



KelseyCare
Advantage
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FDR COMPLIANCE PROGRAM GUIDE

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I. Introduction – KelseyCare Advantage Commitment to Compliance

KS Plan Administrators, LLC, d/b/a KelseyCare Advantage (“KCA”), is committed to conducting business with the highest ethical standards and in compliance with all applicable federal and state laws and regulations. KCA strives to effectively prevent, detect, and correct non-compliance with laws and regulations, including at the vendor level. KCA promises to demonstrate continued commitment to compliance and a sustainable delegation oversight program.

Requirements for a Compliance Program

KCA contracts with the Centers for Medicare & Medicaid Services (CMS) as a Medicare Advantage Organization (MAO) to provide Medicare-eligible beneficiaries Part C medical and Part D prescription drug coverage.

The contract with CMS requires KCA to maintain an effective Compliance Program as described in the CMS guidance:

- Title 42 of the Code of Federal Regulations (C.F.R.), Parts 422 and 423
- Medicare Managed Care Manual, Chapter 21 – Compliance Program Guidelines
- Prescription Drug Benefit Manual, Chapter 9 – Compliance Program Guidelines

Vendors Providing Cost-Effective Solutions

KCA contracts with individuals and entities (“vendors”) that possess the expertise, skill, and knowledge of their respective industries, trades, or professions and who can provide efficient and cost-effective administrative, healthcare, and/or prescription drug services. When a vendor provides one or more of these services on behalf of KCA, the vendor meets the definition of a First Tier, Downstream, or Related (FDR) entity. Other examples include, but are not limited to, third-party marketing organizations, handling appeals and grievances, utilization management, and pharmacy benefit manager, to name a few.

CMS recently added new oversight and monitor provisions for third-party marketing organizations (TPMOs), including standardized disclaimers, display of and a verbal disclaimer, subcontractor relationships, call recording, disciplinary action reporting, and lead generation and beneficiary notification. As such, these requirements only apply to TPMOs and do not apply to all FDRs. A determination is made based on the contract with KCA and the vendor.





II. Definitions and Terms

- A. Abuse:** means 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.
- B. Auditing:** means a formal review of compliance with a particular set of standards (e.g., policies, processes, laws, and regulations) used as a base measure.
- C. Corrective Action Plan (CAP):** means a step-by-step plan of action that the organization develops to correct findings where an audited standard is not met.
- D. Downstream Entity:** means any party that enters 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 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.
- E. FDR:** means First Tier, Downstream or Related Entity.
- F. First Tier Entity:** means any party that enters a written arrangement, acceptable to CMS, with an MAO 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.
- G. Fraud:** means knowingly and willfully executing, or attempting to execute, a scheme 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. (See 18 U.S.C. §1347).
- H. FWA:** means fraud, waste, and abuse
- I. General Services Administration (GSA):** means is an independent agency of the United States government that maintains the System for Award Management that includes information on entities debarred, suspended, proposed for debarment, excluded or disqualified from receiving federal contracts or certain subcontracts and from certain types of federal financial and non-financial assistance and benefits.
- J. Monitoring Activities:** means regular reviews performed as part of normal operations to confirm ongoing compliance and to ensure that corrective actions are undertaken and effective.
- K. Office of Inspector General (OIG):** means an agency with the Department of Health and Human Services (DHHS). The Inspector General is responsible for audits, evaluations, investigations, and law enforcement efforts related to DHHS program and operations, including the Medicare program.
- L. Offshore Services:** means any company providing services that are performed by workers located in offshore countries (any country that is outside of the United States and its territories), regardless of whether the workers are employees of American or foreign companies.
- M. Protected Health Information (PHI):** means information that is created or received by a Covered Entity and related to the past, present, or future physical or mental health condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and that identifies the individual for which there is a reasonable basis to believe the information can be used to identify the individual. PHI includes information on persons living or deceased.
- N. Related Entity:** means any entity that is related to an MAO or Part D sponsor by common ownership or control and
- Performs some of the MAO or Part D plan sponsor's management functions under contract or delegation.
 - Furnishes services to Medicare enrollees under an oral or written agreement; or
 - Leases real property or sells materials to the MAO or Part D plan sponsor at a cost of more than \$2,500 during a contract period. (See, 42 C.F.R. §423.501).
- O. Special Investigations Unit (SIU):** means an internal investigation unit responsible for conducting investigations of potential FWA.
- P. Waste:** means the overutilization of services, or other practices that, directly or indirectly, result in unnecessary costs to the Medicare program.
- Q. Investigations Medicare Drug Integrity Contractor (I-MEDIC):** means an organization selected by the Centers for Medicare & Medicaid Services to detect, prevent, and proactively deter, fraud, waste, and abuse in Medicare Programs.
- R. Personally Identifiable Information (PII):** means information that can be used to distinguish or trace an individual's identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual.
- S. Third-Party Marketing Organizations (TPMOs):** means organizations that are compensated to perform lead generation, marketing, sales, and enrollment related functions as a part of the chain of enrollment, that is the steps taken by a beneficiary from becoming aware of a Medicare plan or plans to making an enrollment decision. TPMOs may be first tier, downstream or related entity (FDRs), as defined under §§ 422.504(i) and 423.505(i), but TPMOs may also be other businesses which provide services to customers including an MA or Part D plan or an MA or Part D plan's FDRs.

III. What Is the Purpose of the FDR Compliance Guide?

This guide is provided because your organization has been identified as an FDR by KCA through its contractual relationship. CMS requires FDRs to fulfill the same Compliance Program requirements that apply to KCA. This guide also contains additional expectations KCA requires of all FDRs.

You will find a summary of the requirements in this guide. Please use this as a quick reference to understand the CMS Compliance Program requirements and to ensure that you have internal processes to support your Compliance Program.

Note: Section I of this guide provides information where you can obtain more detailed guidance on the CMS Compliance Program requirements.





IV. FDR Compliance Delegation Oversight Program Requirements

KCA is committed to ensuring that our FDRs are compliant with applicable laws, rules, and regulations. It is important that you follow these requirements. FDRs are expected to adhere to CMS Compliance Program requirements and KCA standards when conducting business on behalf of KCA. Part of KCA's due diligence process includes a pre-delegation review of the FDRs before contracting is finalized. The review encompasses a Compliance Program, Information Technology Security questionnaires, and requests for copies of relevant policies and procedures as they relate to the vendor's compliance program and privacy controls to protect member data. The pre-delegation assessment also includes a review of physical and logical accesses of protected health information (PHI), and information related to offshore contracting activities.

Compliance Program Elements

Your organization and your downstream entities (if any) must comply with CMS Compliance Program requirements. There are seven elements to ensure that your Compliance Program meets CMS's standards.

- Element 1:** Written Policies, Procedures, and Standards of Conduct
- Element 2:** Designation of a Compliance Officer and Oversight of the Compliance Program
- Element 3:** Effective Training and Education
- Element 4:** Effective Lines of Communication
- Element 5:** Well-Publicized Disciplinary Standards
- Element 6:** Effective System for Routine Monitoring and Identification of Compliance Risks
- Element 7:** Prompt Response to Compliance Issues



ELEMENT ONE: Written Policies, Procedures, and Standards of Conduct

FDRs must provide written policies and procedures and Standards of Conduct to all employees providing administrative, healthcare, and/or prescription drug services on behalf of KCA. FDRs must also ensure their downstream entities distribute appropriate policies and procedures and Standards of Conduct that support similar requirements to their employees.

These policies and procedures and Standards of Conduct should include the following information:

1. FDR's commitment to comply with all applicable federal and state standards
2. FDR's expectations of its employees to comply with the policies and Standards of Conduct
3. FDR's Compliance Program operations
4. Appropriate guidance for employees and others on dealing with suspected, detected, or reported compliance issues
5. Details on how employees should communicate compliance issues to appropriate compliance personnel

6. Description of how suspected, detected, or reported compliance issues are investigated/resolved
7. Non-intimidation and non-retaliation protections for individuals who make good faith reports of non-compliance activity to its Compliance Program

Such information must be distributed to FDR employees and contractors:

1. Within 90 days of hire and/or contracting and
2. When updated or annually thereafter

FDR can determine the most effective method to distribute the policies and procedures and Standards of Conduct (e.g., via hardcopy at the time of hire/contracting, electronic, posting on the FDR's intranet). FDR's must maintain documentation that demonstrates the information was distributed. Feel free to distribute KCA's Code of Conduct to your employees. Additionally, you must retain evidence that these written standards were distributed to all applicable parties for the period under contract plus 10 years.

ELEMENT TWO: Designating a Compliance Officer and Oversight of Compliance Program

Each FDR must designate a senior-level employee to act as the Compliance Officer for its organization. The Compliance Officer must maintain responsibility for the implementation of the FDR's Compliance Program, including responding to reports of potential fraud, waste, and abuse (FWA) and non-compliance. The

Compliance Officer maintains documentation on the Compliance Program and is responsible to oversee, develop, and monitor corrective action plans. The Compliance Officer must also have direct access to the FDR's senior-most leader (e.g., the CEO, president/owner) and/or the FDR's governing body, if applicable.



ELEMENT THREE: Effective Training and Education

KCA requires FDRs contracted to provide administrative, healthcare and/or prescription drug benefit services on behalf of KCA members to conduct general compliance and FWA training for employees upon hire and annually thereafter. FDRs will be required to complete an annual attestation that general compliance and Medicare FWA was completed.

Privacy and Security Training

FDRs are required to protect all KCA's member information, including Protected Health Information (PHI) and Personally Identifiable Information (PII). Employees who have access to PHI and/or PII must receive Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security training within 90 days of hire and annually thereafter. FDRs must retain records of training completion and the topics.

Privacy and Security training should address topics such as:

1. Federal and state laws governing the confidentiality of PHI and PII
2. When PHI and PII may be accessed, viewed, used, and disclosed
3. Safeguards to protect the integrity, confidentiality, and availability of PHI and PII

ELEMENT FOUR: Effective Lines of Communication

An FDR must maintain effective communication between its employees and its downstream entities. FDRs should include the name, contact, and location of its Compliance Officer for its employees and downstream entities.

FDRs must adopt a policy of non-intimidation and non-retaliation against employees for good faith reports of suspected or actual non-compliance, including FWA. Alternative reporting mechanism includes anonymous reporting via the FDR's website or hotline.

KCA provides additional reporting mechanisms for FDR employees via its online reporting form <https://www.surveymonkey.com/r/TBLMG7G>. Please share the link with your employees. For any credible report of potential FWA, KCA will conduct a reasonable investigation and may refer the issue, as appropriate, to the MEDIC, CMS, and/or law enforcement.

ELEMENT FIVE: Well-Publicized Disciplinary Standards

FDRs must require their employees to adhere to the requirements of their Compliance Program. FDRs should provide employees with examples of what constitutes non-compliant, unethical, and/ or illegal behavior that violates the Compliance Program, as well as publicize disciplinary standards that will be enforced when non-compliance is identified. Some examples of the type of publication methods include:

1. FDR's intranet site
2. General compliance training
3. Posters prominently displayed throughout employee work and break areas

Enforcement of Disciplinary Standards

FDRs must be able to demonstrate that disciplinary standards are enforced timely, consistently, and effectively. Records pertaining to any disciplinary action in response to a compliance violation should be maintained for 10 years.

*FDRs must report any issue of non-compliance or FWA immediately if it pertains to KCA.

ELEMENT SIX: Effective System for Routine Monitoring and Identification of Compliance Risks

KCA is ultimately responsible for fulfilling the terms and conditions of its contract with CMS. If any function is performed by an FDR, CMS requires monitoring and auditing to ensure such functions are performed in accordance with applicable laws and regulations.

Debarment and Exclusion Screenings

Federal law prohibits the payment to any individual or entity for items or services provided by debarred or excluded individuals and entities and from participation in any federal healthcare program.

FDRs must screen employees, temporary workers, volunteers, consultants, governing body members, contractors, and downstream entities against the following debarment and exclusion sites before employing or contracting with the employee/contractor and monthly thereafter. You can use these websites to perform the required debarment and exclusion list screening:

1. Office of Inspector General (OIG):
<https://exclusions.oig.hhs.gov/>
2. General Services Administration (GSA) System for Award Management (SAM):
<https://www.sam.gov/SAM>

FDRs must maintain the records of evidence that they checked these sources for the period under contract plus 10 years. Your organization will be required to complete and submit an annual attestation that it performs OIG and GSA screenings, and upon request provide evidence for the screenings.

Required Action

If any individual or entity performing a service on behalf of KCA is on the OIG or SAM exclusion list, your organization must confirm that the debarment or exclusion match is valid. Upon confirmation, the individual or entity shall not work on any KCA business and KCA must be notified immediately.

Preclusion List Screening

As of 2019, CMS publishes a Preclusion List of providers and pharmacies that CMS has identified as being excluded from receiving payment from a Medicare plan for healthcare items, services, and Part D drugs. CMS publishes the Preclusion List monthly, and KCA sends it to our applicable FDRs to ensure the requirements, notifications, and timeframes are met.

For more information: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSuppEnroll/PreclusionList>.

Your organization “may” be identified as an entity required to run checks of providers and pharmacies against the Preclusion List. KCA may require your organization to submit an annual Preclusion List attestation. By completing the annual attestation, your organization attests that it meets the CMS requirements and will report any findings to KCA. Your organization may be required upon request to provide evidence of the screening.

1. Complete a review to determine if the organization has any providers or pharmacies on the Preclusion List.
2. If providers or pharmacies are identified on the preclusion list, you are required to report this to KCA on a monthly basis.
3. If none, return the Preclusion List attestation to KCA by the required timeframe.

Required Action

If yes, remove the provider or pharmacy. Also, notify all affected enrollees who have received care from the provider or pharmacy within the last 12 months.

1. Please contact KCA if you do not have a copy of the enrollee notification letter. Send to:
ComplianceList@kelsey-seybold.com.

Avoiding Conflicts of interest

A Conflict of Interest (COI) exists when the interests of an FDR or its employees influence or has the appearance of influencing their ability to make objective decisions during the FDR's job duties and responsibilities. A COI may also exist if the demands of any outside activities hinder or distract an employee from the performance of job duties or result in the use of resources for other than company purposes. FDRs and their employees must always avoid a COI.

If a potential COI arises, the activity must be reported to the FDR's Medicare Compliance Officer. If a COI relates to KCA's business, this must be reported immediately to KCA's Compliance Department at 855-741-4518 or mail to: KelseyCare Advantage, Attn: Compliance Department, 11511 Shadow Creek Parkway, Pearland, Texas 77584.

ELEMENT SEVEN: Prompt Response to Compliance Issues and Non-Permitted Disclosures of PHI and PII

There are confidential ways to report suspected or detected non-compliance or potential FWA to KCA. Reporting mechanisms are on our website at <https://www.surveymonkey.com/r/TBLMG7G>, or call the Hotline at 855-741-4518. Information may also be submitted anonymously.

You can share the link with your employees or downstream entities. You can also keep them as a reference tool and use your own internal processes for reporting and collecting these issues. If you choose to use your own processes, make sure that any issues of non-compliance and/or FWA are reported promptly to KCA's Compliance department. Any issues of detected non-compliance or potential FWA must be investigated promptly and reported to the appropriate parties.

Reporting Compliance Concerns

FDRs are required to protect KCA's member information, including PHI and PII. If an FDR detects or is made aware of a non-permitted disclosure ("breach") of PHI or PII affecting KCA members or its employee data, they are to report it immediately to KCA's Compliance Department.

FDRs use their own system of non-permitted disclosure ("breach") reporting and forward a copy of it to KCA's Compliance Department at privacyissues@kelsey-seybold.com.

Use the KCA Compliance Department's Issue Reporting Form (provided upon request) and return the completed form to KCA at: privacyissues@kelsey-seybold.com.

Corrective Action Plans

Your organization must notify the KCA Compliance department immediately if non-compliance is identified related to functions and services provided to KCA. Your organization may be required to conduct a root cause analysis and implement a Corrective Action Plan (CAP). The CAP must, at a minimum, contain the following elements:

1. Date issue identified
2. Root cause
3. Duration of the issue
4. How it was identified
5. Summary of issue – impacted members, providers
6. Corrective action

KCA expects FDRs to take timely action on all issues of non-compliance and FWA. This includes timely implementation of disciplinary actions, when applicable to prevent a recurrence of non-compliance.



V. Routine Monitoring and Auditing

KCA monitors and audits all First-Tier Entities. This promotes compliant administration of its contracts with CMS and ensures compliance with applicable laws and regulations. FDRs must cooperate and participate in any monitoring and auditing activities. KCA monitoring and auditing are reported on the annual Compliance Program Effectiveness audit, as well as any CMS Program Audits.

First-Tier Entities are also responsible for monitoring and auditing functions provided to KCA. If a First-Tier Entity contracts with other individuals or entities to provide administrative, health care, and/or prescription drug benefit services to fulfill its obligations with KCA, the First-Tier Entity must

monitor and audit the downstream entity to ensure it performs such functions in accordance with all applicable laws and regulations and in accordance with the First-Tier Entity's contract with KCA. The First-Tier Entity must also ensure its contracts with downstream entities contain CMS-required provisions. First-Tier Entities are required to provide quarterly oversight and monitoring activities.

If FDR functions are not in compliance with applicable laws and regulations or do not meet the terms of its contract with KCA, KCA will require the FDR to develop and submit a CAP.

VI. Offshore Operations and CMS Reporting

All work performed by FDRs on behalf of KCA is usually performed in the United States and its territories. An FDR may request approval in advance from KCA to use employees and vendors outside the United States. This work is considered "offshoring," and the FDR must notify KCA's Compliance department prior to contracting with any offshore FDR related work that was delegate to KCA if it does or plans to directly contract with an entity that offshores. Please notify us at FDRCompliance@KelseyCareAdvantage.com.

If KCA approves the offshore proposal, KCA must report the offshore arrangement to CMS. FDRs must also sign an attestation annually as to how they will oversee the offshore functions.



VII. FDR Attestation Requirements

KCA further requires the following:

1. An annual attestation that all employees and vendors are being appropriately screened monthly against the exclusion and debarment lists, and, if applicable, their provider network has been screened against the OIG and GSA CMS Preclusion list.
2. An annual attestation that all employees (including temporary workers, volunteers, and vendors) agree to comply with your organization's Code or Standards of Conduct and policies and procedures within 90 days of initial hiring or contracting with KCA and annually thereafter or comply with KCA's Standards of Conduct and policies and procedures; conduct education and training to comply with all statutes, regulations, and CMS program-specific requirements and maintain these records of your employees, including temporary workers and volunteers for ten (10) years; screen your employees, including temporary workers, volunteers, vendors, consultants, and governing body members against the OIG List of Excluded Individuals and Entities (LEIE list) and the System for

Award Management (SAM) exclusion listing, formerly known as Excluded Parties Lists System, prior to hiring or contracting and monthly thereafter; monitor the compliance of the entities with which your organization contracts "downstream entities;" complete an offshore attestation and, if applicable, ensure their provider network has been screened against the CMS Preclusion List.

Your organization must have a system in place that receives, records, responds, and tracks compliance questions, concerns, and potential fraud, waste, and abuse and that emphasizes a policy of non-retaliation and non-intimidation for good faith reporting of allegations of non-compliance and potential fraud, waste, and abuse within your organization, and you must take steps to ensure that such a policy is well-publicized throughout your facilities (See: 42 C.F.R. §§ 422.503(b)(4)(vi) and 423.504(b)(4)(vi)).

An authorized representative from the FDR must attest to its compliance with these requirements. An authorized representative may include the Compliance Officer, Chief Executive Officer, Chief Operations Officer, Chief Financial Officer, or an individual of similar title and authority.

VIII. What if an FDR Fails to Comply?

If an FDR fails to meet any of these Compliance Program requirements, this puts KCA at risk for non-compliance with CMS or there could be potential harm to members, which could result in:

1. Development of a Corrective Action Plan
2. Additional monitoring or auditing
3. Monetary penalties
4. Possible contract termination

KCA's response to issues of non-compliance will depend on the circumstances and severity of the compliance issue. If an FDR, KCA, federal, or state agency identifies areas of non-compliance by an FDR, the FDR must take prompt action to correct the issue and prevent a recurrence.

IX. Questions or Comments

If you have any questions regarding this guide or the CMS Compliance Program requirements, please contact us at FDRCompliance@KelseyCareAdvantage.com or you can contact our Compliance Department at the contact info below:

Compliance Department

ComplianceList@kelsey-seybold.com
[713-442-9502](tel:713-442-9502)

Attention: Compliance Department
11511 Shadow Creek Parkway
Pearland, Texas 77584.

Website: [Medicare Compliance | KelseyCare Advantage](#)

*<https://health.usnews.com/medicare>. This information is not a complete description of benefits. Call for more information: prospective members, call 713-442-5646 (TTY: 711), October 1 – March 31, 8 a.m. - 8 p.m. CT, seven days a week; or April 1 – September 30, 8 a.m. - 8 p.m. CT, Monday through Friday. Medicare beneficiaries may also enroll in KelseyCare Advantage online at KelseyCareAdvantage.com/Enroll or through the CMS Medicare Online Enrollment Center located at medicare.gov. Limitations, copayments, and restrictions may apply. Benefits, premiums, and/or copayments/coinsurance may change on January 1 of each year. The formulary, pharmacy network, and/or provider network may change at any time. You will receive notice when necessary. All benefits are not available on all plans. Every year, Medicare evaluates plans based on a 5-Star rating system. Out-of-network/non-contracted providers are under no obligation to treat KelseyCare Advantage members, except in emergency situations. Please call our customer service number or see your Evidence of Coverage for more information, including the cost-sharing that applies to out-of-network services. KelseyCare Advantage, a product of KS Plan Administrators, LLC, is an HMO and POS Medicare Advantage plan with a Medicare contract. Enrollment in KelseyCare Advantage depends on contract renewal. © 2023 KelseyCare Advantage. All rights reserved. H0332_FDR1594V2_M

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