



Alignment Health Plan®



FDR COMPLIANCE PROGRAM GUIDE

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ALIGNMENT HEALTH PLAN'S **FDR OVERSIGHT COMPLIANCE PROGRAM GUIDE**

We are pleased to collaborate with you as a valued First Tier, Downstream or Related Entity (FDR) and vendor. At Alignment Health Plan (Alignment), we recognize that our success in serving our members depends on the strength of our partnerships with trusted organizations like yours.

This guide was developed to help you understand your compliance responsibilities as an FDR and vendor and to support your adherence to regulatory requirements and our shared commitment to excellence. Together, we can ensure that our members receive high-quality services in a manner that is compliant, ethical and consistent with Centers for Medicare & Medicaid Services (CMS) expectations.

Thank you for your ongoing collaboration and dedication to supporting our mission of delivering exceptional care and service. We look forward to collaborating with you to maintain a strong and effective compliance culture.

INTRODUCTION

CMS, along with other federal and state regulators, require all that Medicare Advantage Organizations (MAOs) — including Alignment and its subsidiaries — effectively communicate and oversee specific compliance and fraud, waste and abuse (FWA) requirements with their FDRs.

Although Alignment delegates certain administrative and/or health care service functions to its FDRs, it retains ultimate responsibility for fulfilling its contractual obligations with CMS and for ensuring compliance with all Medicare program requirements. This includes confirming that FDRs comply with all applicable federal and state laws, regulations and CMS guidance related to their delegated responsibilities.

This FDR Compliance Program Guide (Guide) outlines the key compliance program elements, monitoring expectations and documentation standards required of all FDRs and vendors that perform delegated services on behalf of Alignment. It is your reference point for understanding how to meet these obligations and remaining in good standing as a trusted partner in the Medicare Advantage program.

COMPLIANCE PROGRAM REQUIREMENTS

To maintain an effective compliance program as described in the CMS guidance below, Alignment is required to adopt and implement an effective compliance program:

- Title 42 of the Code of Federal Regulations (“CFR”), Parts 422 and 423, sub-regulatory guidance published in both Pub. 100-18 and in Pub. 100-16, 42 C.F.R. §§422.503(b)(4)(vi) and 423.504(b)(4)(vi)
- Medicare Managed Care Manual, Chapter 21 Compliance Program Guidelines
- Prescription Drug Benefit, Chapter 9 Compliance Program Guidelines

WHAT IS AN FDR?

While Alignment contracts with FDRs to provide administrative and health care services for our members, Alignment is accountable for complying with the State and Federal laws and regulations and fulfilling the terms and conditions of our contract with CMS. This includes ensuring our FDRs are following the necessary requirements to fulfill the obligations of administrative and health care services to Alignment.

WHAT ADMINISTRATIVE AND HEALTH CARE SERVICE FUNCTIONS DO FDRS PROVIDE?

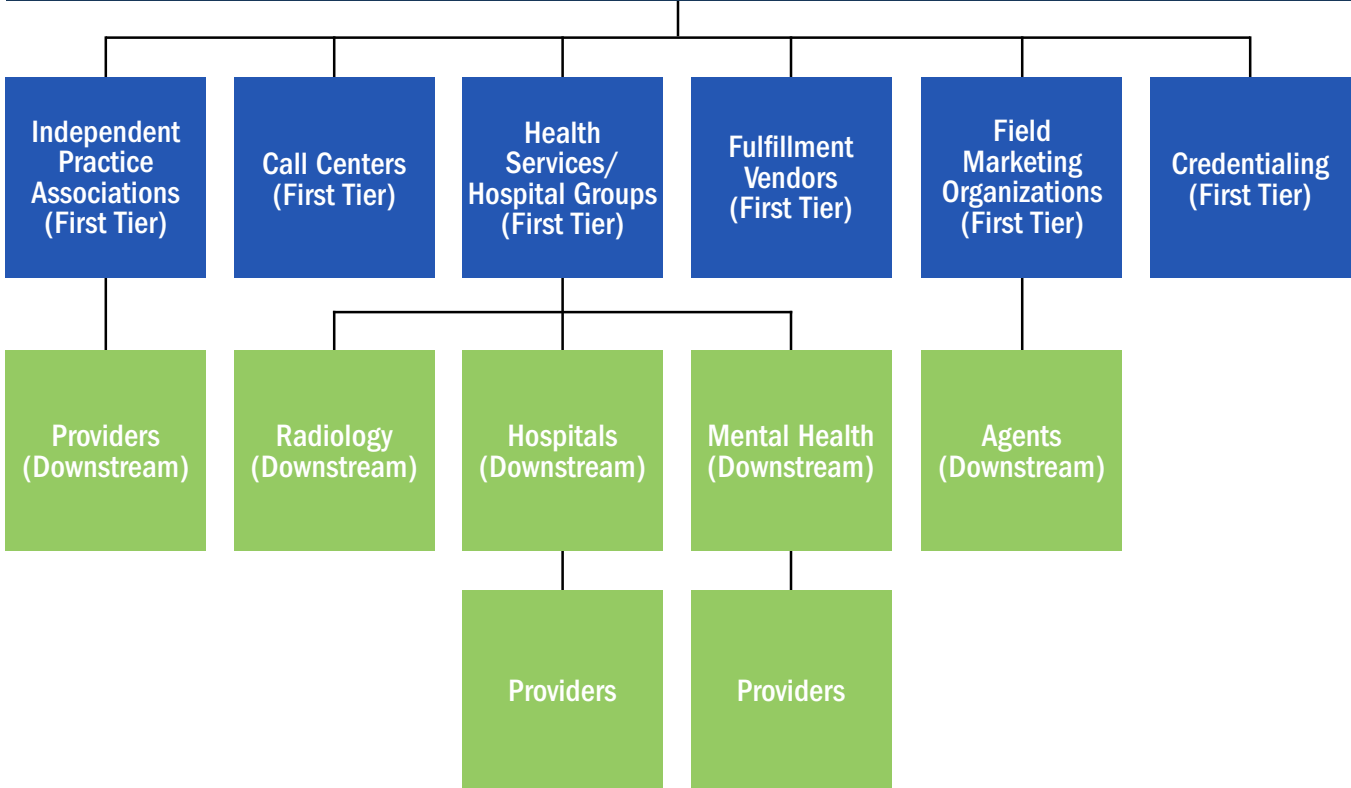
Medicare program requirements apply to FDRs to whom Alignment has delegated administrative or health care service functions related to Medicare Part C and D contracts.

Below is an example of functions FDRs performed on behalf of Alignment:

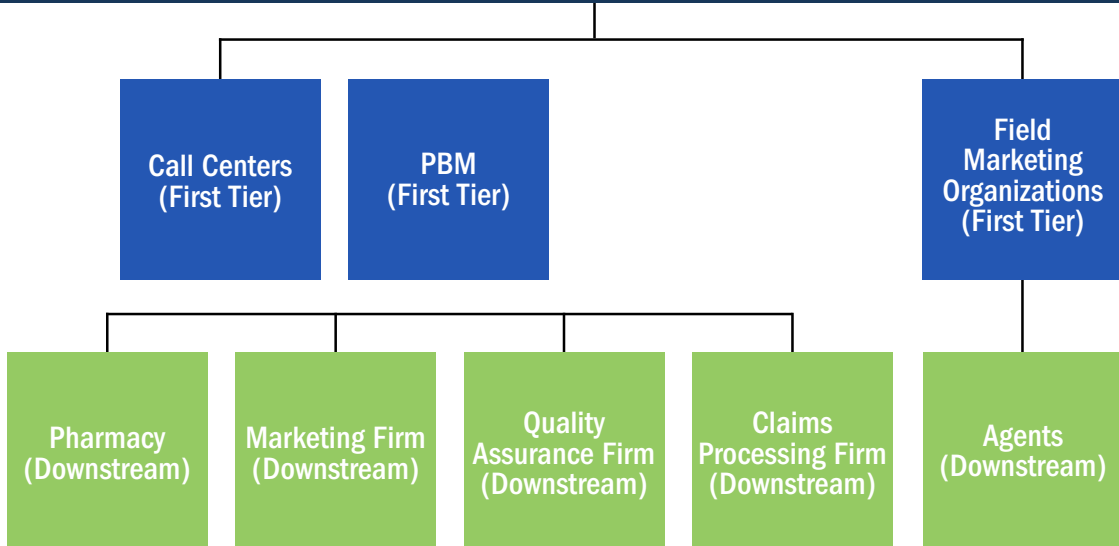
- Sales and marketing
- Utilization management
- Quality improvement
- Applications processing
- Enrollment, disenrollment, membership functions
- Claims administration, processing and coverage adjudication
- Appeals and grievances
- Licensing and credentialing
- Pharmacy benefit management
- Hotline operations
- Customer service (e.g., telehealth, tele-medicine, call center, etc.)
- Bid preparation
- Outbound enrollment verification
- Provider network management
- Processing of pharmacy claims at the 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

The following images display examples of the relationships between Alignment, your organization and any downstream entity (or subcontractor) you may use to provide the administrative and health care services:

CMS CONTRACTOR (PART C PLAN SPONSOR)



CMS CONTRACTOR (PART D PLAN SPONSOR)



ELEMENTS OF AN EFFECTIVE COMPLIANCE PROGRAM

Your organization and your downstream entities (including offshore) must comply with CMS' Compliance Program requirements. There are seven elements to ensure your compliance program meets CMS standards.

- Element 1: Written Policies, Procedures and Standards of Conduct
- Element 2: Compliance Officer, Compliance Committee and High-Level Oversight
- 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, Auditing and Identification of Compliance Risks
- Element 7: Procedures and System for Prompt Response to Compliance Issues

ELEMENT 1: WRITTEN POLICIES, PROCEDURES AND STANDARDS OF CONDUCT

FDRs must provide written policies and procedures and Standards of Conduct to all employees and contractors providing administrative and/or health care services on behalf of Alignment within 90 days of hire and/or contracting, annually thereafter or when updated. FDRs must also ensure downstream entities distribute policies and Standards of Conduct that support Alignment to their employees. FDRs can distribute their own or provide [Alignment's Code of Conduct](#).

Policies and procedures and Standards of Conduct should include, but are not limited to, the following information:

1. FDR's commitment to comply with all applicable federal and state standards.
2. Expectations of its employees to comply with policies and Standards of Conduct.
3. FDR's implementation of compliance program operations.
4. Guidance for employees and downstream entities to report suspected and detected compliance issues.
5. Details on how employees should communicate compliance issues to designated compliance personnel.
6. Description of how suspected, detected or reported compliance issues are investigated, tracked and resolved.
7. Non-intimidation and non-retaliation protections for employees who make good faith reports of non-compliance activity to designated compliance personnel.

FDRs may determine the most effective method to distribute or make available their compliance policies and Standards of Conduct; however, you must maintain documentation that demonstrates this information was appropriately distributed to all applicable employees for contract period and through 10 years after the final date of contract or the final date of completion of an audit — whichever is later.

ELEMENT 2: COMPLIANCE OFFICER, COMPLIANCE COMMITTEE AND HIGH-LEVEL OVERSIGHT

FDRs must designate a compliance officer or equivalent to oversee their organization's compliance program. This individual is responsible for managing compliance-related activities including responding to compliance concerns, addressing FWA and monitoring the implementation and resolution of corrective actions.

ELEMENT 3: EFFECTIVE TRAINING AND EDUCATION

Beginning Calendar Year 2019, CMS no longer requires their General Compliance and FWA training to be completed by FDRs. However, compliance training is still required of Health Plans. Therefore, Alignment is still obligated under our contract to CMS to conduct routine monitoring, auditing and oversight of FDRs. This includes requiring FDRs we are contracted with to complete General Compliance and FWA training within 90 days of hire and annually thereafter. We have provided links to our compliance training presentations below.

Note: FDRs that have met FWA certification requirements through Medicare program enrollment or CMS-approved accreditation are considered deemed to have met the FWA training and education requirement.

To ensure compliance:

- FDRs must complete an annual FDR Compliance Attestation confirming that the required training has been administered and completed.
- During routine audit, FDRs will be asked to provide a copy of the training presentation and evidence of training completion, which may include, but are not limited to:
 - Certificates of completion
 - Training transcripts
 - Attestations
 - Sign-in sheets or attendance logs

FDRs must retain training documentation for 10 years and provide records upon request during monitoring or audit activities.

1. General Compliance Training

FDRs must have general compliance policies and training in place to demonstrate how all employees, subcontractors and related entities receive CMS approved training within 90 days of hiring and annually thereafter.

Alignment Training Resource: [Alignment Health General Compliance Training](#)

2. FWA Training

FDRs must have FWA policies and training in place to demonstrate how all employees, subcontractors and related entities receive CMS approved training within 90 days of hiring and annually thereafter.

Alignment Training Resource: [Alignment Health FWA Training](#)

3. HIPAA Training

FDRs must have HIPAA Privacy and Security policies and training in place to demonstrate how all employees, subcontractors and related entities receive CMS approved training within 90 days of hiring and annually thereafter.

Training Resource: [U.S. Department of Health and Human Services Training Materials](#)

Alignment Training Resource: [Alignment Health HIPAA Privacy Training](#)

ELEMENT 4: EFFECTIVE LINES OF COMMUNICATION

FDRs must establish and maintain effective lines of communication between their organization, employees and downstream entities.

These communication channels must:

- Be accessible to all personnel, including temporary workers and contractors.
- Allow for the reporting of compliance concerns, including FWA.
- Support anonymous and confidential good faith reporting without fear of retaliation.

FDRs should clearly communicate reporting options and ensure that employees are aware of how to access them. At minimum, FDRs must share the name, office location and contact information of their designated compliance officer or leader as part of this effort.

ELEMENT 5: WELL-PUBLICIZED DISCIPLINARY STANDARDS

FDRs must implement and maintain well-publicized disciplinary standards through policies and procedures that promote good faith participation in the compliance program by all affected individuals, including employees, contractors and downstream entities.

These standards must include policies that:

- Clearly articulate expectations for identifying and reporting compliance issues.
- Support the timely resolution of reported issues.
- Identify and address non-compliance or unethical behavior.
- Ensure timely, consistent and effective enforcement of disciplinary actions when violations are identified.
- Include a non-retaliation policy that protects individuals who report concerns in good faith.

FDRs should use multiple methods to communicate these standards throughout the organization.

Examples of publication methods include:

- Posting on the FDR's intranet site.
- Presentations during staff meetings or team huddles.
- Internal newsletters or bulletins.
- Inclusion in general compliance training sessions.
- Communications with downstream and related entities.
- Posters or signage displayed in workspaces and break areas.

Enforcement of Disciplinary Standards

FDRs must be able to demonstrate that disciplinary standards are enforced in a timely, consistent and effective manner. Documentation of disciplinary actions must be retained for 10 years and made available upon request.

In addition, any instances of non-compliance or suspected FWA must be reported to Alignment immediately. Prompt reporting ensures appropriate investigation, mitigation and corrective action.

ELEMENT 6: EFFECTIVE SYSTEMS FOR ROUTINE MONITORING AND IDENTIFICATION OF COMPLIANCE RISKS

Because Alignment is ultimately responsible for fulfilling the terms and conditions of its contract with CMS, any functions delegated to an FDR must be subject to ongoing monitoring and auditing. This oversight ensures that all delegated activities are performed in accordance with applicable laws, regulations and Alignment's contractual obligations.

Routine Monitoring and Auditing

FDRs must conduct monitoring and auditing activities to evaluate and confirm compliance with Medicare regulations, sub-regulatory guidance, applicable laws and the terms of Alignment's contractual agreement. These activities are essential to detect and prevent Medicare program non-compliance and potential FWA.

Monitoring refers to ongoing reviews performed as part of routine operations to verify continued compliance and to ensure that any identified issues are appropriately addressed through effective corrective actions.

Auditing is a formal, periodic review that assesses compliance with established standards including internal policies and procedures, CMS regulations and applicable laws.

FDRs are also responsible for conducting oversight of any downstream and offshore entities they engage. This includes monitoring and auditing these entities to ensure they also meet Medicare compliance program requirements and contractual obligations.

FDRs must document and retain evidence of all monitoring and auditing activities, including those involving downstream and offshore entities, and provide supporting records upon request. These records must be maintained for 10 years.

OIG/GSA Exclusion Screening

Federal law prohibits payments to any individual or entity that has been debarred, excluded or otherwise ineligible from participation in federal health care programs, including Medicare. To ensure compliance, FDRs are required to perform exclusion screenings using the following databases:

- U.S. Department of Health & Human Services Office of Inspector General (OIG) – List of Excluded Individuals and Entities (LEIE): <https://exclusions.oig.hhs.gov/>.
- U.S. General Services Administration (GSA) – System for Award Management (SAM): <https://www.sam.gov/SAM>.

FDRs must:

- Conduct exclusion screenings prior to the hire or contracting of any new employee, temporary worker, volunteer, consultant, governing body member, vendor or downstream entity.
- Screen all individuals and entities monthly thereafter to ensure none have been added to exclusion lists.
- Maintain documentation that validates exclusion screenings were completed as required. Records must be retained for the duration of the contract period plus 10 years.

FDRs are also required to attest that exclusion screenings are being conducted appropriately during the annual FDR Compliance Attestation process and provide evidence during a routine audit.

If an individual or entity performing work on behalf of Alignment appears on the OIG LEIE or SAM exclusion list:

- Your organization must confirm the match is valid (e.g., name, date of birth, SSN or TIN).
- If confirmed, the individual or entity must be immediately removed from any Alignment-related work and Alignment must be notified immediately.

Preclusion List Screening

The CMS Preclusion List includes providers and prescribers who are excluded from receiving payment for Medicare Advantage (MA) items and services or Part D drugs that are furnished or prescribed to Medicare beneficiaries. For more information regarding preclusions, refer to the [Provider Operations Manual](#).

CMS established this list to:

- Replace previous MA and Part D prescriber enrollment requirements.
- Protect beneficiaries and the Medicare Trust Funds from providers and prescribers who have been identified as presenting a risk due to integrity or compliance concerns.

FDRs are responsible for ensuring that no precluded providers or prescribers are involved in the delivery of services or prescriptions billed to Medicare on behalf of Alignment. CMS updates the Preclusion List regularly and provides access through secure systems.

FDRs should establish internal processes to:

- Screen against the Preclusion List on a routine basis.
- Confirm provider and prescriber eligibility before services are rendered or prescriptions are filled.
- Immediately report any potential match to Alignment for verification and guidance.

ELEMENT 7: PROCEDURES AND SYSTEM FOR PROMPT RESPONSE TO COMPLIANCE ISSUES

FDRs must provide confidential channels for reporting suspected or detected non-compliance or potential FWA. Reports may also be submitted anonymously if desired, ensuring protection for individuals who report in good faith.

Alignment provides the following secure and confidential reporting methods:

- Submit a report via the Ethics and Compliance Hotline Weblink (available 24/7/365): <http://www.lighthouse-services.com/ahcusa>
- Ethics and Compliance Hotline
 - **English:** 877-222-1541
 - **Spanish:** 800-216-1288

These channels are available to report compliance concerns confidentially or anonymously, ensuring that individuals can report any issues without fear of retaliation.

HIPAA Privacy and Security Compliance Concerns

FDRs are required to protect Alignment’s member information, including protected health information (PHI) and personally identifiable information (PII), in accordance with all applicable privacy and security regulations.

If an FDR detects, suspects or becomes aware of any non-permitted disclosure of member information, the FDR must immediately report the incident to Alignment’s Privacy or Security teams for investigation and corrective action. Prompt reporting helps mitigate risks and ensures compliance with HIPAA and other privacy regulations.

	Privacy	Security
What are privacy and security incidents?	Privacy incidents involve the unauthorized use or disclosure of any form of PHI (electronic, paper or verbal).	Security incidents involve the confidentiality, integrity or availability of electronic Protected Health Information (ePHI).
What are examples of these incidents?	<ul style="list-style-type: none"> • Sending PHI to the wrong patient, provider or email address • Verbal disclosures of PHI to unauthorized individuals • Accessing patient information without a business need (snooping) • Discarding paper records containing PHI in an unsecured manner • Faxing PHI to the wrong recipient • Sharing PHI on unauthorized platforms (e.g., texting PHI via personal phones) 	<ul style="list-style-type: none"> • Malware or ransomware attacks involving systems that store or transmit ePHI • Phishing emails that result in unauthorized access to ePHI • Unauthorized access to systems or applications containing ePHI • Loss or theft of devices (laptops, mobile phones, USB drives) containing ePHI • Improper access by workforce members to electronic records
How do I report?	hipaaprivacy@ahcusa.com	Contact your Alignment Business Owner and send notice to hipaaprivacy@ahcusa.com
When should I report?	Immediately	Immediately

When reporting incidents, provide the following details:

1. Date of disclosure
2. Date of discovery
3. Date your compliance or privacy team made aware of the incident
4. Summary of the incident
5. Root cause of the error
6. How was the incident discovered?
7. Type of PHI disclosed
8. Impacted member information (including the number of members impacted)
9. Intendent recipient
10. Who the PHI was disclosed to
11. Mitigation
12. Corrective actions
13. Proposed risk analysis

As specified in the Business Associate Agreement, Alignment shall make the ultimate determination, in its sole discretion, whether there is a breach and if so, whether the required notifications will be provided by Alignment or the FDR. Alignment's approval shall also be required for the manner of delivering notice of the breach.

If an FDR is responsible for a HIPAA breach involving Alignment member information, it is the FDR's responsibility to comply with applicable breach notification requirements. FDRs must report the breach to both the impacted member(s) and the [U.S. Department of Health & Human Services Office for Civil Rights \(OCR\)](#) within specified timeframes.

Required Reporting Timeframes for FDRs:

- To Affected Member(s):
 - Without unreasonable delay, and no later than 60 calendar days from the discovery of the breach.
- To the OCR:
 - If the breach affects 500 or more individuals:
 - Report to the OCR at the same time as the member notification, but no later than 60 calendar days from discovery.
 - If the breach affects fewer than 500 individuals:
 - Report to the OCR no later than 60 days after the end of the calendar year in which the breach was discovered.

Alignment will request confirmation notifications were sent to the impacted member(s) and a copy of the OCR report.

FDR COMPLIANCE'S MONITORING AND AUDITING

As part of an effective compliance program, CMS and other federal and state regulators require Alignment to monitor and audit FDRs to ensure compliance with all applicable laws and regulations and to ensure you are monitoring the compliance of downstream entities you contract with. Compliance will notify FDRs of compliance activities 30 days prior to the activity start date. FDRs will have 30 days to submit their annual attestation and initial audit responses.

ANNUAL FDR COMPLIANCE ATTESTATION

Alignment is required to monitor its FDRs to ensure compliance with Medicare program requirements. As part of this oversight, the Compliance Department distributes an annual FDR Compliance Attestation. This attestation confirms that FDRs acknowledge and attest to adhering to the core elements of CMS's compliance program requirements, including, but not limited to:

- Written policies and Standards of Conduct.
- Effective compliance training and education.
- OIG and GSA exclusion screenings.
- Reporting mechanisms and non-retaliation policies.
- HIPAA Privacy.
- Records management.
- Internal monitoring and auditing activities.
- Subcontracting oversight (downstream and offshore entities).
- Prompt response and corrective action for detected issues.

ANNUAL TPMO COMPLIANCE ATTESTATIONS FOR SALES AGENCIES

As part of Alignment's Third-Party Management Program Oversight (TPMO), sales agencies are required to complete the annual Compliance Attestation to confirm adherence to applicable compliance requirements and delegated responsibilities.

These TPMO attestations serve to:

- Verify that your sales organization is fulfilling its obligations under the terms of its agreement with Alignment.
- Sales agencies must submit these attestations accurately and in a timely manner. Failure to comply with attestation requirements may result in additional oversight actions, including corrective action plans or changes to contract status.
- An authorized representative of the organization must complete compliance attestation. Failure to complete the attestation may result in additional oversight actions or impact the status of the FDR's delegation.
- Sales agents are considered FDRs and are required to complete the standard annual Compliance Attestation.

ROUTINE AUDITS

Compliance conducts routine audits to validate the FDRs compliance program effectiveness. During these audits, Alignment requests documentation to verify compliance elements, which may include but are not limited to:

- Distribution of compliance policies and Standards of Conduct.
- General compliance, fraud, waste and abuse training completion and policies.
- Screening against the OIG and GSA exclusion lists.
- Internal monitoring and auditing policy.
- Methods to report non-compliance or FWA, including non-retaliation policies.
- HIPAA training completion, policies and procedures and incident reporting.
- Records Management policies and procedures.
- Subcontracting oversight (downstream and offshore entities).
- Implementation of timely corrective actions when issues are identified.

FDRs are expected to cooperate fully with audit requests and provide documentation by the specified deadlines. All documentation should be accurate, complete and retained in accordance with applicable recordkeeping requirements.

Routine audits are a critical part of ensuring program integrity and Alignment's continued compliance with CMS regulations. Failure to comply with audit requests or demonstrate adherence to program requirements may result in corrective action or escalation to compliance and operational leadership.

DOWNSTREAM ENTITIES

If an FDR subcontracts to downstream entities to perform delegated administrative or health care services on behalf of Alignment, the FDR is responsible for ensuring those downstream entities comply with all applicable Medicare compliance program requirements. The FDR is required to obtain Alignment's prior written approval before sub-delegating services that Alignment has delegated the FDR to perform. The Compliance & Regulatory Affairs Department will request a Downstream Entity Attestation.

If an FDR discloses that it contracts with downstream entities during the annual FDR Compliance Attestation or routine audit, the Compliance & Regulatory Affairs Department will request a Downstream Entity Attestation. This attestation confirms that the downstream entity has an effective compliance program.

The FDR must maintain documentation to support compliance of all downstream relationships and provide it upon request during audits or reviews.

OFFSHORE OPERATIONS AND CMS REPORTING

FDRs must submit an Offshore Subcontractor Attestation to Alignment's Compliance & Regulatory Affairs Department to obtain approval before entering or amending any agreement with an offshore subcontractor or employing workers who are located offshore. This includes new offshore subcontractor relationships or if indicated in the annual Compliance Attestation or routine audit. Alignment's Offshore Subcontractor Information and Attestation Form is accessible to FDRs on the [Alignment website](#).

This attestation confirms that:

- Appropriate safeguards are in place to protect beneficiary PHI.
- Contractual terms address CMS and HIPAA privacy and security standards.
- Offshore activities are limited to those permitted under CMS guidelines.

Failure to disclose offshore subcontracting or to complete the required attestation will result in escalation to executive leadership for corrective action.

CMS requires that Alignment and our FDRs take precautions when contracting with offshore subcontractors — that is, entities located outside the United States or its territories — due to heightened risks around data privacy, security and regulatory enforcement. Prior written consent of the Health Plan is required before an FDR may employ or contract with a person or entity to which Medicare beneficiary PHI will be sent or accessed offshore.

“Offshore” refers to countries outside the 50 United States and its territories (American Samoa, Guam, Northern Marianas, Puerto Rico and the U.S. Virgin Islands). Examples of countries that meet the definition of “offshore” include, but are not limited to, Mexico, Canada, India, Germany and Japan.

Subcontractors that are considered offshore can either be American-owned companies with certain portions of their operations performed outside of the United States or foreign-owned companies with operations performed outside of the United States.

Offshore subcontractors include any entity providing administrative or health benefit services performed by employees or contractors located in offshore countries, whether employed or contracted by American or foreign companies.

CMS must be informed if the offshore employee or subcontractor is receiving, processing, transferring, handling, storing or accessing beneficiary PHI in oral, written or electronic form. Examples of PHI include name, birth date, address, Social Security number, Medicare identifier, health insurance claim number, patient identifiers, treatment records, payment information or any information that could reasonably lead to the identification of a beneficiary.

CORRECTIVE ACTION PLANS

FDRs must notify Alignment's Compliance department immediately if non-compliance relating to functions and services provided on Alignment's behalf is identified.

When deficiencies are identified during monitoring and routine audits, Alignment will issue a corrective action request. Your organization will be required to conduct a root cause analysis and provide a corrective action plan (CAP) 30 days after receiving the request. The CAP must at a minimum contain the following:

1. Date issue identified
2. Summary of the issue — impacted members and/or providers
3. Root cause analysis
4. Duration of the issue
5. How it was identified
6. Corrective action
7. Supporting documentation
8. Expected remediation dates

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

WHAT IF AN FDR FAILS TO COMPLY?

Failure to comply with CMS requirements and Alignment's contractual agreement may result in corrective actions, which may include:

- Corrective action plans to address and resolve compliance issues.
- Termination of contracts or agreements with Alignment.
- Financial penalties or reimbursement requests for non-compliant services or activities.
- Exclusion from participation in the Medicare Advantage program.

Alignment maintains the right to take appropriate action to ensure that all FDRs adhere to CMS regulations, federal and state laws and Alignment's contractual agreements. Non-compliance may also lead to increased monitoring or auditing to ensure that deficiencies are corrected and do not recur.

QUESTIONS OR COMMENTS

If you have any questions or comments regarding the FDR Compliance Guide or the compliance requirements outlined herein, please contact Alignment's Compliance & Regulatory Affairs Department. Our team is available to assist you and provide additional clarification as needed.

You can reach us through the following methods:

- Compliance Department Email: ahcfdrcompliance@ahcusa.com
- Mailing Address: Compliance & Regulatory Affairs Department
Alignment Health Plan
1100 W. Town & Country Rd., Suite 1600
Orange, CA 92868

FDR COMPLIANCE TEAM

CHRISTALYN BAKER
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cbaker@ahcusa.com

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COMPLIANCE OFFICER & PRIVACY OFFICER

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CMS DEFINITIONS

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

BUSINESS OWNER is Alignment’s internal employee responsible for the day-to-day business relationship with the FDR.

CORRECTIVE ACTION PLAN (CAP) is a step-by-step plan of action that the FDR develops to correct deficiencies when a compliance standard is not met.

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 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. (See 42 C.F.R. §, 423.501).

EXTERNAL AUDIT means an audit of the sponsor — or its FDRs conducted by outside auditors — not employed by or affiliated with, and independent of, the sponsor.

FDR means First Tier, Downstream or Related Entity.

FIRST TIER ENTITY is any party that enters into 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. (See 42 C.F.R. § 423.501).

FRAUD is 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. 18 U.S.C. § 1347.

FWA means fraud, waste and abuse.

GSA is the General Services Administration.

HIPAA is the Health Insurance Portability and Accountability Act.

MONITORING ACTIVITIES are regular reviews performed as part of normal operations to confirm ongoing compliance and to ensure that corrective actions are undertaken and effective.

OFFSHORE ENTITY is any company providing services that are performed by staff located in countries outside of the United States and its territories.

OIG is the Office of the Inspector General within DHHS. The Inspector General is responsible for audits, evaluations, investigations and law enforcement efforts relating to DHHS programs and operations, including the Medicare program.

PERSONALLY IDENTIFIABLE INFORMATION (PII) is any information that can be used to distinguish or trace an individual's identity — either alone or when combined with other personal or identifying data. This may include, but is not limited to, name, address, phone number, email address, date of birth, Social Security number or financial account information. PII is not limited to health-related data and applies broadly across various sectors.

PROTECTED HEALTH INFORMATION (PHI) is individually identifiable health information that is created, received, maintained or transmitted by a covered entity or its business associate, in any form (electronic, paper or oral). PHI includes information related to an individual's past, present or future physical or mental health condition, the provision of health care to the individual or payment for health care and that identifies or could reasonably be used to identify the individual.

RELATED ENTITY means any entity that is related to an MAO or Part D sponsor by common ownership or control and (1) Performs some of the MAO or Part D plan sponsor's management functions under contract or delegation; (2) Furnishes services to Medicare enrollees under an oral or written agreement; or (3) Leases real property or sells materials to the MAO or Part D plan sponsor at a cost of more than \$2,500 during a contract period. (See, 42 C.F.R. §423.501).

THIRD-PARTY MARKETING ORGANIZATIONS (TPMOS) are sales agencies compensated to perform lead generation, marketing, sales and enrollment related functions on Alignment's behalf.

WASTE is 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.