SUMMIT HEALTH	Policy & Procedure

Company:	Summit Health	**Department Name:**	Legal
Subject:	**Medicare First Tier, Downstream and Related Entities**		
Adopt Date:	1/1/2021	**Review Revision Date:**	1/28/2022
Reference Number:	SUM016	Next Annual Review:	1/28/2023
Business Unit:	Medicare Compliance		

State (select all boxes applicable to this policy)

☒ Dental ☒ Medical ☒ Pharmacy ☐

Type of Business (check all boxes applicable to this policy)

☐ Commercial Group ☐ Commercial Individual ☐ Exchange Business ☐ EOCCO ☐ OHP ☒Medicare

☐ Self-funded ☐ Other _____

I. Policy

Summit Health may delegate functions to third parties related to its Medicare Advantage (Part C) and Medicare Prescription Drug (Part D) plans. Medicare program requirements apply to third parties who contract with Summit Health to provide certain administrative or health care services for enrollees on behalf of Summit Health. This policy establishes how Summit Health identifies third parties that qualify as a First Tier, Downstream, or Related Entity (FDR), describes how Summit Health complies with Medicare program requirements for FDRs, and states Summit Health's expectations and requirements of its FDRs.

Summit Health may enter into contracts with FDRs to provide administrative or health care services for Medicare members on behalf of Summit Health. However, Summit Health retains ultimate responsibility for complying with all CMS requirements and may not assign this obligation via contract. CMS may hold Summit Health accountable for the failure of its FDRs to comply with Medicare program requirements. Summit Health requires all FDRs to comply with applicable Medicare program requirements and, with respect to a First Tier Entity, to ensure that such First Tier Entity's downstream entities also comply with applicable Medicare program requirements.

II. Definitions

Abuse: Actions that may, directly or indirectly, result in unnecessary costs to the Medicare Program, improper payment, payment for services that fail to meet professionally recognized standards of care, or services that are medically unnecessary. Abuse involves payment for items or services when there is no legal entitlement to that payment and the provider has not knowingly and/or intentionally misrepresented facts to obtain payment. Abuse cannot be differentiated categorically from fraud because the distinction between "fraud" and "abuse" depends on specific facts and circumstances, intent and prior knowledge, and available evidence, among other factors.

Audit: A formal review of compliance with a particular set of standards (e.g., policies and procedures, laws and regulations) used as base measures.

CMS: Centers for Medicare and Medicaid Services.

Downstream Entity: A party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with Summit Health's Part C or Part D contract, below the level of the arrangement between Summit Health and one of its First Tier Entities. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

FDR: First Tier, Downstream or Related Entity.

First Tier Entity: A party that enters into a written arrangement, acceptable to CMS, with Summit Health to provide administrative services or health care services to a Medicare-eligible individual under Summit Health's Part C or Part D program.

Fraud: Knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any health care benefit program or to obtain (by means of false or fraudulent pretenses, representations, or promises) any of the money or property owned by, or under the custody or control of, any health care benefit program.

FWA: Fraud, waste and abuse.

Monitor: Conduct *r*egular reviews as part of normal operations to confirm ongoing compliance and to ensure that corrective actions are undertaken and effective.

Related Entity: An entity that is related to Summit Health by common ownership or control and

1. Performs some of Summit Health'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 Summit Health at a cost of more than $2,500 during a contract period.

Waste: The overutilization of services, or other practices that, directly or indirectly, result in unnecessary costs to the Medicare program. Waste is generally not considered to be caused by criminally negligent actions but rather the misuse of resources.

III. Contracting with FDRs

A. Identifying an FDR. A combination of the Delegated Entity Review Committee (DERC), Medicare Compliance Department, and or Legal will conduct an analysis to determine whether the third party qualifies as an FDR. In determining whether an entity is an FDR and thus subject to the FDR requirements as detailed by CMS, the DERC must consider: (a) the function to be performed by the delegated entity; (b) whether the function is something Summit Health is required to do or to provide under its contract with CMS, the applicable federal regulations or CMS guidance; (c) the extent to which the function directly impacts members; (d) the extent of direct member interaction, either orally or in writing; (e) whether the delegated entity has access to member information, including personal health information; (f) whether the delegated entity has decision-making authority or simply takes direction from Summit Health; (g) the extent to which the function places the delegated entity in a position to commit health care FWA; and (h) the risk that the entity could harm enrollees or otherwise violate Medicare program requirements or commit FWA.

B. Pre-Contract Exclusion Screening. If it is determined that the entity is an FDR, before Summit Health enters into a contract with the FDR, the Compliance Department will review the DHHS OIG List of Excluded Individuals and Entities (LEIE list) and the System for Award Management (SAM) (formerly known as the Excluded Parties Lists System (EPLS)) to ensure that the FDR is not sanctioned or excluded. If the entity appears on either list, Legal will contact the Medicare Compliance Officer to initiate an analysis of whether or to what extent the proposed contract may be executed.

If the FDR is not excluded or sanctioned, and the contract between Summit Heath and the FDR is executed, the Medicare Compliance Department will add the contracting party to its list of FDR's. This list will be made available to the Medicare Compliance team to allow Compliance (i) to conduct its periodic assessments with respect to FDR risk exposure, and (ii) to screen the FDR monthly in accordance with the Medicare Compliance/Human Resources *OIG/SAM Exclusion Checks* policy. The results of the screening will be kept for a minimum of 10 years in accordance with the above-referenced policy, the Medicare Compliance Plan, and Summit Health's record retention policy.

C. Contract Addendum. Inclusion of FDR Addendum. Every contract with an FDR must contain the provisions required by CMS in its rules, regulations and guidelines. Legal will review every FDR contract to confirm compliance with Medicare program requirements. Legal may use the checklist attached as Exhibit 1 to this policy to ensure that all required provisions are in the FDR contract and may attach or use as a reference the Medicare Advantage Contract Addendum attached to this Policy as Exhibit 2.

D. FDR Training Requirement: All employees of each FDR must complete all training and education required by Summit Health and CMS, including but not limited Medicare Part C and Part D Compliance and FWA Training. This training must be completed by all employees annually and within 90 days of hire for all new employees. FDR must be capable of producing records demonstrating the completion of training by each employee, related entity, contractor and subcontractor. Records may include copies of the training, attendance logs, completion certificates, or other evidence including the name and date each individual completed the training. These records must be maintained for a minimum of ten (10) years and furnished to Summit upon request. A copy of trainings created by CMS may be obtained on the Summit Health Compliance website: www.yoursummithealth.com/compliance and can be used

by the FDR in lieu of creating their own training.

Note: Summit will not require providers to attest to the training.

IV. Compliance with Summit Health Policies

FDRs must comply with the Summit Health Medicare Compliance Plan, Code of Conduct, and this Policy. These documents may be found on the Summit Health Web site at https://www.yoursummithealth.com/compliance.

V. FDR Oversight and Monitoring

The Summit Health Medicare Compliance Department will Monitor and Audit Summit Health's First Tier Entities to ensure that they are in compliance with all applicable laws, rules and regulations with respect to Medicare Parts C and D delegated responsibilities, and to ensure that the First Tier Entities are monitoring the compliance of entities with which they contract (their downstream entities). The Medicare Compliance Department will also monitor Related Entities to ensure those entities are compliant with all applicable Medicare laws, regulations, and policies. Summit Health may request proof of downstream monitoring activities.

A. Risk Assessment and Auditing. To ensure that FDRs are following the applicable laws, rules and regulations, Summit Health will utilize risk assessment, monitoring and auditing tools.

i. *Risk Assessment*: On not less than an annual basis, the Medicare Compliance Department will conduct a risk assessment of the FDRs. The assessment will take into account the types and levels of risk that the FDRs pose to the Medicare program and to Summit Health. Factors considered in determining the risks associated with the FDRs include the amount of work completed by the FDR, complexity of work, training, and past compliance issues. The formal risk assessment is not a static document and shall be reviewed throughout the year to determine if the priorities remain accurate in light of changes to CMS requirements and any identified issues of non-compliance.

ii. *Auditing and Monitoring*: The Medicare Compliance Department will use a monitoring and auditing work plan that will identify the number of First Tier Entities that will be audited and will describe scope and timing of each audit. The work plan will include:

- The number of audits to be performed;
- The FDRs to be audited and audit schedules, including start and end dates;
- Necessary resources;
- Person(s) responsible;
- Final audit report due date to Compliance Officer; and
- Follow up activities from findings.

Each FDR work plan will contain a process for responding to all monitoring and auditing results and for conducting follow-up reviews of areas found to be non-compliant to determine if the implemented corrective actions have fully addressed the underlying problems. Corrective action and follow-up shall be led or overseen by the Medicare Compliance Officer and include actions such as

reporting findings to CMS or to the National Benefit Integrity Medicare Drug Integrity Contractor (MEDIC), if necessary.

Audits shall utilize a randomized selection process for sample selection and sample selection size shall reflect the then-current CMS audit guidelines. Where appropriate, the audit shall assess the FDR's compliance with relevant policies and procedures.

B. Reporting of Compliance Issues and FWA. All FDRs and their employees are required to report any suspected or potential compliance issue. FDRs may report suspected compliance violations anonymously through EthicsPoint (1-866-294-5591 or www.ethicspoint.com) or by calling Summit Health's anonymous compliance and FWA reporting hotline (1-855-801-2991). In addition to or in lieu of submitting a report via EthicsPoint, FDRs may also directly report compliance issues to the Summit Health Medicare Compliance Officer at medicarecompliance@yoursummithealth.com and suspected fraud, waste and abuse to the Special Investigations Fraud Unit at stopfraud@yoursummithealth.com.

C. Summit Health Plan Disciplinary Policies. Failure to report suspected Medicare program violations and/or fraud, waste and abuse concerns may result in disciplinary action up to and including termination of your contract with Summit Health. Summit Health has a strict policy of non-intimidation and non- retaliation against FDRs and employees for good faith reporting and participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self- evaluations, audits and remedial actions, and reporting to appropriate officials. This policy is in all FDR contracts as well as in the Summit Health Code of Conduct. Summit Health expects FDRs to have disciplinary standards in place and publicized for employees and downstream entities and related entities, and the Summit Health Medicare Compliance Department may ask to see them.

D. Identifying and Investigating Compliance Issues. Compliance issues with respect to FDRs may be discovered through auditing and monitoring or otherwise disclosed to Summit Health. Regardless of the source of notification, Summit Health will investigate such matters to determine if a true issue of non- compliance exists. The FDR will be required to fully cooperate with Summit Health in any such investigation. Summit Health will immediately report any issue of non-compliance to CMS and will report FWA to the MEDIC. In the instance of any non-compliance, all FDRs are subject to the enforcement of disciplinary actions, up to and including termination of the underlying agreement with Summit Health.

Corrective Action: When identified compliance issues are confirmed, including FWA, Summit Health will determine the appropriate corrective action, with such action designed to correct the underlying problem that results in program violations and to prevent future noncompliance. A root cause analysis determines what caused or allowed the non-compliance, FWA, problem or deficiency to occur. A corrective action must be tailored to address the particular non-compliance, FWA, problem or deficiency identified, and must include timeframes for specific achievements. The elements of the corrective action will be detailed in writing and include ramifications if the FDR fails to implement the corrective action satisfactorily. Summit Health will work with the applicable FDR to develop a corrective action plan designed to address the deficiencies. Confirmation that a corrective action plan has been successfully completed will be required from any FDR that is assigned such a plan. All FDR contracts include language allowing Summit Health to continually monitor FDRs, including FDRs that have completed a compliance action plan, to ensure compliance and to ensure that any problems previously identified will not reoccur. All FDR contracts include language setting forth the

consequences for failing to maintain compliance, or engaging in FWA, up to and including contract termination.

VI. Revision Activity

New P & P /Change / Revision and Rationale	Final Review/Approval	Approval date	Effective Date of Policy/Change
New P & P	Brenda Noble	1/1/2021	1/1/2021
Update training section	Brenda Noble	4/22/2021	1/1/2021
Annual review – modify exclusion policy reference.	Brenda Noble	1/28/2022	1/28/2022

VII. Affected Departments

All employees that manage contractual relationships with FDRs; all First Tier, Downstream and Related Entities.

VIII. References

Medicare Managed Care Manual, Chapter 21 Medicare Prescription Drug Benefit Manual, Chapter 9
FDR Compliance Checklist (Exhibit 1 to this policy)
FDR Contract Addendum (Exhibit 2 to this policy)

EXHIBIT 1
FDR Compliance Checklist

On an at least annual basis, the following items must be reviewed with respect to each First Tier, Downstream, and related Entity:

A. Training, Education and Exclusion List Checking

- Evidence that general compliance training was timely provided to the FDR.
- Evidence that sampled non-deemed first tier entities' employees received timely FWA training.
- Evidence that Summit Health provided FWA training or training materials to the non-deemed first tier entity for its employees' timely FWA training or otherwise ensured that the first tier entity completed the CMS FWA training module through the Medicare Learning Network (MLN), if courses are available.
- Evidence that Summit Health requires the sampled first tier entities to maintain records for ten years of the training of their employees, including the following details: time, attendance, topic, certificate of completion, if applicable and test scores, if any.
- Evidence that sampled first tier entities' employees were timely checked against the OIG/GSA exclusion lists.

  (**Note**: Effective January 1, 2019, Compliance and FDR training may not apply if the FDR is a provider of care, as CMS no longer requires the training.)

B. Effective Communication

- Evidence that Summit Health's compliance/FWA reporting mechanism(s) are accessible to its FDRs.
- Evidence that Summit Health's compliance/FWA reporting mechanism(s) has been publicized and/or provided to its FDRs
- Evidence that a sampled subset of FDRs' employees have been notified of the no-retaliation policy for reporting potential FWA.
- Evidence that either Summit Health or the first tier entity has communicated to the FRD employees of the obligation to report compliance concerns and potential FWA.

C. Disciplinary Standards

- Evidence that Summit Health has published its disciplinary standards to its FDRs, including the duty and expectation to report.

D. Monitoring/ Auditing Records

- Evidence that Summit Health audited first tier entities to determine whether the FDRs are monitoring / auditing downstream entities' compliance with Medicare regulations and requirements