South Carolina

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MEDICARE ADVANTAGE

2024 DELEGATION OVERSIGHT AND COMPLIANCE PROGRAM GUIDE

BLUECROSS BLUESHIELD OF SOUTH CAROLINA
MA COMPLIANCE

January 2024

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To our Medicare Advantage Compliance Partners,

Welcome to BlueCross BlueShield of South Carolina (BlueCross) Medicare Advantage (MA). This guide has been created to communicate The Centers for Medicare and Medicaid Services (CMS) Compliance Program requirements for monitoring, oversight, reporting and audits of our first tier, downstream, and related entities (FDRs).

Some of these expectations are communicated in FDR contracts with BlueCross. Others are requirements specific to CMS Regulation and provisions in BlueCross' contract(s) with CMS to provide administrative or health care services to our Medicare Advantage members.

We hope this guide will facilitate transparent communication of compliance expectations to all of our compliance partners, including BlueCross Business and Contract Owners, our Legal team, MA Compliance, and our contracted FDRs.

We each have specific responsibilities that must be carried out to ensure performance and CMS standards continue to be met and that BlueCross, as a Plan Sponsor, remains compliant. CMS requires Plan Sponsors to routinely oversee, monitor, and audit the performance of its contracted FDRs. We must all work together to ensure ongoing compliance as these important activities are performed.

Please do not hesitate to contact us at any time with any questions or concerns you may have.

We are looking forward to working with you all!

Sincerely,

The BlueCross Medicare Advantage Compliance Team:

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(Please Note: Documents in this Appendix may not represent the most current/updated versions)

INTRODUCTION

BlueCross created this Compliance Guide to communicate specific compliance expectations for our business/contract owners, contractors, subcontractors, sales agents, and applicable first tier, downstream, and related entities (FDRs) who provide or oversee delegated services to our members.

What is a First Tier, Downstream, or Related Entity (FDR)?

CMS defines First Tier, Downstream and Related Entities as follows:

First Tier Entity is any party that enters into a written arrangement, acceptable to CMS, with an MA organization or Part D plan sponsor or applicant to provide administrative services or health care services to a Medicare-eligible individual under the MA program or Part D program. (See 42 CFR §§ 422.500 and 423.501.)

Downstream Entity is 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 an MA 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 and 423.501.)

Related Entity means any entity that is related to an MA organization or Part D sponsor by common ownership or control and:

- Performs some of the MA organization or Part D plan sponsor's management functions under contract or delegation
- Furnishes services to Medicare enrollees under an oral or written agreement
- Leases real property or sells materials to the MA organization or Part D plan sponsor at a cost of more than $2,500 during a contract period (See 42 CFR §§ 422.500 and 423.501.)

BlueCross contracts with Vendors as a cost-effective and efficient way of providing administrative and health care services to its Medicare Advantage members. We are required to perform most of these services under our contract(s) with CMS.

Pre-delegation Reviews

Prior to performing delegated activities for our Medicare members, all Vendors must undergo a pre-delegation assessment process which includes evaluation against certain specific criteria, carefully considered by BlueCross Business/Contract Owners, Corporate Legal, and MA Compliance. To identify a Vendor as an FDR it must meet some or all of the following criteria:

- BlueCross is required to provide this function under its contract with CMS, federal regulations, or CMS guidance

- The function directly impacts members or prospective members
- The entity interacts directly with members or prospective members either orally or in writing
- The delegated entity has access to beneficiary information or personal health information (PII or PHI)
- The delegated entity has decision-making authority (e.g., enrollment vendor deciding time frames) or whether the entity strictly takes direction from the sponsor
- The delegated entity is in a position to commit health care fraud, waste, or abuse (FWA)
- There is risk that the entity could harm enrollees or otherwise violate Medicare program requirements or commit FWA

In addition, designated FDRs performing material functions related to a Sponsor's Medicare Part C and/or D contracts are subject to specific oversight, monitoring, reporting and routine auditing by BlueCross. Functions of a Sponsor's contract(s) with CMS include:

- Sales and Marketing
- Utilization Management
- Quality Improvement
- Applications Processing
- Enrollment, Disenrollment, Membership Functions
- Claims Administration, Processing, Coverage Adjudication
- Appeals and Grievances
- Licensing and Credentialing
- Pharmacy benefit management
- Hotline operations
- Customer service
- Bid preparation
- Outbound Enrollment Verification
- Provider Network Management
- Processing of Pharmacy Claims at Point of Sale
- Negotiation with prescription drug manufacturers and others for rebates, discounts, or other price concessions on prescription drugs
- Administration and tracking of enrollees' drug benefits, including TrOOP balance processing
- Coordination with other benefit programs such as Medicaid, state pharmaceutical assistance or other insurance programs
- Entities that generate claims data
- Health Care Services

CONTRACT REQUIREMENTS

MA Addendum and Material Provisions

The contract between CMS and a Plan Sponsor must contain certain CMS material provisions and standards for health and prescription drug plans as outlined at 42 CFR Sections 422.503, 422.504, and 423.505. Since a Plan Sponsor is ultimately responsible for the performance of all administrative and health care services under its contract with CMS, our written arrangements with FDRs must contain these same provisions. BlueCross incorporates some of these provisions into its contracts with FDRs in the form of a Medicare Advantage Addendum. *See example at Exhibit A in the Appendix at the end of this document.* In addition, all FDR contracts must reference specific delegated activities, responsibilities of all parties under the agreement, CMS contract and regulatory standards, performance standards and penalties for non-performance.

Existing Corporate Agreements

BlueCross Business/Contract owners negotiate various types of agreements with vendors, depending on the delegated services and line(s) of business. These include, but are not limited to agreements with contractors, providers and facilities, general agencies, and include corporate master service agreements, administrative agreements, and statements of work. Sometimes delegated activities for the Medicare Advantage line of business are added to an existing Corporate Agreement which was developed for another line of business. It is important that the proper agreement format is incorporated if the Medicare Advantage line of business is added, as certain contractor and provider agreements do not adequately capture the specific nuances required for contracts between MA Plan Sponsors and FDRs.

Initial Contract Negotiations and Routine Reviews

Prior to delegation of activities, the Business/Contract Owner, Corporate Legal, and MA Compliance must conduct a thorough review of the contract to ensure these provisions are included and the proper type of agreement is being negotiated. If, in turn, an FDR enters into its own agreement with a downstream entity to further delegate these activities, these same provisions must be included in that agreement. Should any new responsibilities be added or removed from an FDR agreement, our Business/Contract Owners are responsible for notifying and working with our Legal Department for facilitation of such changes. To ensure changes and updates are maintained, Business/Contract Owners are required to perform an annual review of the FDR contracts they have responsibility for. During annual Compliance program reviews, MA Compliance will also review contract documentation for FDRs. Business/Contract Owners must provide MA Compliance with copies of all executed and updated agreements with FDRs.

Offshore Operations and CMS Reporting

To ensure that BlueCross complies with applicable federal and state laws, rules and regulations, FDRs are required to request permission to perform offshore services or to use an individual or entity (offshore entity or employee working at an offshore location) to perform services for BlueCross' Medicare plans, when the individual or entity is physically located outside the United States or one of its territories.

FDRs are required to request approval from a BlueCross business owner and advise MA Compliance in advance and in writing of such use of any offshore individual or entity and complete and submit to BlueCross our Offshore Subcontracting Attestation Form within thirty (30) calendar days after the offshore subcontract is signed. *See Exhibit B in the Appendix.*

MA Compliance will submit the information via the Offshore Subcontractor Data Module in HPMS. This provision is in your contract with BlueCross and must also be included in any contract with your downstream entities.

COMPLIANCE PROGRAM REQUIREMENTS

Our Medicare Compliance Program helps us to serve our members ethically. We are committed to practicing business in an ethical manner and our Medicare Compliance Program helps us to reduce or eliminate incidents of non-compliance or FWA, ensure we comply with applicable laws, rules and regulations, and reinforce our commitment to compliance.

What are the "elements" of an effective compliance program?

Plan Sponsors and FDRs are required to develop and implement a comprehensive and effective compliance program. There are seven "elements" to this program that must be implemented. During MA Compliance's pre-delegation assessment, we review each FDRs compliance program to ensure that these elements are in place.

An effective compliance program should include:

- Written policies, procedures, and standards of conduct
- A Designated Compliance Officer and Compliance Committee and High Level Oversight
- Effective Education which includes training on Compliance and Fraud, Waste, and Abuse, Standards of Conduct, HIPAA Privacy, Conflict of Interest, and Routine Exclusion Screening
- Effective Lines of Communication

- Well publicized disciplinary standards
- Implementation of an Effective System for Routine Monitoring, Auditing and Identification of Compliance Risks
- Implementation of an Effective Procedure and System for Prompt Response to Compliance Issues, Investigation of Potential Compliance Problems, and Prompt Correction to Ensure Ongoing Compliance with CMS Requirements

Standards of Conduct and Compliance Policies

Plan Sponsors and FDRs must provide Standards of Conduct and Medicare compliance policies and procedures to all employees, board members, and Downstream Entities who provide administrative and/or health care services for our Medicare plans. The written compliance policies and standards of conduct must contain all of the elements set forth above (Section 50.1 and its subsections of the Medicare Managed Care Manual, Chapter 21 and Prescription Drug Benefit Manual, Chapter 9), and articulate the entity's commitment to comply with federal and state laws, ethical behavior and compliance program operations.

FDRs may utilize the policies and procedures described in the BlueCross standards of conduct, "Our Values" document, or FDRs may use their own comparable standards of conduct and compliance policies and procedures. FDRs must distribute standards of conduct/compliance policies to employees, board members, and FDRs:

- Within 90 days of hire or the effective date of contracting
- When there are updates to the standards of conduct
- Annually thereafter

Also, FDRs must retain evidence of distribution of the standards of conduct.

The standards of conduct requirements are referenced at:

- 42 CFR § 422.503(b)(4)(vi)(A) for MA
- 42 CFR § 423.504(b)(4)(vi)(A) for Part D
- CMS Managed Care Manual, Chapters 9 and 21 at § 50.1

EXCLUSION/PRECLUSION LIST SCREENINGS

Office of Inspector General/General Services Administration Exclusion Lists

Federal law prohibits Medicare, Medicaid, and other federal health care programs, from paying for items or services provided by a person or entity excluded from participation in these federal programs. Therefore, before hiring or contracting, and monthly thereafter, each FDR must check exclusion lists from the Office of Inspector General (OIG) List of Excluded Individuals and

Entities (LEIE) and the U.S. General Services Administration (GSA). This is to confirm that employees, board members, and Downstream Entities performing administrative and/or health care services for BlueCross' Medicare plans are not excluded from participating in federally funded health care programs.

FDRs can use these websites to perform the required exclusion list screenings:

- OIG List of Excluded Individuals and Entities (LEIE), http://oig.hhs.gov/exclusions/index.asp
- GSA's System for Award Management (SAM), https://www.sam.gov

Provider/Entity Preclusion List

In a 2018 CMS Final Rule, (published April 16, 2018), CMS implemented a new requirement, which became effective January 1, 2019, for MA Sponsors to check all providers, suppliers, or prescribers, prior to payment, against the new "Provider/Entity Preclusion List."

This requirement affects all FDRs that contract directly with providers and/or perform delegated credentialing functions, or contract with or maintain a network of providers to provide health care or medical management services for our members. The Preclusion list is only available to Plan Sponsors, however, MA Compliance provides this list monthly to all of its affected FDRs.

Regulatory guidance at 42 CFR Section 422.504 was updated on April 16, 2019, to include the requirement that provider agreements contain verbiage similar to the following that:

> if a provider or entity appears on the Preclusion list, and after expiration of a 60-day member notification period, it will not be eligible for payment and will be prohibited from pursuing payment from the beneficiary. The provider will be liable for all services, items, and drugs that are furnished, ordered, or prescribed. *See Exhibit C in the Appendix for more information regarding the Provider Preclusion List requirements.*

Documentation and Actions Required

FDRs must maintain evidence of performing these exclusion/preclusion list screenings. Evidence includes logs, screenshots, etc., to include date of occurrence, results of the screening and any actions taken if excluded or sanctioned individuals or entities were identified. MA Compliance will request documentation for these screenings during annual compliance program audits. FDRs are not alone in this requirement. We are also required to check these exclusion lists before hiring or contracting with any new employee, temporary employee, volunteer, consultant, board member, or FDR, and monthly after that. We cannot check these exclusion lists for our FDR's employees and Downstream Entities. So, to make sure we comply with this CMS

requirement, FDRs must confirm that employees and Downstream Entities that provide administrative and/or health care services for our Medicare plans are not on any of these lists.

FDRs must take action if an employee of a downstream entity is on any exclusion list. If any employee or downstream entity is on one of the exclusion lists, FDR must immediately remove them from work related to BlueCross' Medicare plans and notify us right away.

FDRs must also notify MA Compliance if any contracted provider or entity appears on the Provider Preclusion list and inform us as to actions taken to remove the provider from their network and stop payments to precluded providers or entities.

OVERSIGHT, REPORTING, MONITORING AND AUDITING REQUIREMENTS

General Requirements Related to FDRs performing delegated functions

At a minimum, BlueCross Business/Contract Owners and MA Compliance will perform pre-delegation and routine audits of an FDR's Compliance Program based on risk assessment criteria. Compliance Program Audits include initial vendor assessment and pre-delegation audits, contract review, and review of specific validation documentation provided to MA Compliance by the FDR's Compliance and Audit team(s).

In addition, MA Compliance will request FDRs to complete an Annual Compliance Program Attestation. In addition, an Annual New Hire Training Report will be requested from all FDRs that are not on our Audit Workplan for the current year. This is to confirm, where an FDR's Compliance Program is not audited during a coverage year, that the FDR is continuing to train and screen new hires appropriately. *See Exhibits D and E in the Appendix.*

BlueCross is required to oversee and monitor the performance of its FDRs. As part of this ongoing oversight and monitoring, BlueCross must receive routine reporting to verify that performance standards in the agreement are being met. Business Owners will reach out to FDRs to obtain monthly, quarterly, annual, and ad hoc reporting metrics on specific performance and CMS standards as outlined in the FDR's contract with BlueCross. Business Owners will report results to the Medicare Advantage Delegation Oversight and Medicare Advantage Compliance Committees on a quarterly basis.

CMS requires additional timeliness and performance standards for some FDRs depending on which delegated activities are performed. Some examples of FDRs with additional CMS timeliness or other requirements are call centers or claims processors. The Business Owner will work with the FDR to identify these metrics and to provide dashboard reporting to MA Compliance.

Corrective Actions

Should performance standards not be met, the Business Owner will work with the FDR and MA Compliance to develop a corrective action plan (CAP) to remediate the deficiency. Corrective actions may include training, system changes, or other remediation to correct the issue. Business Owner and MA Compliance will monitor the effectiveness and satisfactory completion of all CAPs and ensure enforcement of any penalties should the issue(s) not be remediated.

FDRs are expected to report any incidence of non-compliance or FWA to the Business/Contract Owner, MA Compliance, and/or proper federal or state agencies immediately, so that proper investigation and/or corrective action(s) can be taken.

Requirements Related to Contracts Between BlueCross and FDRs

MA Compliance and Business/Contract Owners will review current contract documentation as part of a pre-delegation assessment or annual compliance program audit. MA Compliance will also request routine status updates from Business Owners at quarterly and annual intervals and at MA Delegation Oversight Committee meetings. Updates are necessary throughout the coverage year to identify additions or removal of delegated activities which might necessitate revisions/additions to the contract. If changes are necessary, the Business/Contract Owner will engage BlueCross Legal and MA Compliance to remediate.

Requirements Related to Training and Education, OIG and GSA Monthly Screening, and Compliance Program Elements

BlueCross will monitor FDRs completion of Compliance and FWA, Code of Conduct, HIPAA Privacy, and Conflict of Interest training/attestations. FDRs should retain rosters and other documentation confirming this training has occurred. We will continue to assess FDR compliance program effectiveness through annual attestations, routine compliance audits, and annual training reports.

BlueCross will also request documentation during annual compliance program audits to confirm monthly OIG and GSA screening and/or Provider/Entity Preclusion List screening (as applicable) of all employees and downstream entities.

During annual compliance program audits BlueCross will confirm that the FDR has policies and procedures for all delegated and compliance program activities and that they are reviewed annually. We will confirm adherence to all compliance program requirements and that mechanisms are in place to report suspected or detected noncompliance or potential FWA.

CONCLUSION

We hope that the information in this document has been helpful and has effectively communicated ongoing oversight, monitoring, reporting and other compliance expectations to all of our Compliance Partners.

For questions or concerns regarding this guide, please contact:

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(803) 264-4639
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Or email our FDR Delegation Oversight Mailbox at: Delegation.Oversight@bcbssc.com

To report any suspected or actual compliance violations please contact:

For: Compliance and Privacy	For: Fraud, Waste and Abuse
Medicare Advantage: BCBSSC.MA.COMPLIANCE@bcbssc.com	**BlueCross BlueShield of South Carolina Fraud Hotline:** **Phone:** 800-763-0703 **Fax:** 803-264-4050 **Website:** https://www.southcarolinablues.com/web/public/brands/sc/assistance/report-fraud/ **Mail:** BlueCross Anti-Fraud Unit Mail Code AC-200 P.O. Box 24011 Columbia, SC 29224-4011 **Office of Inspector General** **Phone:** 800-HHS-TIPS (800-447-8477) **Online:** https://oig.hhs.gov/fraud/report-fraud/index.asp **Fax:** 800-223-8164 **TTY:** 1-800-377-4950 **Mail:** Office of the Inspector General ATTN: OIG Hotline Operations P.O. Box 23489 Washington, DC 20026 **Medicare Drug Integrity Contractor (MEDIC) – Qlarant Integrity Solutions, LLC formally Health Integrity, LLC** **Phone:** 877-772-3379 **Fax:** 410-819-8698 **Website:** www.qlarant.com

REFERENCES: Specific regulatory requirements outlined in this document can be found in:

- Code of Federal Regulations (CFR) Section(s) 422.503, 422.504, 423.504, 423.505
- Section 1862 (e)(1)(B) of the Social Security Act
- Medicare Managed Care Manual, Chapter 21, Compliance Program
- Prescription Drug Benefit Manual, Chapter 9, Compliance Program
- Medicare Managed Care Manual, Chapter 11, Contract Requirements

APPENDIX

Exhibit A – Medicare Advantage Addendum


MA Addendum

Exhibit B – Offshore Attestation Form


Offshore
Attestation Form

Exhibit C – Preclusion List Information


6g. 42 CFR 422.222
(as of 10-03-2022).p

Exhibit D – Annual FDR Attestation of Compliance


2024 MA Annual
Compliance Attestat

Exhibit E – New Hire Training Report


2024 New Hire Trng
Rpt Template.docx