

Mercy Care Advantage
4500 E Cotton Center Blvd
Phoenix, AZ 85040



Compliance Program Requirements for Medicare Advantage First Tier, Downstream or Related Entities (FDRs), Annual Attestation and Disclosure Statement

July 2021

Dear: First Tier Delegated Entity

Your Organization is receiving this “Annual Attestation and Disclosure Statement” because your Organization is contracted with Mercy Care as a First Tier, Downstream, or Related Entity (FDR) for our Mercy Care Advantage plan. Under our Medicare contract with the Centers for Medicare & Medicaid Services (CMS) Mercy Care is committed to ensuring proper communication and education for employees and FDRs to help understand and conduct business ethically and in compliance with the federal laws applicable to the Medicare program, which includes CMS rules, regulations, and sub-regulatory guidance.

As a contracted FDR, your Organization is required to have processes in place to prevent, detect, and correct non-compliance with the CMS program requirements. Your Organization’s employees and sub-contractors must abide by federal laws related to the Medicare program as well as CMS rules, regulations, and sub-regulatory guidance.

This packet explains the CMS program requirements that apply under your Organization’s contract with Mercy Care related to our Mercy Care Advantage plan. Please review the packet which consists of the following:

- **Section 1) Medicare Compliance Requirements for Mercy Care’s First Tier, Downstream and Related Entities**
- **Section 2) Attestations, Organization Information and Signature Page**

CMS definitions of a First-Tier, Downstream, and Related Entity

First Tier Entity is any party that enters into a written arrangement, acceptable to CMS, with a Medicare Advantage Organization or Part D plan sponsor or applicant to provide administrative services or healthcare services to a Medicare eligible individual under the Medicare Advantage program or Part D program.

Downstream Entity is any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the Medicare Advantage benefit or Part D benefit, below the level of the arrangement between a Medicare Advantage Organization 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 means any entity that is related to a Medicare Advantage Organization or Part D sponsor by common ownership or control and:

1. Performs some of the Medicare Advantage Organization 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 Medicare Advantage Organization or Part D plan Sponsor at a cost of more than \$2,500 during a contract period.

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ACTION REQUIRED

- **If you are an existing contracted FDR**, please review this packet, complete, sign, and return the enclosed Annual Attestation and Offshore Attestation within (30) calendar days of the date on this notice.
- **If you are a newly contracted FDR**, please review this packet, complete, sign and return the enclosed Annual Attestation and Offshore Attestation within (60) calendar days of the date on this notice.
- Please refer to page 7 for instructions and options available to return your Organizations completed attestations.
- The attestation's must be completed and signed by the person within your Organization who is authorized to do so, such as the Compliance Officer or other applicable management personnel.

If you have any questions regarding the information in this packet, please contact me at 909.792.3937 or MaciasC1@mercycaresaz.org.

To report identified non-compliance or potential fraud, waste and abuse, please contact me at 909.792.3937 or MaciasC1@mercycaresaz.org. You can report anonymously by contacting our toll-free Ethics Line at 1-877-287-2040 in the U.S. (available 24 hours a day, 7 days a week).

Thank you,
Chris Macias
Medicare Compliance Officer
Mercy Care Advantage
MaciasC1@mercycaresaz.org
Office: 909.792.3937

Section 1. Medicare Compliance Requirements applicable to Mercy Care's First Tier, Downstream and Related Entities

Standards of Conduct, Written Policies and Procedures

Mercy Care operates under a Management Services Agreement with Aetna and CVS Health. Mercy Care utilizes and complies with the CVS Code of Conduct. Contracted FDRs are required to maintain an effective Compliance Program that includes Standards of Conduct as well as specific policies and procedures that implement the operations of the compliance program. The Standards of Conduct must explain your Organization's over-arching principles and the values by which your Organization operates and define the underlying framework for the compliance policies and procedures. It must include the standards by which all employees and sub-contractors also referred to as downstream entities, will conduct themselves including the responsibility to perform duties in an ethical manner and in compliance with laws, regulations, and policies. It must include provisions to help ensure that employees, managers, officers, directors, and sub-contractors responsible for the administration or delivery of the Medicare benefits are free from any conflict of interest in administering or delivering Medicare benefits. Conflicts of interest are created when an activity or relationship renders a person unable or potentially unable to provide impartial assistance or advice, impairs a person's objectivity, or provides a person with an unfair competitive or monetary advantage.

Policies and procedures must include detailed and specific guidance regarding the prevention, detection and correction of Medicare non-compliance and fraud, waste, and abuse (FWA) and how to report improper conduct, Medicare non-compliance and suspected FWA in a timely and well documented manner.

FDR Organizations must have processes to ensure employees and sub-contractors, as a condition of employment, read and agree to comply with the standards of conduct and all written compliance policies and procedures within 90 days of date of hire or contracting, when updated, and annually thereafter. Employee statements or certifications must be retained for 10 years and made available upon request to Mercy Care or CMS.

Medicare Compliance Program Guidelines

To help organizations understand and comply with Compliance Program expectations, CMS issued the Medicare Managed Care Manual Chapter 21 and the Prescription Drug Benefit Program Manual Chapter 9 – which contains the Compliance Program Requirements for Part C and Part D respectively. Medicare program requirements apply to FDRs delegated to provide administrative or health care service functions relating to Mercy Care's Medicare Part C and D contracts. A link to this CMS manual is provided below; contracted FDRs must review this manual and ensure appropriate protocols are in place to comply with CMS requirements and guidelines.

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf>

A copy of the CVS Code of Conduct is available at:

<https://cvshealth.com/sites/default/files/cvs-health-code-of-conduct.pdf>

Sanction/Exclusion Lists Screening

Contracted FDRs providing services for Mercy Care's government programs warrant that they meet all applicable terms of participation in the Medicare program. FDRs may not employ or subcontract with an individual who is excluded from participation in Medicare under Section 1128 or 1128A of the Social Security Act. FDRs agree to review the OIG and GSA exclusion lists to ensure its board members, employees (including temporary and volunteer) and sub-contractors are not on such lists on prior to hire or contracting and monthly thereafter. FDRs agree to notify Mercy Care immediately upon any changes in its Medicare participation or other status, or the imposition of any sanction or remedial remedy by

applicable state or federal authorities. If an FDR employee or subcontractor is found to be on such lists, FDRs will take corrective action to immediately remove that employee or subcontractor from any work directly or indirectly related to all government programs. Upon discovery of an excluded individual, FDRs must provide immediate disclosure to Mercy Care. To assist FDRs in conducting the required verification process, included below are links to the GSA and OIG exclusion websites:

GSA' System for Award Management (SAM) – <https://www.sam.gov>

List of Excluded Individuals and Entities (LEIE) – http://oig.hhs.gov/exclusions/exclusions_list.asp

CMS Preclusion List

CMS implemented the Preclusion list requirements effective January 1, 2019. A list of providers and prescribers who are precluded from receiving payment for Medicare Advantage (MA) items and services or Part D drugs furnished or prescribed to Medicare beneficiaries. Individuals or entities who meet the following criteria are on the list:

- 1) Are currently revoked from Medicare, are under an active reenrollment bar, and CMS has determined that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program; or
- 2) Have engaged in behavior for which CMS could have revoked the prescriber, individual or entity to the extent applicable if they had been enrolled in Medicare and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program. Such conduct includes, but is not limited to, felony convictions and Office of Inspector General (OIG) exclusions.

In order for providers or prescribers to receive payment for health care items, services or Part D drugs furnished to beneficiaries enrolled in a Medicare Advantage plan, they must not be included on the Preclusion List. CMS issues an updated list approximately every 30 days. Mercy Care has implemented processes to comply this new requirement, which requires advance member notification when a provider has furnished services and is identified on the Preclusion list. Mercy Care must prevent future payments to identified contracted and non-contracted providers and must terminate contracted providers, individuals or entities identified on the CMS Preclusion list, which may include FDR contracted providers. For more information visit:

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/PreclusionList>

Effective Lines of Communication and Reporting Mechanisms

Contracted FDRs agree to communicate and publicize the methods available to employees and subcontractors for reporting potential non-compliance and suspected FWA activity. FDRs must also publish the ability to make an anonymous report to the toll-free Mercy Care Ethics Line at 1-877-287-2040 (available 24 hours a day, 7 days a week in the U.S.). FDRs agree not to discriminate or retaliate against any employee or agent for reporting a compliance concern or for cooperating in any government or law enforcement authority's investigation or prosecution.

FDRs must promptly disclose identified compliance deficiencies and/or suspected FWA that involves Mercy Care. When an FDR receives a report of, or becomes aware of, potential non-compliance or suspected FWA incident, the FDR agrees to disclose such instances to Mercy Care within 10 calendar days of identification. Upon the discovery of any compliance deficiency, either through an FDRs own internal compliance activities or through notification from Mercy Care, FDRs must take immediate action to determine root cause, member impact and develop a corrective action plan that includes a timeframe for required remediation. Prompt disclosure allows Mercy Care to assist in remediation and provide notification to CMS (as applicable), in accordance with CMS rules, regulations, and guidance.

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FDRs need to report identified non-compliance and suspected FWA concerns involving Mercy Care Advantage to:
Chris Macias
Medicare Compliance Officer
Mercy Care Advantage
MaciasC1@mercycaresaz.org
Office: 909.792.3937

Well-Publicized Disciplinary Standards and Enforcement

FDRs must agree to publicize disciplinary standards to all employees and sub-contractors, including the duty and expectation to report issues and concerns. Disciplinary standards must identify noncompliant, unethical, or illegal behavior through examples. This may be done through trainings, communications, or posters. FDR agrees to take corrective action against its employees and sub-contractors when non-compliant or unethical behavior is detected and to maintain records of compliance violation disciplinary actions for 10 years.

Training and Education

It is CMS' expectation that contracted FDRs have an effective compliance program implemented to prevent, detect, report, and correct identified Medicare non-compliance and fraud waste and abuse in a timely and well documented manner. FDRs must have processes to provide general compliance, FWA, and specialized training at the time hire and annually thereafter, for all applicable employees and downstream entities. FDRs must provide timely training and education for employees and sub-contractors when new Medicare regulatory requirements and sub-regulatory guidance is issued.

Operational Oversight and Identification of Compliance Risks

Mercy Care shall establish and maintain ongoing delegation monitoring and oversight of all aspects of contracted FDR performance. The Mercy Care delegation agreement describes the following:

- The responsibilities of Mercy Care and the delegated entity,
- The delegated activities, performance and reporting requirements, and the processes by which Mercy Care evaluates the entity, and remedies for noncompliance.
- FDR agrees to provide Mercy Care access for auditing and monitoring purposes as required by CMS.

FDRs agree to conduct internal oversight of the services performed on behalf of Mercy Care to ensure that compliance is maintained with applicable laws, rules, and regulations. If an FDR engages in conduct, that constitutes a breach of the delegation agreement, Mercy Care will take appropriate actions to enforce the delegation agreement. FDR agrees to implement corrective actions for identified deficiencies. At minimum, the corrective action plan shall specify the actions taken to remedy the breach or deficiencies, a timeframe for required remediation, and the parties responsible for implementation. All documentation of corrective actions must be provided to Mercy Care in writing.

In addition, Mercy Care will audit FDRs for the following Medicare compliance program requirements:

- Standards of conduct and/or compliance policies
- U.S. Department of Health & Human Services Office of Inspector General (OIG) and General Services Administration's System for Award Management (SAM) exclusion screening
- Reporting mechanisms
- Operational and Downstream entity oversight

Reference: Center for Medicare & Medicaid Services Medicare Managed Care Manual – Chapter 21 Compliance Program Guidelines: <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf>

CMS Audits and Monitoring Projects

CMS performs routine monitoring projects and conducts Medicare Advantage program audits of contracted Medicare Advantage plans. These monitoring projects and audits help CMS evaluate and validate Mercy Care and FDR compliance for delivering benefits and services in accordance with the Medicare Advantage contract and core program requirements. FDRs delegated to provide services and functions for the Mercy Care Advantage contract are required to provide supporting documentation and participate in monitoring projects and audits conducted by CMS and/or Mercy Care upon notification.

CMS releases annual audit protocols for identified Part C and D performance areas that explain their audit approach, universe layouts, and documentation required to measure a plan's performance. FDRs delegated for Part C or D functions applicable to the Mercy Care Advantage contract are required to review and comply with the current CMS Audit Protocols available at: <https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.html>

Sub-Delegation

When a contracted FDR gives another entity the authority to carry out a delegated responsibility that Mercy Care has delegated to the FDR, this constitutes sub-delegation. If your Organization decides to sub-delegate any current delegated functions, you must first obtain prior approval from Mercy Care. Requests for sub-delegation must be submitted in writing to Mercy Care ninety (90) days in advance of the anticipated sub-delegation effective date. If approved, the contract between Mercy Care and your Organization will be amended to include the sub-delegation function and this change will be communicated to the appropriate regulatory agencies, as applicable. Any sub-delegation shall be subject to all requirements set forth herein as mandated by CMS.

Offshore Subcontractors

To help ensure Mercy Care is compliant with CMS and AHCCCS Medicaid regulations for offshore subcontracting, Mercy Care only contracts with Organizations based in the United States and its territories. If your Organization decides to sub-delegate any current delegated functions for Mercy Care or Mercy Care Advantage to an offshore sub-contractor, your Organization must first obtain Mercy Care's approval by following the process described above under sub-delegation.

The term "Offshore" refers to any country that is not one of the fifty (50) United States or one of the United States Territories (American Samoa, Guam, Northern Marianas, Puerto Rico, and 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 offshore countries, regardless of whether the workers are employees of American or foreign companies.

Note: *your Organization must complete and submit the offshore attestation included in this packet even if your Organization does not conduct any work offshore.*

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Section 2. Attestations and Organization Information and Signature Page – Action Required

Existing contracted FDR: you must review, complete, sign, and return the enclosed Annual Attestation and Offshore Attestation within (30) calendar days of the date on this notice. *Please keep copies for your records.*

New contracted FDR: you must review complete, sign, and return the enclosed Annual Attestation and Offshore Attestation within (60) calendar days of the date on this notice. *Please keep copies for your records.*

- *Annual Attestation and Organization Information and Signature Page (pages 8-9)*
- *Offshore Attestation (page 10)*

Please return the Attestation's found on pages 8-10 to Mercy Care's Medicare Compliance Department. Please use one of the methods below to return your Organization's attestations:

Email scanned copies to: MercyCareAdvantageMedicareCompliance@AETNA.com

OR

Mail hard copies to:

Mercy Care Plan
4500 E Cotton Center Blvd
Phoenix, AZ 85040
Attention: LaRetha Taylor, Medicare Compliance Department

If you have any questions regarding the information in this packet, please contact me at 909.792.3937 or MaciasC1@mercycaresaz.org.

To report identified non-compliance or potential fraud, waste and abuse, please contact me at 909.792.3937 or MaciasC1@mercycaresaz.org. You can report anonymously by contacting our toll-free Ethics Line at 1-877-287-2040 in the U.S. (available 24 hours a day, 7 days a week).

Mercy Care FDR Web Page

Mercy Care has an FDR web page on our Mercy Care Provider website. This web page contains information and resources such as our Compliance Program and policies, Aetna/CVS Code of Conduct and FDR newsletters to assist our contracted FDRs. We encourage you to routinely check this web page for new information and resources.

<https://www.mercycaresaz.org/providers/advantage-forproviders/fdr>

Annual Attestation

Our Organization, and contracted downstream entities, if any, who are providing administrative, and or health care services on behalf of Mercy Care Advantage agree to commitment to comply with the following Centers for Medicare & Medicaid Services (“CMS”) requirements:

1. Our Organization has established and publicized compliance policies and procedures, standards of conduct, and compliance reference material that meet the requirements outlined in 42 CFR § 422.503(b)(4)(vi)(A) and 42 CFR § 423.504(b)(4)(vi)(A) that are distributed to all applicable Organization officers, board members, employees and downstream entities at time of hire, appointment or contracting and at least annually thereafter or when requirements change that require updating.
2. Our Organization screens the US Department of Health & Human Services Office of Inspector General (OIG) and the General Services Administration’s System for Award Management (SAM) exclusion lists prior to hire or contracting, and monthly thereafter, for employees and Downstream Entities. Our Organization removes any person or entity from work on Mercy Care Advantage if found on these lists.
3. Our Organization communicates to employees how to report suspected or detected non-compliance or potential FWA, and that it is their obligation to report without fear of retaliation or intimidation against anyone who reports in good faith. Our Organization either requests employees to report concerns directly to Mercy Care or maintains confidential and anonymous mechanisms for employees to report internally. In turn, we report these concerns to Mercy Care, when applicable.
4. Our Organization will conduct appropriate training and education for employees and downstream entities that includes but is not limited to: specialized training including training on laws, regulatory requirements and sub-regulatory guidance and general compliance and FWA training. Training is provided at the time hire, annually thereafter, or when regulatory or sub-regulatory changes occur.
5. Our Organization will conduct internal oversight of the services that we perform for Mercy Care and Mercy Care Advantage to ensure that compliance is maintained with applicable laws, rules and regulations. This includes robust oversight of any approved downstream entities to ensure they comply with all the requirements described in this attestation. Our Organization will provide required information and participate in monitoring projects and audits conducted by CMS and/or Mercy Care.
6. Our Organization understands that any violation of any laws, regulations, or Mercy Care Policies is grounds for disciplinary action, up to and including termination of Organization’s contractual status.
7. Our organization acknowledges the Mercy Care must approve in advance any work being considered to be performed offshore. We will provide Mercy Care with a completed Offshore Services Attestation for review and consideration of such requests.
8. Our organization will retain documented evidence of compliance with all of the above, including training and exclusion screening (i.e. sign-in sheets, certificates, attestations, OIG and GSA search results, etc.) for at least ten (10) years, and provide such documentation to Mercy Care or CMS upon request.

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Important Note: If you're Organization or contracted downstream entities are not compliant with any of the regulatory requirements listed in this attestation, please include a written explanation below identifying the area(s) of non-compliance. Explain the action steps that will be taken to remediate and expected implementation timeframe.

Non-compliance Explanation (please describe areas of noncompliance identified):

Organization Information and Signatures

I certify, as an authorized representative of my Organization, that the statements made above are true and correct to the best of my knowledge. Our Organization agrees to maintain documentation supporting those statements and in accordance with federal regulations, which is no less than 10 years. We'll produce this evidence, upon request. We understand the inability to produce this evidence may result in a request for a Corrective Action Plan or other contractual remediation.

Authorized representative printed name and title

Signature of authorized representative

Date

Phone number of authorized representative _____

Organization name printed

Organization mailing address

Please note that the certification is intended to be completed at the contract level. If your Organization has multiple tax identification numbers (TINs) under one contract, please list them below.

Tax Identification Numbers	

Offshore Attestation

As a contracted Mercy Care FDR, you must complete and return this Offshore Attestation with the required FDR Annual Attestation.

- If your organization is using offshore services for Mercy Care delegated functions, please select the “Yes” box below and complete the other sections of the Offshore Attestation. Mercy Care will review the information you provide in this attestation and contact your Organization if we have any questions.
- If your organization is not using any offshore services, complete the selection below and select the “No” box.

Organization Name:

Name of Authorized Person:

Title:

Phone:

Date:

Are any administrative or other functions conducted on behalf of your organization by entities located offshore? *This includes employees of your organization, downstream entities, and any third-party subcontractors.*

- ☐ No - Our Organization is currently not using any Offshore Subcontractors and/or Employees.
- ☐ Yes - Our Organization is using Offshore Subcontractors and/or Employees. If yes, please complete section below. We will contact you with additional questions.

If Yes, please provide response for questions below.

1. Name of Offshore Subcontractor:
2. Offshore Subcontractor Location:
3. Proposed or Actual Effective Date your Organization began using the Offshore Subcontractor and/or Employees:
4. Describe the administrative or other functions conducted on behalf of your Organization by Offshore Subcontractor:
5. Describe type of Personal Identification Information (PII) or Personal Health Information (PHI) shared with the Offshore Subcontractor: