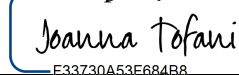


Title: Compliance Oversight of First Tier, Downstream, and Related Entities	Policy Number: CMP07.02
Issued For: <input checked="" type="checkbox"/> BayCare Select Health Plans, Inc.	Original Issue Date: 06/26/2020 Select one below and input date, if applicable: <input type="checkbox"/> Date Last Reviewed / Revised _____ OR <input type="checkbox"/> Date Last Reviewed / No Revisions _____ OR <input checked="" type="checkbox"/> New Policy / N/A
Issuing Department: Compliance	Effective Date: 06/26/2020
Approved and Owned by: Joanna Tofani, Chief Compliance Officer  <small>E33730A53E684B8</small> <hr/> Signature	Date Approved by Compliance Committee: 06/26/2020 Compliance Committee

I. **PURPOSE**

To comply with CMS regulatory guidance, BayCare Select Health Plans, Inc. (BayCare Select) requires the appropriate oversight of any FDR with which it contracts to provide certain administrative or health care service functions relating to its Medicare Parts C and D contracts. The purpose of this policy is to describe the compliance oversight of such entities.

II. **SCOPE**

This policy applies to BayCare Select’s Workforce members involved in the selection, contracting, and performance management of delegated entities and / or first tier, downstream, and related entities (collectively FDRs).

III. **DEFINITIONS**

CMS: The Centers for Medicare & Medicaid Services. This is the agency within the Department of Health and Human Services (HHS) that is responsible for directing the national Medicare program.

Delegate / Delegated Entity: A delegated entity is a subcontractor that performs a core function or any other administrative or management function that BayCare Select is required to perform under a government contract. This may include an entity that performs any other subcontracted function that requires specific oversight by an accreditation body; and is otherwise determined to be a delegate based on the examples and factors set forth in Section 40 of Chapter 21 / Chapter 9 of the Medicare Managed Care Manual.

Delegation: For purposes of this policy, assigning to an outside party, through a written contract, the performance of specific duties, responsibilities, or services that would normally be the responsibility of BayCare Select.

First Tier, Downstream, or Related Entity (FDR): Has the meaning of the respective terms as defined in the Medicare Managed Care Manual, Chapter 21 – Compliance Program Guidelines and Prescription Drug Benefit Manual, Chapter 9 – Compliance Program Guidelines.

Workforce: For purposes of this policy, the full- and part-time team members, consultants, volunteers, trainees, and governing body (Board) of BayCare Select, and other persons whose conduct in the performance of work for BayCare Select is under the direct control of BayCare Select, whether or not they are paid by BayCare Select.

IV. OWNERSHIP

The Chief Compliance Officer (CCO) is responsible for administration and oversight with regard to performance under this policy and procedure.

V. POLICY

A. It is BayCare Select’s policy to comply with applicable federal, state and local laws, including adherence to the rules and regulations established by the CMS and other regulatory requirements for contracted entities, as applicable to BayCare Select in managing the operations of Medicare Advantage Organizations. This includes the oversight of FDRs as part of its Compliance Program.

B. BayCare Select may enter into contracts with FDRs to provide certain administrative or health care service functions relating to its Medicare contract(s) on behalf of BayCare Select. Such functions include, but are not limited to:

1. Provider network management
2. Sales and marketing
3. Enrollment, disenrollment, membership functions
4. Fulfillment
5. Claims and customer service
6. Finance services
7. Bid preparation and loading
8. Pharmacy management
9. Medication therapy management
10. Revenue management and risk adjustment services
11. Quality improvement
12. Licensing and credentialing
13. Appeals and grievances
14. Care coordination
15. Disease management
16. Transition of care management
17. Wellness program management
18. Utilization management
19. Oversight of delegated activities of other FDRs
20. Fraud, waste and abuse (FWA) program management
21. Complaint tracking and management
22. Sales surveillance

C. Medicare program requirements apply to all FDRs to which BayCare Select has delegated administrative or certain health care services. BayCare Select maintains ultimate responsibility

for FDR fulfillment of the terms and conditions of its contract with CMS relative to any delegated functions.

- D. The BayCare Select Compliance Department determines whether an entity serves in the capacity of an FDR consistent with the procedures of this policy.
- E. The BayCare Select Compliance Department maintains a list of identified FDRs, working with operational business owners to add new and archive outdated data.
- F. All oversight activities by the BayCare Select Compliance Department of FDRs will be documented. Such documentation will be consistent with BayCare Select data retention policies and procedures. CMP13 Health Plan Document and Data Retention

VI. PROCEDURES

A. Designation of Contracted Entity as FDR:

1. BayCare Select has a method in place to evaluate whether contracted entities qualify as FDRs. The BayCare Select Compliance Department, in conjunction with the business owner of the delegated function and legal counsel, when appropriate, shall make the determination as to whether a contracted entity is an FDR.
2. Factors considered in making such determinations include:
 - a. The function to be performed by the entity;
 - b. Whether the function being delegated is something BayCare Select is required to do or to provide under its contract with CMS, the applicable federal regulations, or CMS guidance;
 - c. To what extent the function being delegated directly impacts BayCare Select enrollees;
 - d. To what extent the entity has interaction with enrollees, either orally or in writing;
 - e. Whether the entity has decision-making authority or whether the entity strictly takes direction from BayCare Select;
 - f. The extent to which the delegated function places the entity in a position to commit health care fraud, waste or abuse (FWA);
 - g. The risk that the entity could harm enrollees or otherwise violate Medicare program requirements or commit FWA; and
 - h. Whether the entity has access to beneficiary information or personal health information.
3. If the only qualifying factor that applies to the entity is access to beneficiary or personal health information, BayCare Select considers the frequency, volume, and level of information access by the entity.

4. Compliance maintains a list of all FDRs including, at minimum, whether pre-delegation and annual attestations were conducted and FDR main points of contact (i.e., BayCare Select and FDR leads).

B. Pre-Delegation Audit:

1. *Before* executing a contract with an entity, BayCare Select’s Workforce member involved in the contracting process requests the CCO perform an evaluation to determine if the entity is an FDR. The operational / functional lead area within BayCare Select is responsible for developing and presenting the draft agreement which must clearly define which functions are to be delegated, including specific service level agreement requirements, if any. The CCO reviews available information, including the draft agreement, and makes a determination if the entity is an FDR.
2. If the entity is an FDR:
 - a. The CCO reviews such agreements to determine compliance with applicable regulations;
 - b. The contract must also undergo review by legal counsel;
 - c. The CCO checks the OIG and GSA exclusion lists to be sure the FDR is not excluded from participation in healthcare programs; and
 - d. Before contracting with the FDR, a Pre-Delegation Audit must be conducted. In limited circumstances, at the discretion of the CCO and with the consent of the Compliance Committee, BayCare Select operations may proceed with contracting with an FDR before the Pre-Delegation Audit is completed, if:
 - i. The Pre-Delegation Audit is completed as soon as is administratively possible; and
 - ii. The prospective FDR agrees to accept and implement any corrective action plans deemed necessary by the CCO as a result of issues detected during the Pre-Delegation Audit and to timely remediate findings to the satisfaction of BayCare Select.
3. BayCare Select Compliance and the operational / functional team within BayCare Select responsible for the FDR relationship will develop a checklist of items to assess during the Pre-Delegation Audit, which may include:
 - a. The FDR’s ability to perform the delegated function(s).
 - b. Policies and procedures specific to the delegated function.
 - c. Resources (administrative and financial) sufficient and qualified to perform the required function(s).
 - d. Documentation systems.
 - e. Performance monitoring and activity reports.
 - f. Capabilities related to sub-delegated functions/oversight.

- g. Confirmation that the proposed FDR has all required licenses and certifications.
 - h. The FDR has an adequate compliance program.
 - i. The FDR has an adequate HIPAA privacy and security program.
4. BayCare Select Compliance and the operational / functional team within BayCare Select responsible for the FDR relationship will conduct the Pre-Delegation Audit of the proposed FDR.
5. The results of the Pre-Delegation Audit must be presented to the Compliance Committee.
- a. If issues are not detected, the contract with the FDR may be signed.
 - b. If issues are detected:
 - i. The CCO may recommend contracting contingent upon the implementation of a Corrective Action Plan and / or recommend not to proceed with the contract.
 - ii. The CCO presents its recommendation to the Compliance Committee for approval.
 - iii. The Compliance Department may approve contracting contingent upon a Corrective Action Plan and / or recommend not to proceed with the contract.

C. FDR Agreements:

- 1. All agreements with FDRs must be in writing.
- 2. FDR agreements must include language as appropriate to satisfy the following CMS required elements:
 - a. Clearly identify the functions that are delegated to the FDR;
 - b. Set forth any service level agreements, as determined by the operational / functional team within BayCare Select responsible for the FDR relationship in conjunction with the CCO;
 - c. Identify reporting required by the FDR;
 - d. Include the applicable terms set forth in the most recent CMS Model Contract Amendment (*available at <https://www.cms.gov/Medicare/Medicare-Advantage/MedicareAdvantageApps>*);
 - e. State that the FDR agrees to comply with BayCare Select's Code of Conduct and policies and procedures;
 - f. Detail the ramifications and BayCare Select's remedies (i.e., revoking delegation / termination, recourse, sanctions) of the FDR failing to maintain compliance, failing to timely correct non-compliance, or engaging in FWA;
 - g. Address any restrictions and / or notice requirements related to the FDR sub-delegating any

of the services to other entities;

- h. If a delegation agreement involves the disclosure of Protected Health Information to the FDR, the FDR must sign a Business Associate Agreement; and
- i. Require the FDR to annually to timely complete and submit to BayCare an attestation of compliance with the compliance-related terms of its agreement.

D. Distribution of BayCare Compliance Policies and Procedures and Standards of Conduct:

1. As part of BayCare Select's Compliance Program tracking and oversight of FDRs, the CCO distributes all compliance policies and procedures, as well as BayCare Select's Code of Conduct to its FDRs. It is the responsibility of the First Tier Entity to furnish such compliance policies and procedures and Code of Conduct to any Downstream Entities. See CMP22 Code of Conduct & Compliance Policy Distribution.
2. The distribution of this documentation must occur within 90 days of contracting, annually thereafter, and if there is any material change to the BayCare Select Compliance policies and procedures and / or BayCare Select Code of Conduct. BayCare Select notifies FDRs of substantive changes to its compliance policies and procedures or Code of Conduct in a timely manner, using the most effective method of communication based upon the nature and urgency of the change to be communicated.
3. The Compliance Department documents its distribution of compliance policies and procedures and Code of Conduct to FDRs.

E. Delegation Oversight: The CCO and BayCare Compliance Committee determine appropriate FDR oversight activities. Such activities may include but are not limited to:

1. Establishing and maintaining lines of communication between BayCare Select and its FDRs, including informing FDRs of BayCare Select's system for asking compliance questions and reporting potential Medicare program noncompliance or FWA;
2. Identifying any FDR offshore subcontracting arrangements that may impact BayCare Select;
3. Implementing processes to monitor and audit FDR performance, including compliance with Medicare Parts C and D program requirements;
4. Issue resolution processes;
5. Data analysis for prevention and detection that arises in connection with any FWA commitment by or at the FDR; and
6. Review of annual evaluations of the First Tier Entity, including, but not limited to attestations and / or annual certifications of compliance submitted to the First Tier Entity by BayCare Select's CCO.

F. Lines of Communication and Reporting Compliance Concerns: BayCare Select makes available its Compliance contact information and details about reporting compliance concerns through its FDR compliance education communications process.

1. Contact information for the CCO, Privacy Officer, Special Investigations Unit, and the Compliance Hotline number is communicated as part of its annual communication(s) in distributing its Code of Conduct and Compliance Department policies and procedures. See CMP22 Code of Conduct & Compliance Policy and Procedure Distribution policy and procedure).
2. FDRs and their employees are advised of BayCare Select's requirement to report in good faith, in a timely manner and without fear of retaliation, any problems and concerns about BayCare Select-related practices, regulations, policies, or business issues, including any actual or suspected compliance violations.
3. BayCare Select provides mechanisms for such reporting. BayCare Select's policy on non-retaliation extends to its FDRs. See CMP20 Nonretaliation / Duty to Report.

G. Annual Compliance Attestations, Audit and Monitoring Activities:

1. Annual Compliance Attestations:

- a. The CCO sends an annual certification of compliance to each FDR. The document includes a description of the requirements that must be complied with, as well as an attestation form to be signed by the Chief Executive or the Chief Compliance Officer of the FDR to serve as a certification that all regulatory / contractual requirements have been met. The annual Certification of Compliance should contain statements that address key requirements:
 - i. Code of Conduct / Review and Distribution.
 - ii. Policies and Procedures Review and Distribution.
 - iii. Sanction Screening/Exclusion Checks.
 - iv. Subcontractor Off-Shoring.
 - v. Oversight of Downstream Entities.
 - vi. Reporting Incidents of Suspected Non-Compliance, Fraud, Waste and Abuse.
- b. FDRs must timely complete and return such certifications of compliance to the CCO. The CCO may, in his or her sole discretion, accept the FDR's own certification of compliance, instead of requiring the FDR to complete BayCare's certification of compliance.
- c. The CCO will review the completed certifications of compliance. If the CCO detects any issues of non-compliance during the review, the CCO may request the FDR develop and implement a Corrective Action Plan (CAP) in accordance with CMP 23 Corrective Action Plan Policy and Procedure.
- d. If an FDR fails to timely complete and submit the compliance attestation(s), or to provide requested follow-up documentation including a CAP, the CCO will consult with the legal counsel, operational business owner(s), and/or BayCare Compliance Committee to determine what actions to take against the FDR, up to and including revoking the delegated function from the FDR.

2. Audit Activities:

- a. BayCare may periodically audit its FDRs and / or a specific delegated function to evaluate compliance with applicable laws, regulations and requirements, as well as performance

against contract provisions and specific criteria. Audit priorities and methodologies will be established and governed by BayCare Select Compliance Department policies. See CMP04 Compliance Audit and Monitoring Program and CMP26 Risk Assessment.

- b. The CCO reports the results of all audits to the Compliance Committee and the Board of Directors.
 - c. If the audit findings identify noncompliance with the designated standards, a plan of corrective action must be developed. See CMP23 Corrective Action Plan Policy and Procedure.
 - d. If BayCare has reason to believe the FDR's ability to perform a delegated function is compromised, a discretionary audit may be performed. The CCO may also recommend discretionary audits upon evaluation of non-compliant trends or reported incidents. A discretionary audit may be triggered by the following:
 - i. Failure to comply with CMS requirements;
 - ii. Diminished or non-reported service level performance;
 - iii. Failure to comply with a corrective action plan;
 - iv. Reported or alleged fraud, waste and abuse;
 - v. Significant policy variations that deviate from BayCare or any regulator's, including accreditation entity, requirements;
 - vi. Bankruptcy or impending bankruptcy which may impact services to members (either suspected or reported);
 - vii. Sale, merger or acquisition involving the FDR;
 - viii. Significant changes in the management of the FDR;
 - ix. Changes in resources which impact operations.
3. **FDR Auditing and Monitoring:** BayCare Select has a system for routine monitoring and identification of compliance risks to evaluate FDR compliance with Medicare regulations, sub-regulatory guidance, contractual agreements, and all applicable Federal and State laws, as well as internal policies and procedures to protect against Medicare program noncompliance and potential FWA.
- a. Operations business owners are responsible for monitoring the performance of any FDRs that are contracted to provide services within their functional area, and for documenting all monitoring activities and results. Monitoring may include review of performance metrics, routine or ad hoc conference calls to discuss services and performance, on-site visits, or other activities.
 - b. The Compliance Department is involved in FDR oversight activities through participation in routine and ad hoc meetings and telephone calls, its education and screening activities, audit activities, monitoring oversight activities, and review/discussion with operational leaders relative to contracted entity monitoring.
 - c. Business owners should notify the CCO in a timely manner of any contracted entity performance concerns or issues, failure to fulfill contract terms, negative trends, compliance violations, FDR self-reports of non-compliance or performance deficiencies, or significant changes to entity business operations, so that issues or trends can be evaluated and further monitoring, auditing, or corrective actions can be initiated, if necessary.

- d. FDRs are included in BayCare's Risk Assessment process. Compliance monitoring and auditing of BayCare's First-Tier entities is undertaken in accordance with the procedures for Compliance auditing and monitoring. FDRs are expected to monitor the compliance of the entities with which they contract (BayCare's downstream entities). BayCare must monitor any related entities to verify that those entities are compliant with applicable laws and regulations. See CMP04 Compliance Audit and Monitoring Program and CMP23 Risk Assessment policies and procedures.
- e. The CCO will establish an auditing and monitoring work plan to oversee FDRs as is otherwise outlined in CMP04 Compliance Audit and Monitoring Program.

H. Verification of Non-Exclusion from Federal Contracting: BayCare Select will screen FDRs prior to contracting and monthly thereafter to ensure that none of these persons or entities are excluded or become excluded from participation in federal programs. FDRs are responsible for compliance with screening requirements for their own workforce members, and for their First-Tier entities, which are BayCare's downstream entities. See CMP11 Exclusion from Federal Healthcare Programs.

I. Identifying Offshore Subcontracts: FDRs that delegate any administrative or health care services relating to BayCare Select's Medicare contracts to an individual or entity located outside the United States or its Territories must *immediately* disclose such delegation to BayCare Select. Upon disclosure, the CCO and legal counsel reviews the delegation for impact to business and communicates as needed with the FDR relative to any necessary actions. As applicable, the CCO (or designee) shall report the offshore relationship to CMS, or other involved parties in accordance with the agreements with those parties.

J. Special Investigations Unit (SIU): As part of BayCare Select's monitoring of FDRs, data analysis for FWA prevention and detection is conducted to identify unusual patterns or trends that may suggest potential errors or possible FWA. The SIU is responsible for such analysis and reports its findings (if any) to the CCO via formal and routine meetings. The SIU is also responsible for addressing any complaints and / or sales investigations. Specifically, the scope of these meetings includes, but is not limited to, overseeing the SIU and its activities, in identifying, addressing, and monitoring potential FWA, investigations of sales complaints and complaints by members and / or providers (i.e., Complaints Tracking Modules that come in through Health Plan Management System (HPMS) or otherwise).

K. Reporting Responsibilities of the CCO:

- 1. The CCO receives regular reports from FDRs regarding compliance incidents, auditing and monitoring, and the status and effectiveness of corrective actions taken.
- 2. The CCO (or designee) provides updates on FDR activities to the Compliance Committee, the CEO, and senior leadership on at least a quarterly basis.

L. Disciplinary Actions:

- a. BayCare Select may require its FDRs to agree to a CAP when issues of non-compliance are identified, in accordance with CMP23 Corrective Action Plan Policy and Procedure and CMP 21 Disciplinary Policy if applicable.

- b. BayCare Select may take other administrative/disciplinary actions, up to and including termination of the FDR’s contract, if the FDR does not comply with a CAP or does not meet its regulatory obligations and service commitments as outlined in BayCare Select’s contract with the FDR and its contract with CMS.

VII. REGULATORY REFERENCES / CITATIONS

Medicare Managed Care Manual, Chapter 21 – Compliance Program Guidelines and Prescription Drug Benefit Manual, Chapter 9 – Compliance Program Guidelines, Section 40
 42 C.F.R. 422.503(b)(4)(vi); 42 C.F.R. 423.504(i)
 42 C.F.R. 423.504(b)(4)(vi); 42 C.F.R. 423.505(i)

VIII. RELATED POLICIES & PROCEDURES

CMP 04 Compliance Auditing and Monitoring Program
 CMP 08 Compliance Violations Reporting and Investigation
 CMP 11 Exclusion from Federal Healthcare Programs
 CMP 13 Health Plan Document and Data Retention
 CMP 20 Non-Retaliation / Duty to Report
 CMP 21 Disciplinary Policy
 CMP 22 Code of Conduct & Compliance Policy Distribution
 CMP 23 Corrective Action Plan Policy and Procedure
 CMP 26 Risk Assessment

IX. ATTACHMENTS

None

VERSION & REVIEW HISTORY:

Version #	Action (Original Issue, Reviewed, Revised)	Date Action Taken	Brief Summary of Revision, if applicable	Individual Taking Action	Effective Date	Date Approved and By Whom
01	Original Issue	09/01/2017	N/A	Paul Christy, CCO	09/01/2017	N/A – James Beermann, President
02	Revised	06/26/2020	Materially reviewed and revised to outlined additional detail in relation to oversight of FDRs.	Joanna Tofani, CCO	06/26/2020	Compliance Committee 06/26/2020