



MEDICAL MUTUAL®

Medicare Advantage Policy & Procedure

FDR Compliance Identification and Oversight

Policy No. MACP.PP.002	Responsible Area: Medicare Compliance	
Date of Approval: 11/11/2024	Approved by: Nicole Slee, Medicare Compliance Officer	Date Reviewed/Revised: 11/11/2024

REFERENCE:

Chapter 21 of the Medicare Managed Care Manual (MMCM), including, but not limited to Section 40 and 50.6 2016 CMS Readiness Assessment

SCOPE:

Medicare Compliance and Medicare Operational Departments

DEFINITIONS:

BOD - Medical Mutual of Ohio’s Board of Directors

CMS - Centers for Medicare and Medicaid

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. (See 42 CFR §§ 422.500 & 423.501).

Employees - for the purpose of this document, employees are defined as all FDR employees including board members, officers, consultants, contractors, volunteers, and temporary employees involved in the administration or delivery of Part C and D delegated services on behalf of MMO.

FDR - First-Tier, Downstream, or 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. (See 42 CFR §§ 422.500 & 423.501).

HPMS - Health Plan Management System; a CMS system with restricted access for Plan

MMCM - Medicare Managed Care Manual

MMO - Medical Mutual of Ohio, the Medicare Advantage Plan Sponsor

Related entity - 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’s or Part D plan sponsor’s management functions under contract or delegation; or
- (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. (See 42 CFR §§ 422.500 & 423.501).

POLICY:

Medical Mutual of Ohio (MMO) maintains signed written agreements with vendors which describe the scope of the business arrangements, financial terms, performance expectations, reporting responsibilities and consequences for failure to meet contractual requirements. Prior to execution, operational areas submit documentation for each contract to be reviewed by Compliance for the purposes of identifying if the vendor qualifies as an FDR. This determination is made based on the completion of an MMO FDR Matrix, using the criteria outlined in Chapter 21, Section 40 of the MMCM. If the entity is determined to be an FDR, MMO ensures that the appropriate addenda are included to verify commitment to compliance requirements related to the delegated function by the vendor.

Prior to delegating any Medicare function to an FDR, operational areas request a compliance pre-delegation assessment as part of the RFP/RFQ process. The pre-delegation assessment includes, at a minimum, a documented review of the FDR's ability to comply with compliance requirements. The pre-delegation assessment should also include review of the FDR's Medicare Advantage Parts C and/or D policies and procedures, tools and systems utilized by the FDR. During the pre-delegation assessment and annually thereafter, MMO Compliance will verify an FDR's adherence with applicable compliance requirements.

To prevent, detect and correct incidents of non-compliance, MMO conducts thorough oversight of FDRs and delegated functions routinely. MMO communicates the FDR's responsibility to fully understand the CMS requirements that govern the delegated function(s) and will continually monitor their compliance with those requirements. MMO oversees the FDR and delegated function(s) by direct operational monitoring activity as well as review of FDR self-monitoring results reported to MMO. MMO performs audits of FDRs based on the overall risk and specific functions, as well as reported incidents. MMO has the right to inspect and audit the FDR's records either remotely or at its place of business during normal business hours at a mutually acceptable time.

MMO does not allow FDRs to utilize offshore vendors to perform functions supporting the MA product without approval, by exception. Any approved offshoring activity is reported in HPMS.

In accordance with internal policies, any incident of regulatory noncompliance identified through the FDR oversight process has an investigation initiated within two (2) weeks from the date the issue was identified/reported. All substantiated incidents of regulatory noncompliance will be evaluated for appropriateness to be addressed via the corrective action plan (CAP) process and in accordance with disciplinary standards outlined in the FDR Guide, Standards of Conduct and/or terms outlined in the contractual agreement with the FDR. Instances of operational noncompliance, or other issues, are to be documented and followed up by the operational owner in addition to the regular oversight activities.

PROCEDURES:

A. Pre-Delegation Assessment

Once a potential MA vendor has been identified by an operational area, before contract execution/LDER, the operational area is responsible for executing and documenting execution of a pre-delegation assessment.

1. Medicare Part C and D Pre-Delegation Assessment Form

As part of the Medicare Part C and D Pre-delegation Compliance Assessment, the operational owner must ensure the potential MA vendor completes the Medicare Part C and D Pre-Delegation Compliance Assessment form. This assessment must be presented to the potential Medicare Advantage vendor with the minimum criteria provided on the approved template. The approved Medicare Part C and D Pre-Delegation Assessment form is housed by Compliance and a final copy provided to operational owners.

The operational owner obtains the completed Pre-Delegation Compliance Assessment form from the potential Medicare Advantage vendor and reviews the information provided under the Operational Assessment (if requested) to evaluate the vendor's capability to adequately perform the function in compliance with MMO standards and applicable regulations. The operational owners must retain the completed form for ten (10) years and be able to provide it upon request to Compliance or any regulating authority.

The Medicare Part C and D Pre-delegation Assessment is also embedded in the RFP and RFQ process. If the vendor is potentially supporting the MA product, the operational owner is responsible for completing the MA section on the RFP or RFQ form and submitting to the Procurement Department. The completed Pre-Delegation Compliance form is submitted to Compliance for review in advance of contract execution. All compliance deficiencies attested to on the pre-delegation form must be resolved in advance of contract execution.

2. On-site audit
Operational areas may choose to conduct on-site audits to obtain or verify information provided during the pre-delegation activity meet FDR employees, and/or ensure secure and organized facilities.
3. System Testing
When necessary, MMO ensures that all systems supporting a function involved in the administration and/or delivery of Medicare services that has been delegated to an FDR are fully tested. MMO operations ensures a system implementation schedule is established and if applicable, the implementation timeline will include time during which systems will run in parallel to ensure full and accurate functionality.
4. OIG/GSA exclusion screening
Pursuant to the MMO corporate policy, *OIG GSA Screening 2007.004*, vendors are screened by MMO prior to engagement and monthly thereafter. In accordance with this internal policy, the Procurement Department is responsible for screening all potential MA vendors on the OIG and GSA exclusions lists prior to contract. The Compliance department is responsible for screening MMO vendors monthly. Additionally, MMO requires FTEs to screen their entity, as well as any of their employees that are directly involved in the administration of the delegated functions, prior to contract and monthly, and report to MMO immediately if the entity or any of its' employees become excluded.

B. FDR Identification (see Exhibit A for process details)

The MMO operational owner is responsible for submitting the proposed vendor contract agreement and completed FDR Matrix form to Compliance for FDR identification prior to contract execution. Compliance evaluates each proposed Medicare vendor to determine if the entity qualifies as an FDR using the information provided by the operational owner on the FDR Matrix. MMO uses the following criteria, from section 40 of the Medicare Managed Care Manual, Chapter 21, to classify an MA vendor as an MMO FDR:

1. Does the vendor perform one or more of these delegated functions?

Mandatory auditing or monitoring; Facilitate mandatory training; Sales/Marketing; Care Management; Utilization Management; Transportation, Quality Improvement; Applications processing; Enrollment/Disenrollment/Membership functions; Claims; Admin/processing/adjudication; Appeals/Grievances; Licensing/Credentialing; PBM; Hotline Ops; Customer Service; Bid Preparation; OEV; Provider Network Management; Negotiation with Rx Drug Manufacturers; Admin/Tracking of drug benefits; COB; Generate Claims data/reporting; or Health care services.

2. **Is this function required to do or to provide under MMOs contract with CMS or the State of Ohio, the applicable regulations, or CMS/ODM guidance? Yes/No**

If Compliance determines that the vendor qualifies as an FDR, they will notify the Operational Owner, in order to:

1. Ensure all necessary contract language is included in the contract and/or applicable addendums attached thereto; and
2. Ensure that Ops Owner notifies the FDR of their identification status and provides the addenda to be added to contract forms.

C. Compliance Oversight

1. FDR Master List

The FDR list is maintained by Compliance in LogicGate.

- a. Once Compliance notifies operational owner of a new FDR contract relationship, Compliance documents the FDR in LogicGate, the operational owner of the FDR relationship and identifies the level of oversight for that FDR based on a tiered structure.
- b. The operational owner is responsible for ensuring the accuracy of current data for their assigned FDR/s. Compliance requires a formal review from operational owners at least annually to confirm all FDR information is accurate and complete.

2. FDR website

Compliance maintains a website ([FDR Website](#)) to provide current and accessible resources. This website includes but is not limited to the following: MMO contact information, including the hotline phone number, MMO Code of Conduct, FDR Guide, Annual FDR Attestation, and links to CMS resources/guidance.

3. Annual Attestation

On an annual basis, all FDRs, (healthcare providers are managed by Network Development Services (NDS), and not within the scope of this policy), are required to attest to their compliance with the CMS compliance program requirements including but not limited to record retention, exclusion screening, and Compliance and FWA training. The Annual FDR Attestation process is housed on MMO's FDR website. This form is accessed and submitted electronically by the FDR. On an annual basis, MMO provides the link to the FDR Website along with instructions on the completion of the FDR Annual Attestation instructions and due date. MMO uses this process to communicate compliance expectations, verify compliance, and identify FDR compliance risks.

4. Medicare Compliance Quarterly Dashboard

The Medicare Compliance Dashboard is one mechanism used by Compliance to oversee key MA functions. This dashboard includes metrics of some functions that have been delegated to FDRs. The Medicare Compliance Dashboard is reviewed on a quarterly basis by the Compliance Department, the Compliance Committee, and the Board of Directors (BOD).

5. FDR Audits

As a result of the annual risk assessment/s Compliance drafts an audit work plan. Audits of MMO FDRs and delegated functions are scheduled as part of the annual work plan, prioritized by risk, and performed by Compliance. The Audit Work Plan also allows time to conduct ad hoc audits, including ad hoc audits of FDRs, if the need is identified throughout the year.

D. FDR Monitoring

FDR operational owners are responsible for conducting monitoring of the delegated function/s to verify compliance with applicable regulations. The appropriate frequency and level of monitoring is defined based on the delegated functions, by the operational owner and communicated to Compliance. They are also responsible for ensuring that any identified compliance issues are reported in accordance with internal policies and procedures. FDR operational owners are responsible for submitting an annual monitoring plan for their department, which is to include FDR oversight which Compliance monitors throughout the year.

E. Communication and reporting

1. Communication

MMO maintains effective lines of communication with all FDRs to ensure full understanding of expectations, CMS requirements and maintain transparent relationships to perform effective oversight. FDRs are provided instructions to contact the MMO operational owners and/or Compliance via email, phone, or reference resources on the FDR website. In addition, FDRs are included as part of the updated guidance and HPMS Memos distribution processes. Each operational area has established a process to distribute HPMS Memo, sub-regulatory guidance, and updated regulation to staff and FDRs, as applicable. FDRs are also encouraged to subscribe to CMS communications for direct receipt.

2. Reporting

Minimum reporting requirements include but are not limited to:

- a. The FDR must report to MMO:
 - i. Assigned metrics demonstrating FDR's operational performance of delegated function(s) on a routine basis to the MMO operational owner.
 - ii. Potential incidents of non-compliance or FWA to MMO Operational Owner, Compliance Department or Compliance Hotline, immediately upon discovery.
- b. MMO operational owners must report to Compliance:
 - i. FDR monitoring activity, annually or upon request.
 - ii. Quarterly Medicare Compliance Dashboard metrics.
 - iii. Potential incidents of non-compliance or FWA immediately upon discovery.
 - iv. New/updated FDR relationships, or delegated functions.
- c. The Medicare Compliance Officer is responsible for reporting information related to FDR identification and oversight to the Compliance Committee, BOD and/or CMS when necessary. These reports include, but are not limited to:
 - i. New FDRs that perform key Part C and/or D function(s) are reported to the CMS Account Manager at least sixty (60) days prior to the effective date of a contract.
 - ii. Significant incidents of non-compliance deemed are reported to CMS.
 - iii. Quarterly report to the BOD which includes, at a minimum, significant incidents of non-compliance/FWA related to delegated functions.

APPROVED BY:

Nicole Slee, Medicare Compliance Officer
Name, Title

11/11/2024
Date

Record of Reviews and Revisions

Rev. Date	Section	Review / Revision Notes
10/29/2015	All	New Policy
1/9/2017	All	Reviewed
1/19/2018	All	Reviewed
6/21/2018	All	Updated links throughout and updated the FDR Identification section to include the FDR Identification and Risk Matrix
8/19/2019	All	Reviewed, no policy or procedural updates needed. Removed Pam Cleveland as approver and replaced with Megan Grifa.
8/24/2020	All	Added language: The completed pre-delegation form is submitted to MA Compliance for review in advance of contract execution. All compliance deficiencies attested to on the pre-delegation form must be resolved in advance of contract execution; Save a copy of the completed FDR Identification and Risk Matrix in the FDR specific folder on SharePoint

		where this documentation is retained for ten (10) years. Added fifth criteria from the FDR ID and Risk Matrix Removed language regarding the annual assessment.
03/19/2021	All	<ol style="list-style-type: none"> 1. Added the following language in FDR Identification Section: Notify the submitted of the FDR status and provide a copy of the FDR Oversight Guide. 2. Removed the following language in FDR Identification Section: Save a copy of the completed FDR Identification and Risk Matrix in the FDR specific folder on SharePoint where this documentation is retained for ten (10) years. 3. Added the following language to the FDR Master List section: The Medicare Compliance Department schedules FDR owner meet and greets for all new FDR owners to provide an overview of FDR oversight expectations. MA Compliance requires a formal attestation from operational owners at least twice a year to confirm all FDR information is accurate and complete. 4. Added the following language to the FDR Monitoring section: FDR operational owners are responsible for submitting an FDR oversight and training plan for MA Compliance review on an annual basis. 5. Added the following language in the Medicare Part C and D Pre-Delegation Assessment Form section
8/31/2023	All	Added new FDR tiering identification process where applicable; Eliminated references to QHP/ACA vendors as they are out of scope for MA Compliance; eliminated the Compliance and new vendor meetings requirement; Combined all FDR PP and SOP into this single document (SOPs are not Exhibits herein)
11/11/2024	All	Annual Review. Updated information location to LogicGate.

Exhibit A
FDR Identification Process

PROCEDURES:

1. Operational owner identifies the opportunity to propose a new or updated contract agreement with an MA vendor.
2. **Prior to submitting the LDER**, the operational owner completes the FDR Matrix form. The FDR Matrix form is found linked on the pre-contract checklist.
3. Operational owners email the completed FDR Matrix to MACompliance@medmutual.com for review.
4. Compliance reviews for FDR determination. If additional information is required, Compliance will reach out directly to the submitter.
5. Once final FDR Matrix is approved and FDR status is assigned, Compliance shares the final FDR Matrix with the following entities via email:
 - a. Operational Owner/submitter
 - b. Procurement
6. Upon receipt Compliance will enter the information from the FDR Matrix into LogicGate. Procurement will document the information in their system; and FDR addenda will be provided back to the operational owner to have completed by vendor, and subsequently reviewed with the contract by legal.
7. The operational owner is responsible for distributing the link to the MMO FDR website link (<https://www.medmutual.com/FDR>) to the appropriate contacts at the FDR upon confirmation of FDR identification. Compliance distributes the link annually to existing FDRs as part of the annual attestation process.
8. The operational owner is responsible for maintaining the accuracy of the vendor information with Compliance.