller General. In accordance with CMS regulation, submitter agrees to maintain any supporting documentation for all the requirements listed above.

VI. **Incidents of Suspected Noncompliance Fraud, Waste, and Abuse**
Entity/Organization shall promptly investigate any potential and/or suspected incidents of noncompliance with laws, regulations, or fraud, waste, and abuse. The entity/organization must report any such incidents to MMS Compliance Officer in a timely manner after entity/organization becomes aware of such incident. The incident may also be reported by calling the MMS Compliance Hotline: 952-542-5356, which is available 24 hours a day, seven (7) days a week.

VII. **Pre-Employment Background Check**
Entity/Organization shall perform a background check on all personnel (including subcontractors) providing services. Background checks include identification of significant criminal history that could compromise MMS reputation. Background checks include Social Security Validation, Social Security Number Trace, Criminal Felony and Misdemeanor search, National Criminal Database search, Federal Criminal National search, Education verification, Employment verification, Credential verification, and health care exclusion verification.

VIII. **E-Verify**
The Illegal Immigration Reform and Immigrant Responsibility Act (IIRIRA), required the Social Security Administration (SSA) and U.S. Citizenship and Immigration Services (USCIS) to create an employment verification process. As a result E-Verify was implemented 8 U.S.C. 1324a to ensure employees are eligible to receive federally funded dollars. Entity/Organization shall comply with the U.S. Department of Homeland Security E-Verify procedures to verify the employment eligibility of all new employees hired to perform duties within the United States.

IX. **Activities Performed Outside of the United States (Offshore)**
Per CMS requirements, entities/organizations that work with offshore subcontractors to perform Medicare-related work that uses beneficiary PHI as defined above, are requested to provide CMS with specific offshore subcontractor information. MMS is required to submit the offshore subcontractor information to its Clients. Plan sponsor is required to submit information to CMS.

**ATTESTATION STATEMENT**

For each statement below, please check or circle the appropriate response and provide details where requested.

I certify to the best of my knowledge, information, and belief that:

1. CMS General Compliance Training has met the general compliance training program requirements stated above
   
   AGREE  
   
   DISAGREE
   
   Please specify the name and source of Compliance Training:

   **VENDOR:** ____________________________  **ENTITY’S OWN**  **OTHER (please explain)**
   
   Vendor name

2. CMS FWA Training has met the FWA training program requirements stated above
   
   AGREE  
   
   DISAGREE
3. OIG/GSA Exclusion requirements have been met
   AGREE          DISAGREE

4. Conflict of Interest requirements have been met
   AGREE          DISAGREE

5. Code of Conduct requirements have been met
   AGREE          DISAGREE

6. Which Code of Conduct was used?
   MMS          ENTITY’S OWN          OTHER (please explain)

7. Record Retention requirements have been met
   AGREE          DISAGREE

8. Will your organization report incidents of suspected noncompliance fraud, waste, and abuse as stated above?
   AGREE          DISAGREE

9. Pre-Employment Background Checks requirements have been met
   AGREE          DISAGREE

10. E-Verify requirements have been met
    AGREE          DISAGREE

If the entity/organization is utilizing FDRs please complete this section

11. Please provide a list of FDRs your organization utilizes

12. If submitter is using FDRs, have the FDRs met the Compliance and FWA Training requirements listed above?
    AGREE          DISAGREE

13. Have your organizations FDR met the OIG/GSA Exclusion requirements?
    AGREE          DISAGREE

14. Have your organizations FDR met the Conflict of Interest requirements?
    AGREE          DISAGREE

15. Have your organizations FDR met the Code of Conduct requirements?
    AGREE          DISAGREE
16. Which Code of Conduct document was used?
   MMS          ENTITY’S OWN          OTHER (please explain)

17. Will your organization’s FDR report incidents of suspected noncompliance fraud, waste, and abuse as stated above?
   AGREE          DISAGREE

   *If the entity/organization is utilizing Offshore Subcontractors please complete this section*

18. Please provide a list of Offshore Subcontractors your organization utilizes. Additional questions will be provided, should Offshore Subcontractors be utilized.

________________________________________________  _______________________________
Signature                                           Printed Name and Title

________________________________________________  _______________________________
Company Name                                         Date