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1.0 POLICY

To define the process for ongoing delegation oversight of First-tier, Downstream, and Related Entities (FDRs) to ensure compliance with statutory, regulatory, contractual, and Leon Health, Inc. (LH) policy requirements. This policy clearly defines the shared roles and expectations for routine oversight of active FDRs. It ensures adequate oversight of activities delegated to FDRs under the Medicare Advantage (MA) and Prescription Drug plans offered by LH.

LH includes specific terms and conditions in all contracts with FDRs to ensure compliance with State of Florida and Medicare laws, regulations, reporting requirements, and CMS and State of Florida instructions.

These provisions include but are not limited to functions to be delegated, performance standards, penalties for non-performance; audits and inspection by CMS or the State of Florida, or its designees; and maintenance of an effective compliance program to prevent, detect, and correct fraud, waste, and abuse (FWA).

Contract Owners, Compliance, Senior Management, Legal, and oversight committee(s), as applicable (hereinafter referred to collectively as “Oversight Partners”) share responsibility for routine oversight of FDRs to ensure these provisions are met.

Individual Contract Owners are responsible for day-to-day monitoring and oversight of FDRs. Compliance works with Oversight Partners to coordinate daily, weekly, monthly, and annual monitoring and oversight activities and tracks non-compliance and corrective actions when necessary.

Oversight Partners, or the relevant oversight committee, as applicable, meet regularly to ensure adherence to these contractual requirements and to evaluate the appropriateness of the contracts held with FDRs to perform delegated functions of LH Medicare Advantage plans. In addition, if serious compliance issues arise, these issues are escalated to senior management, the committee responsible for compliance oversight, and the Board of Directors as required to ensure effective monitoring and oversight.

2.0 SCOPE


This policy applies to all Oversight Partners performing routine administration and monitoring of delegated functions related to all MA plans offered by LH.

3.0 DEFINITIONS

Contract Owners – refers to the individuals within LH who have negotiated and/or executed agreements with FDRs and who are responsible for oversight of delegated core activities defined in the agreement.

CMS – is the Centers for Medicare and Medicaid Services, the Federal agency within the Department of Health

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and Human Services (DHHS) that administers the Medicare program and oversees all Medicare Advantage Plan (MA) and Prescription Drug Plan (PDP) organizations.

Corrective Action Plan (CAP) – steps taken to remove the causes of an existing nonconformity or non-compliant situation and prevent recurrence by identifying and eliminating causes. A CAP is a step-by-step plan of action and schedule for correcting a deficient process or quality issue. A CAP includes task assignments and accountabilities, additional remedial training, schedules, resource allocations, and evaluation criteria to achieve stated objectives.

Dashboard Reports – reports developed and maintained by Contract Owners. These reports contain quantifiable information that illustrates the FDRs performance regarding contractual obligations and CMS and State regulations.

Delegation Audit Guide – an adjustable template that lists all components of an FDR compliance audit, including pre-delegation, annual and focused audits.

Downstream Entity – Any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the 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.


FDR – First-tier, Downstream or Related Entities – contracted entities to which some functions of the administration of the Medicare Advantage and Prescription Drug plans have been delegated. FDRs are also referred to as “delegated entities” or “vendors.”

FDR Guide – Documentation updated and provided annually to all Oversight Partners and FDRs to communicate compliance expectations.

First-Tier Entity – Any party that enters into a written arrangement, acceptable to CMS, with a MAO or Part D plan sponsor or applicant to provide administrative or health care services to a Medicare-eligible individual under the MA or Part D program.

Focused Audit – the process by which a vendor and/or vendor agreement or specific activities delegated by such agreement are evaluated by Compliance to determine the appropriateness of continuing a delegation relationship with the vendor and/or the need for the correct action to address non-compliance related to any delegated activity. This process includes, but is not limited to, review of the vendor compliance program to include: (a) revisions to the agreement with the vendor, (b) training materials, (c) security, (d) standards of conduct, (e) OIG/GSA employee screening, (f) status of meeting contracted performance standards, and/or (g) policies and procedures.

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Related Entity – Any entity that is related to a 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 service 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 the cost of more than \$2,500 during a contract period.

4.0 PROCEDURE

Upon completion of the onboarding process, Compliance and Legal perform the following ongoing oversight of FDRs:

- Review FDR agreements on an annual basis and inform Compliance of any revisions or contract terminations.
- Provide Compliance with copies of all executed or revised contracts.
- Provide updated dashboard reports to the appropriate committee(s).
- Maintain monitoring and audit universes to document specific oversight and monitoring, including outcomes and remediation activities.
- Provide updated monitoring and audit universes to Compliance.
- Develop, implement, and oversee CAPs imposed due to non-compliance or failure to meet performance standards as defined in the Agreement.
- Provide Compliance with copies of any CAP implemented and provide routine updates on the status of ongoing remediation activities.
- Advise FDR of any regulatory changes affecting delegated activities and ensure system changes or updates to processes, as required.
- Conduct a prospective delegation audit by completing a notification of prospective delegation to the appropriate department. The notification must include the following and be submitted at least 60 days before implementation of the delegated functions:
 - The services and/or functions to be performed by the FDR
 - The services and/or functions to be performed by LH
 - The impact of services and/or functions to be performed by the FDR on Star Ratings measures

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- The name, phone, fax, and email address of the FDR contact person
 - The mailing address of the FDR, including all site locations
 - The name and contact information of the internal Contract Owner
 - The date of anticipated contract implementation proposed service levels (performance standards) and reporting responsibilities of the FDR
 - Sub-delegate information, where applicable
- Should performance standards not be met, the Contract Owner will work with the FDR and Compliance to develop a CAP to include training or other remediation to correct the issue. Additionally, Contract Owner and Compliance will monitor the effectiveness and satisfactory completion of all CAPs and ensure enforcement of any penalties should the issue(s) not be fully remediated.
 - Conducts routine annual compliance program audits, based on annual risk assessments, to ensure sustained compliance with CMS regulation and provides results to the relevant committee(s).
 - Requests and reviews annual Compliance Program Attestation/Questionnaire for each FDR
 - Requests and reviews annual New Hire Training Reports
 - Provides revised “FDR Guide” and the LH Code of Conduct to FDRs annually
 - Provides HPMS memos to appropriate Contract Owners through LH’s document management system to ensure information and regulatory changes are tracked, reviewed, and implemented by FDRs as appropriate.
 - Provides CMS Provider/Entity Preclusion List to FDRs performing credentialing of providers/pharmacies.
 - Tracks FDR compliance with the metrics and activities through its Dashboard and Scorecard criteria.
 - Counsels Compliance and Contract Owners during contract negotiations or contract revisions to ensure agreements include all CMS and State of Florida required provisions.

Management Oversight

The failure of any delegated entity to comply with CMS regulations and contract requirements, including but not limited to FWA training and reporting, and standard of conduct, may result in corrective action or termination of the contract. Any CAP or contract termination should come at the recommendation of the appropriate LH committee(s).

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5.0 REVISION HISTORY

Date	Revision #	Description of Change
06.10.22	1.0	Interim annual updates
10.04.23	2.0	Annual updates

6.0 INQUIRIES

Direct inquiries about this policy to:
 Compliance Department

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