



OPTIMIZE COMPLIANCE OVERSIGHT OF FIRST TIER, DOWNSTREAM, AND RELATED ENTITIES (FDRs) WITH BEST PRACTICES

January 2024

WHAT WE WILL LEARN TODAY



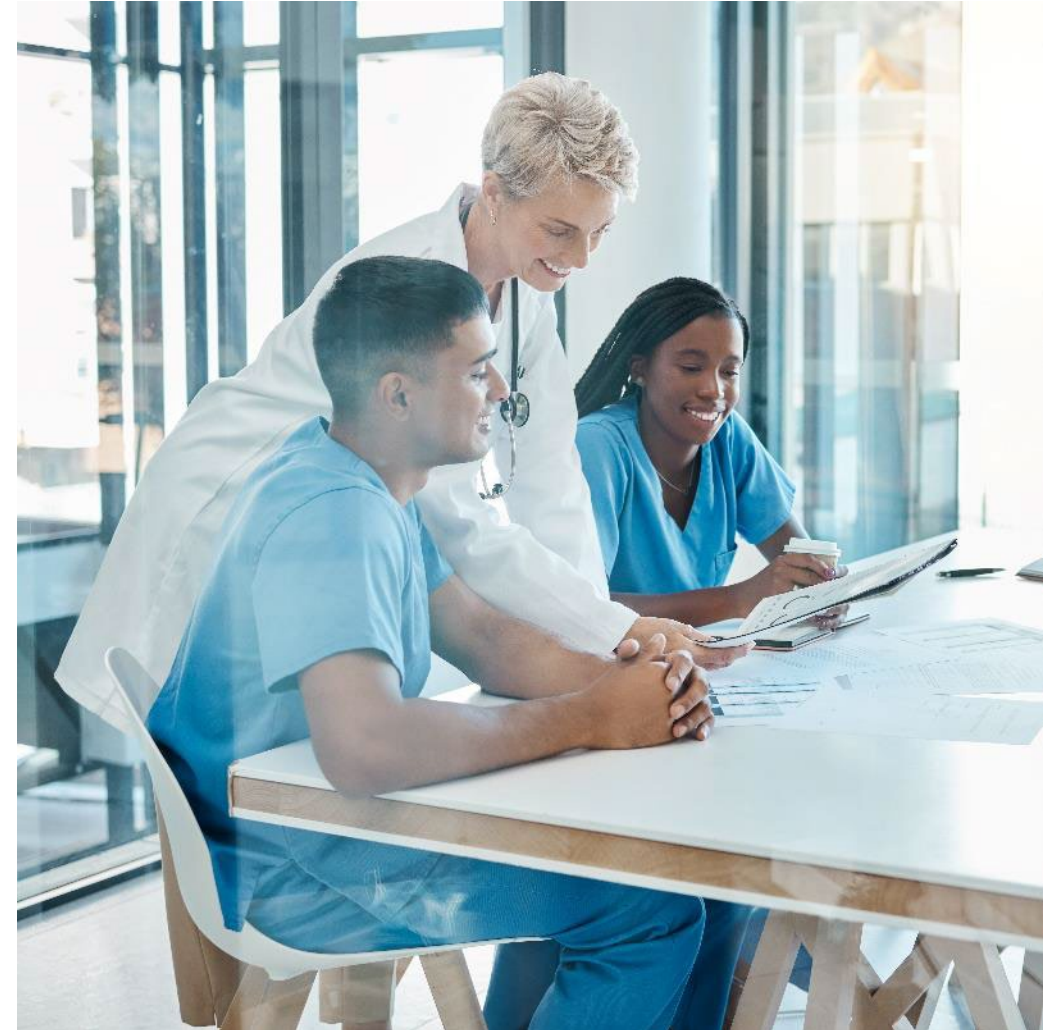
How to effectively apply the 7 elements of an effective compliance program to your FDRs



How to evaluate your FDRs for compliance risks



Best practices you can use to enhance the compliance of your FDRs



SPEAKERS



Megan Geltman

**Care N' Care Insurance
Company**



Megan Allison

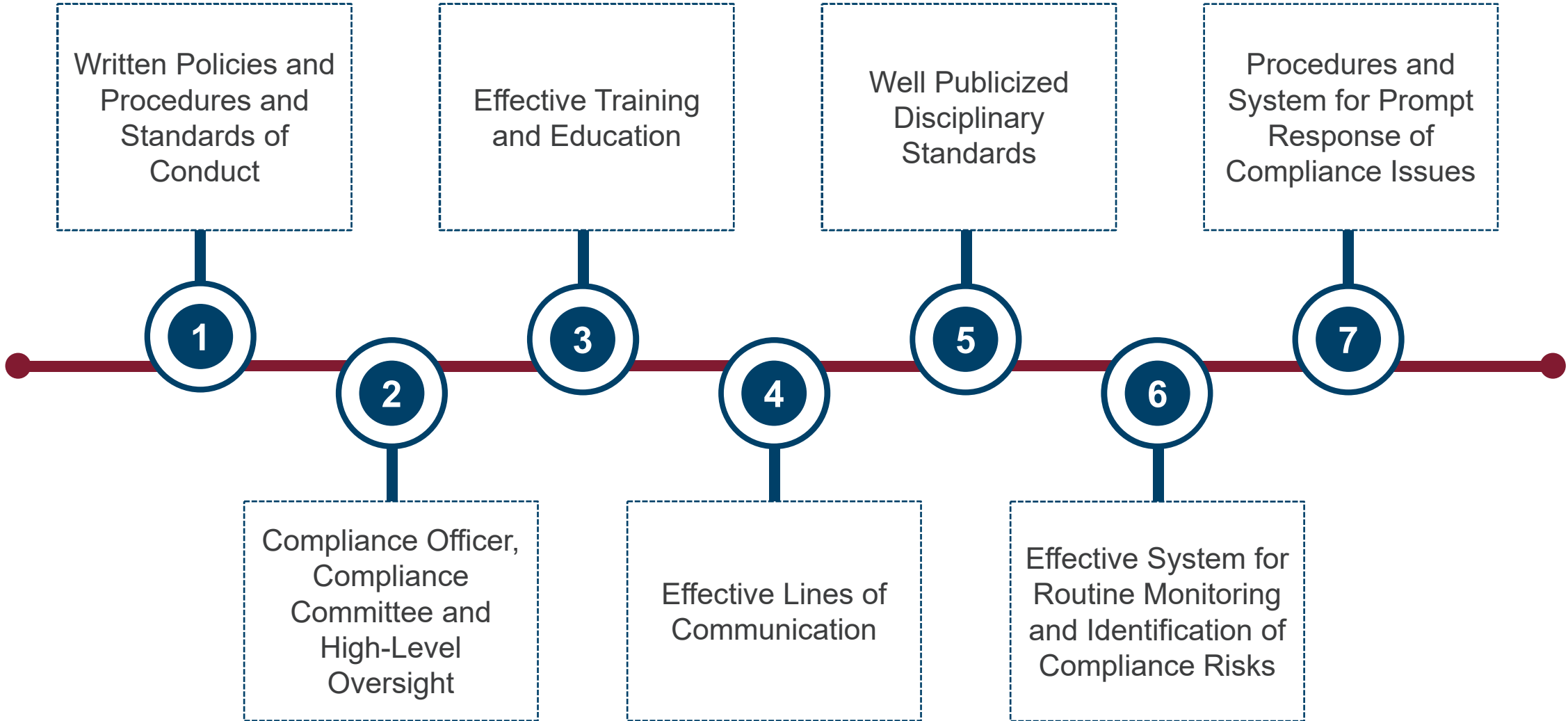
Protiviti



Courtney Allen

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7 ELEMENTS OVERVIEW



WRITTEN POLICIES, PROCEDURES AND STANDARDS OF CONDUCT

Commitment to comply with all applicable Federal and State standards



Standards of Conduct (Code of Conduct)

- Ethical behavior
- Reporting compliance concerns
- Disciplinary actions for noncompliance

- Record retention, compliance training, conflict of interest, nonretaliation, and others



Compliance Policies

- Alternatives for smaller entities



COMPLIANCE OFFICER, COMPLIANCE COMMITTEE AND HIGH-LEVEL OVERSIGHT



Compliance Officer

- FDRs can designate a compliance contact instead



Compliance Committee

- Some FDRs may have a Compliance Committee, others may not
- FDRs can utilize its internal leaders to perform these functions



High Level Oversight (Board of Directors/Senior Leadership)

- FDRs may just have the CEO who is ultimately responsible for Federal health care program compliance



EFFECTIVE TRAINING AND EDUCATION

General Compliance

- Overview of the compliance program, policies and the COC
- Review of reporting noncompliance and disciplinary actions
- HIPAA/PHI confidentiality

Fraud, Waste and Abuse (FWA)

- Laws and regulations related to FWA (False Claims Act, HIPAA, etc)
- Reporting mechanisms
- Protection for reporting

Other

- Job-specific training
- Training substitution



EFFECTIVE LINES OF COMMUNICATION



The ability to report noncompliance must be:

- Accessible to all
- Ensure confidentiality (whenever possible)
- Anonymous
- Available 24/7
- Ensure nonretaliation for good faith reporting



FDRs can use their own platform or train its employees on how to report through their MA plan



WELL PUBLICIZED DISCIPLINARY STANDARDS



Disciplinary standards must be:

- Well-publicized
- Enforced
- Fair and Equitable
- Match the degree of the violation
- Reviewed regularly (may be part of annual compliance training/COC)



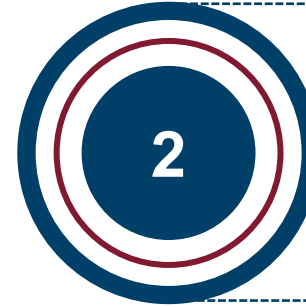
Disciplinary actions must be:

- Reported to the plan sponsor (as applicable)

EFFECTIVE SYSTEM FOR ROUTINE MONITORING AND IDENTIFICATION OF COMPLIANCE RISKS

A strategy must be developed to monitor, detect and mitigate risks for first-tier, downstream and related entities:

Performing risk assessments



Administering compliance attestations

- Auditing the attestation elements for compliance



Reviewing completed corrective action plans

- Performing validation reviews to ensure mitigation



FDRs must screen their employees, downstream, and related entities against the OIG/SAM exclusion lists

PROCEDURES AND SYSTEM FOR PROMPT RESPONSE TO COMPLIANCE ISSUES



Reports made of potential noncompliance must be logged and investigated for validity



Confirmation of noncompliance must follow disciplinary processes



FDRs must report noncompliance to any associated sponsor



Applicable corrective actions must be completed

EVALUATING COMPLIANCE RISKS



Understanding FDR communications for regulatory and compliance program requirements

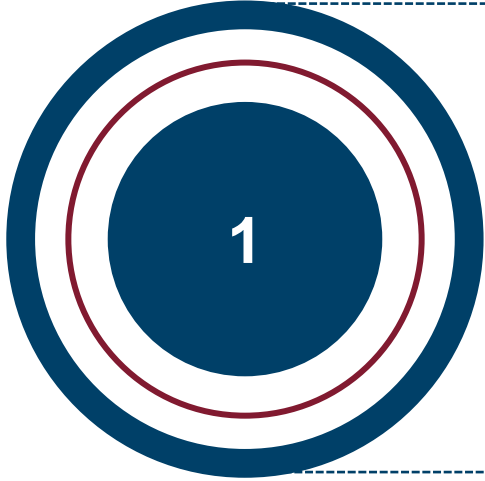
- Whose responsibility are they?
- FDR guides
- Attestations



What's in your FDR contracts?

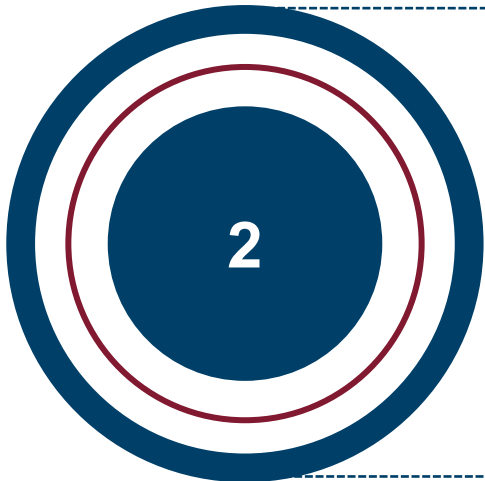
- Many considerations

DEVELOP YOUR RISK ASSESSMENT



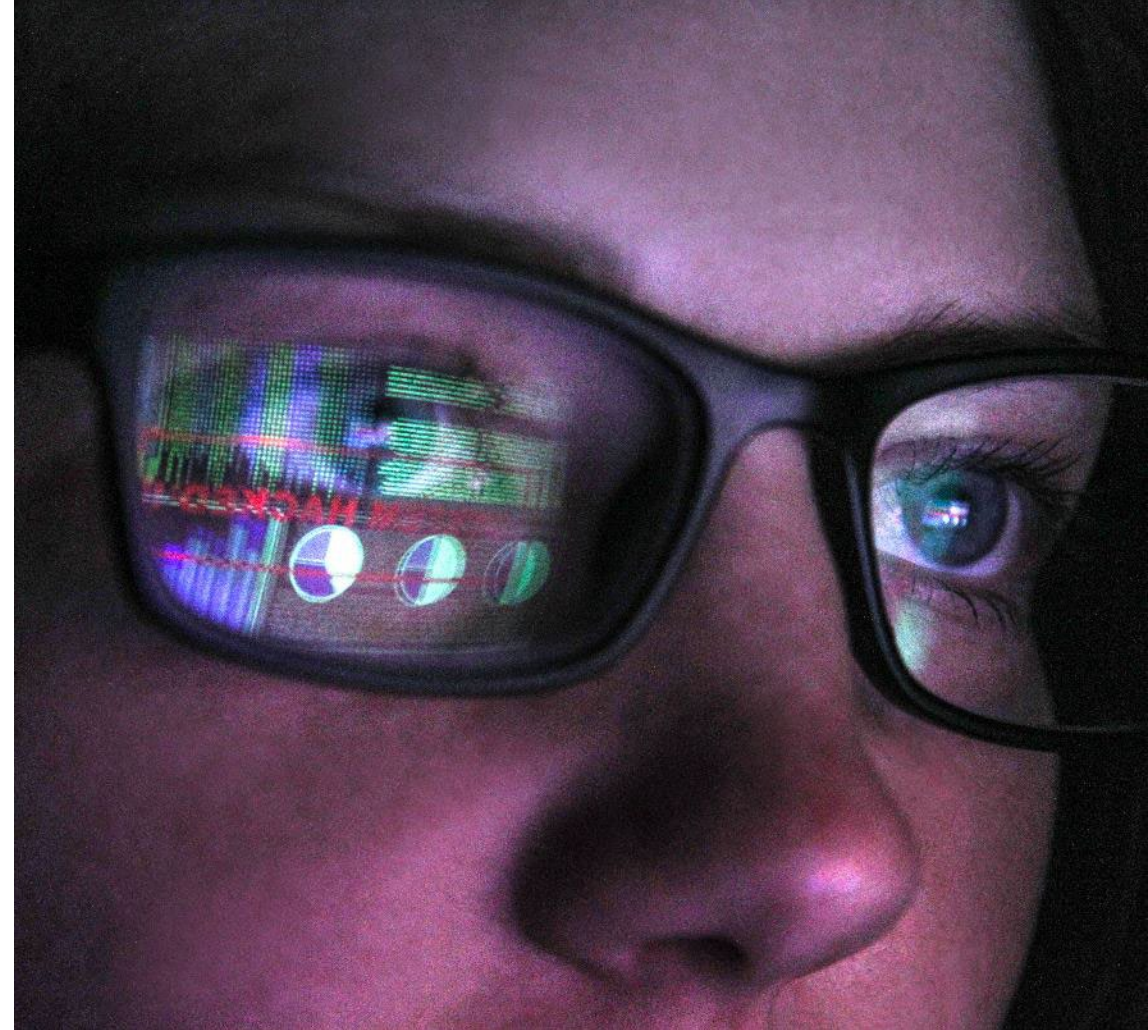
Who should be involved?

- Delegate relationship owners
- Executive leaders
- Mid-level managers
- IT and Privacy SMEs



Logistics

- Surveys
- Interviews



DEVELOP YOUR RISK ASSESSMENT



Factors to consider



Templates available as a starting point



Leverage peers and colleagues



RISK ASSESSMENT EXAMPLE

Delegate name	Function(s)	Delegation(s)	Business owner	What extent delegated function directly impacts enrollees		Does delegate have interaction with enrollees?	Does delegate have access to member info/PHI	Delegate have decision making authority?	Extent that delegate is in a position to commit FWA?		Extent that delegate could harm enrollees or violate Medicare program requirements?		Level of delegate's financial risk to the organization?	
				Severity of Impact	Probability	Yes or No	Yes or No	Yes or No	Severity of Impact	Probability	Severity of Impact	Probability	Severity of Impact	Probability
Sample 1	Sample A	Samples	Sample A Sample	High	High	Yes	Yes	Yes	High	High	High	Medium	High	High
Sample 2	Sample B	Samples	Sample A Sample	Medium	Low	No	Yes	No	Medium	Low	Low	Low	High	Low
Sample 3	Sample C	Samples	Sample A Sample	N/A	N/A	Yes	No	Yes	Low	Low	Low	High	Medium	Low

Delegate included in CMS Program Audit?	Delegate prepared for CMS Audit participation?	Delegated function included in OIG work plans as an area of focus?	Delegated function identified in previous program audits?	Delegation oversight audit performed last year?	Member complaints?		Is delegate meeting metrics/per forming as expected?	CAP issued in last year?	Risk score	Additional comments / considerations
					Complaints received	Probability				
Yes	No	Yes	Yes	Yes	Yes	Low	Yes	No	44	
Yes	Yes	No	No	Yes	Yes	Low	No	Yes	26	
No	N/A	Yes	Yes	No	No	Medium	Yes	Yes	22	

TYPICAL RISKS



BEST PRACTICES FOR FDR OVERSIGHT



Use of an FDR Guide

- Help delegate to understand requirements
- Define who is considered a delegate
- Provide guidance on how to comply with requirements



Toolbox

- Included in FDR guide
- Provides Plan's COC, compliance policies & plan, etc.

BEST PRACTICES FOR FDR OVERSIGHT

Pre-Delegation Oversight

- Ensure your future FDR is compliant prior to contracting
- Tailor the pre-delegation oversight to the FDR:
 - Attestation
 - Obtain supporting evidence
 - Verify with sample review
- Potential Outcomes:
 - Okay to proceed
 - Needs corrective action
 - Do not recommend contracting

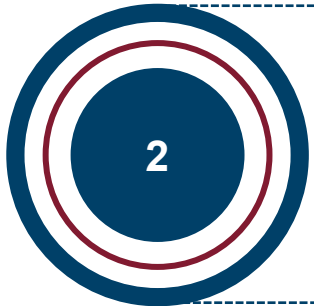


BEST PRACTICES FOR FDR OVERSIGHT



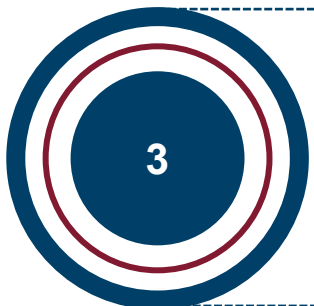
Attestations for Compliance

- Used annually for FDRs to confirm compliance with requirements
- Can be used as part of risk assessment



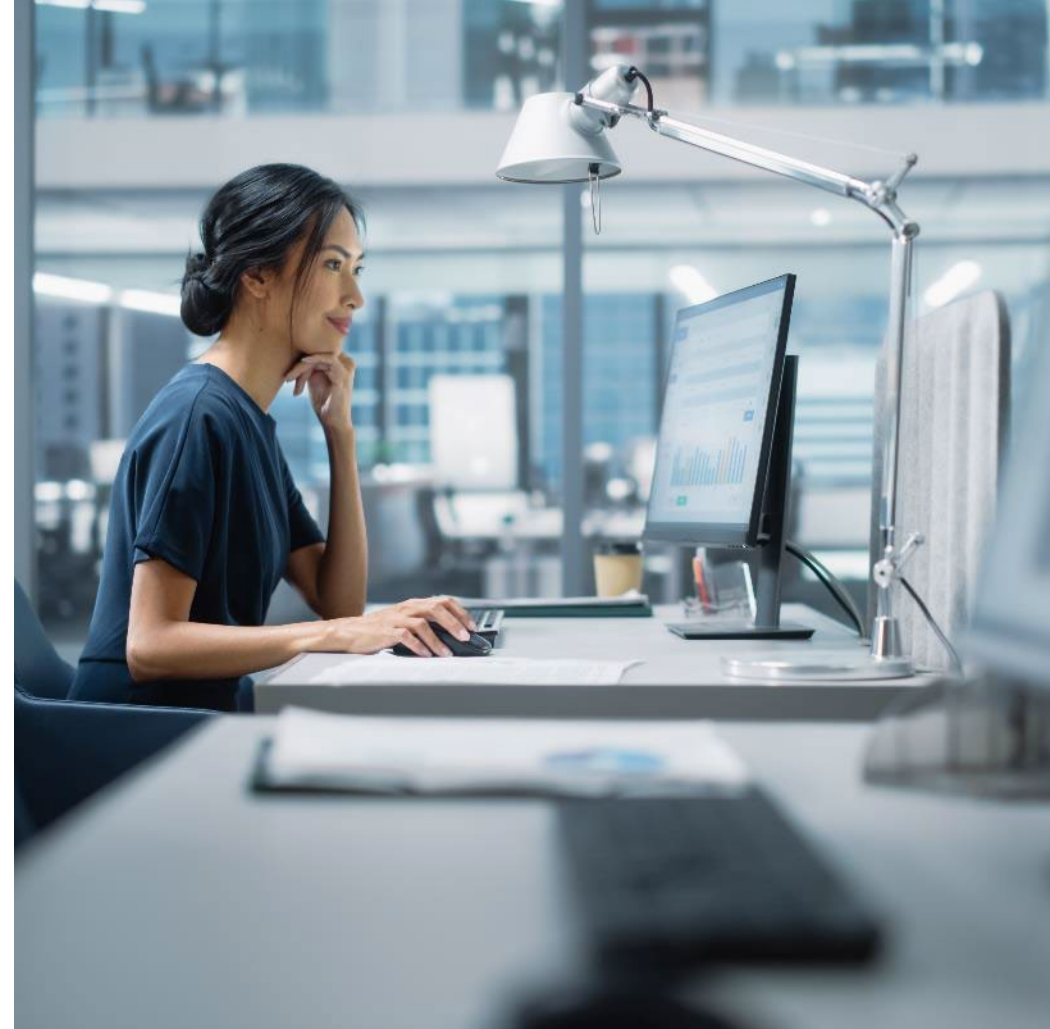
Offshore Attestations

- Special requirements for FDRs who perform offshore work



Attestations for new guidance

- Confirm compliance with emerging guidance



FDR GUIDE



FDR Guide
July 2023



I. What is an FDR?

An FDR is a U.S. Centers for Medicare & Medicaid (CMS) acronym that means first tier, downstream or related entity.

Current CMS definitions¹

A first tier entity is any party that enters a written arrangement, acceptable to CMS, with a Medicare Advantage (MA) organization or Part D plan sponsor or applicant.

These arrangements provide administrative or healthcare services to Medicare-eligible individuals under the MA program or Part D program.

A 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. They are below the level of the arrangement between an MA or Part D plan sponsor and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

A related entity is any entity that is related to an MA organization or Part D sponsor by common ownership or control and has the following characteristics:

- 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.

For more information, review the Code of Federal Regulations, 42 CFR § 422.500 and 432.501.

- [Medicare Managed Care Manual Chapter 9](#)
- [Medicare Managed Care Manual Chapter 11](#)
- [Medicare Managed Care Manual Chapter 21](#)
- [Texas Insurance Code](#)

What administrative services do FDRs provide?

Some examples of administrative functions are:

- Sales and marketing
- Utilization Management (may include Care Management and/or Disease Management)
- Quality improvement
- Applications processing

¹ The U.S. Centers for Medicare & Medicaid Services (CMS). Medicare Managed Care Manual Chapter 21 — Compliance Program Guidelines and Prescription Drug Benefit Manual Chapter 9 — Compliance Program Guidelines. CMS.gov Centers for Medicare & Medicaid Services. January 11, 2013. Available at: [CMS.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf). July 7, 2021.

Fulfilling compliance requirements

As an FDR, you are required to fulfill specific Medicare compliance requirements described in this guide.

Where can I find more information?

We designed this guide to be a reference for our FDRs. The Code of Federal Regulations and the Medicare Managed Care and Prescription Drug Manuals contain the full regulations, which you should read thoroughly to ensure you are fulfilling the requirements. You may also want to refer to your contract with us for any specific contract-level requirements.

Please find helpful resources with links below.

Compliance resource	How to use
Code of Federal Regulations, 42 CFR Part 422 (Medicare Advantage Regulations)	eCFR :: 42 CFR Part 422 -- Medicare Advantage Program
Code of Federal Regulations, 42 CFR Part 423 (Medicare Prescription Drug Regulations)	eCFR :: 42 CFR Part 423 -- Voluntary Medicare Prescription Drug Benefit
Medicare Managed Care Manual	100-16 CMS: <ul style="list-style-type: none"> • Chapter 11 – Medicare Advantage Application Procedures and Contract Requirements • Chapter 21 – Compliance Program Guidelines (this is the same as Chapter 9 in the Prescription Drug Benefit Manual)
Prescription Drug Benefit Manual	100-18 CMS: <ul style="list-style-type: none"> • Chapter 9 – Compliance Program Guidelines (this is the same as Chapter 21 in the Medicare Managed Care Manual)



III. FDR compliance requirements



Together, we are responsible for meeting the terms and conditions of our contracts with CMS and Prescription Drug Plans and must meet applicable Medicare program requirements. All FDRs participating in Medicare Advantage are required to maintain compliance with certain requirements and must ensure that their downstream entities also comply with applicable laws and regulation requirements listed in this guide.

Review compliance program requirements

This guide summarizes the FDR compliance program requirements. Be sure to review it and comply with these requirements each calendar year. Here are some of the actions you must take:

- Distribute a code of conduct and/or compliance policies

FDR TOOLBOX



V. FDR toolbox

Use this toolbox to help your organization meet Medicare compliance requirements.

Frequently asked questions (FAQ)

Have a question?	Reach out to us at: Compliance@yourhealthplan.com
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Code of conduct

Do not have your own code?	Feel free to distribute our Code of Conduct to your employees. Your Health Plan Code of Conduct
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Exclusion list screenings

The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) exclusions database	Complete preclusion (providers/prescribers only) and OIG exclusion list screenings before hiring or contracting, and each month thereafter, for your employees and downstream entities. The sample log below provides a way to track your screenings. Do not forget, you need to also maintain source documentation of your screenings, such as screenshots and input lists.
General Service Administration (GSA) System for Award Management (SAM)	Complete the SAM exclusion list screenings before hiring or contracting, and each month thereafter, for your employees and downstream entities. This sample log provides a way to track your screenings: Exclusion Checks.xlsx (live.com)

Reporting mechanisms

How to report noncompliance or potential fraud, waste, and abuse (FWA)	FDRs must report all suspected or detected non-compliance of FWA to the Plan if those issues impact the Plan or the function(s) delegated to the FDR. The FDR must enforce a non-retaliation policy for anyone reporting suspected misconduct. If an FDR uses their own code of conduct or compliance policies or identifies an issue of non-compliance, they must notify the Plan no later than three (3) days from identification and complete a corrective action plan. <ul style="list-style-type: none"> • Hotline: (800)000-0000 • Reporting Link: Your Health Plan Reporting Link • By email: Compliance@yourhealthplan.com
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Monitoring and oversight

Downstream Entity Oversight	In order for your downstream entities to self-monitor and report the status of their compliance to you, oversight must be conducted for the downstream entities using an FDR Attestation . Your Health Plan FDR Attestation
Check Yourself Tool	You can use this FDR Assessment Tool to assess how you fulfill Medicare compliance program requirements. Your organization can modify the tool to assess compliance of your downstream entities. Your Health Plan FDR Assessment Tool
Which subcontractors are FDRs?	Not every subcontractor is a First Tier, Downstream, or related entity. Review the Grid and Determining Factors below for examples of those that are.

More tools

Offshore Services Attestation form	Use the FDR Attestation link below to request permission for you or your subcontractor to use an offshore individual or entity. Request to perform any of these services for Medicare member PHI: <ul style="list-style-type: none"> • Processing • Transferring • Handling • Storing • Accessing Your Health Plan FDR Attestation Email your completed form to Compliance@yourhealthplan.com and put "New offshore submission" in the subject line.
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FDR ATTESTATION

First Tier, Downstream, and Related Entities (FDR) Annual Compliance Attestation

As a First Tier, Downstream or Related Entity (FDR) for our plan, your organization performs services related to Government programs on our behalf and is required to perform annual compliance attestation. As part of the Compliance requirements set forth in the Federal Acquisition Regulation (FAR), the Department of Justice (DOJ), Office of Inspector General (OIG), and the Centers for Medicare & Medicaid Services (CMS), the Plan must monitor compliance with these regulations.

This attestation confirms your commitment to comply with the compliance requirements that apply to all services your organization or any of your vendors provide related to Medicare, Medicaid, or any other Government programs.

As an FDR, please confirm you are compliant with the compliance program requirements in Chapters 9 and 21 of the Prescription Drug Benefit Manual and the Medicare Manual, respectively, identified within this attestation. Where your organization is not in full compliance, a detailed corrective action plan for remediation (including a timeline) is required to accompany this attestation. For any questions not applicable to your organization, please respond by marking "NA."

1. Code of Conduct

My organization requires all employees (including temporary workers, volunteers, and contractors) to read and abide by the Plan's Code of Conduct or another Code of Conduct that is comparable or exceeds elements found in the Plan's Code of Conduct requirements in Chapters 9 & 21. They are distributed to employees within 90 days of hire, and annually thereafter.

Yes No

Which Code of Conduct (COC) does your organization use to satisfy this requirement?
Plan's COC Your organization's own COC

2. Exclusion Screenings: US Department of Health & Human Services (HHS) General's List of Excluded Individuals and Entities (OIG LEIE) and Administration's System for Award Management (GSA SAM)

My organization reviews the Office of Inspector General (OIG), General Services Administration (GSA), and State exclusions lists prior to hire and monthly thereafter to ensure that temporary employee, volunteer, consultant, governing body member responsible for delivering Medicare and/or Medicaid benefits are excluded from Federal Government programs.

Yes No

For healthcare providers/prescribers only: The CMS Preclusion list is checked prior to hire or contracting and monthly thereafter.

Yes No NA

If the undersigned entity is on such list(s) or identifies an employee as being on such list(s), the undersigned entity will immediately remove the employee from any work related directly or indirectly to any Federal/State health care program and take appropriate corrective action, including notifying the Plan.

Yes No

3. General Compliance Training, HIPAA, and Fraud, Waste, and Abuse Training

My organization has policies and procedures in place for employees, Downstream Entities, and their employees to deliver General Compliance, HIPAA, and Fraud, Waste and Abuse training upon hire, and annually thereafter to all persons (employee or subcontractor) involved in the administration or delivery of Medicare and/or Medicaid benefits. A record of employee training, completing the training, and the materials utilized for training will be maintained for (10) years and available upon request.

Yes No

My organization is using CMS training materials: Yes No

My organization utilizes its own training materials: Yes No

4. Reporting Mechanisms

My organization communicates to employees how to report suspected non-compliance, or potential fraud, waste, and abuse, and it is their obligation to report such concerns in good faith. My organization requests employees report concerns directly to the Plan at compliance@you.com and/or maintains confidential and anonymous mechanisms for employees to report concerns. In turn, we report these concerns to the Plan, when applicable. Yes No

5. Operational Oversight

My organization conducts internal oversight of the services we perform for the Plan and ensures we are compliant with applicable laws, rules, and regulations including regulatory guidance. Yes No

6. Downstream Entity Oversight

My organization uses Downstream Entities (vendors) to perform services on behalf of the Plan.

Yes No

If yes, my organization conducts oversight to ensure Downstream Entities abide by all laws, rules and regulations that apply. This includes ensuring that:

- My organization's contractual agreements with Downstream Entities contain all CMS-required provisions.
- Downstream Entities comply with the compliance program requirements described in this attestation.
- Downstream Entities comply with any applicable operational requirements or contract SLAs with the Plan

Yes No NA

7. Offshore Operations

Does your organization or its Downstream Entities perform services for the Plan at an offshore location?

Yes No NA

Does your organization store any Plan member data, PHI, and/or intellectual property offshore?

Yes No NA

Does your organization or its Downstream Entities access Plan member data, PHI, and/or intellectual property offshore?

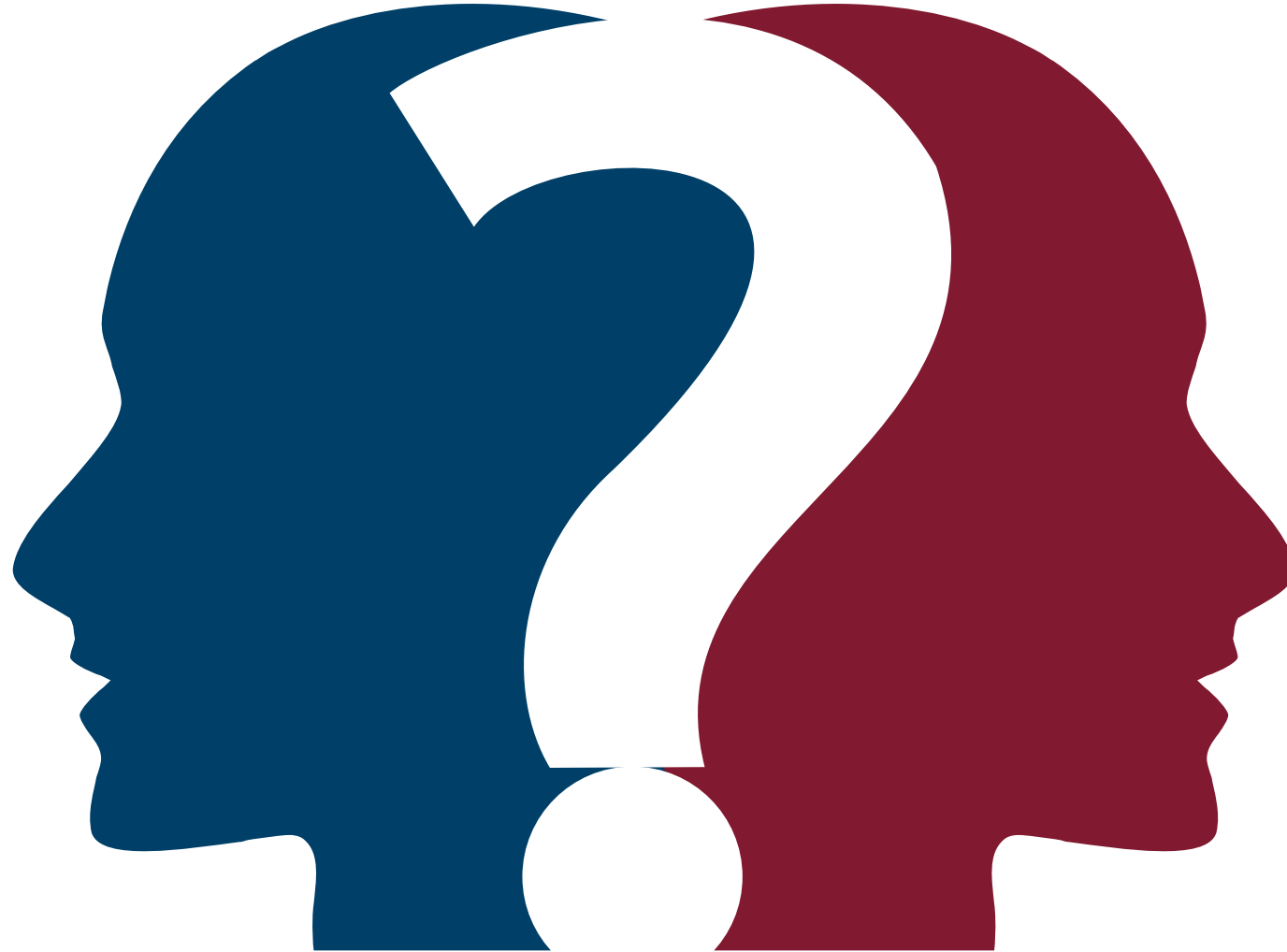
Yes No NA

8. Record Retention

My organization maintains, for a period of the current plan year plus 10 years from their creation date, all books, contracts, medical records, patient care documentation, training records and other records relating to services for Medicare, even if such 10 + 1 year period extends beyond the term of the agreement with the Plan.

Yes No

QUESTIONS



GUIDANCE

Medicare Managed Care Manual Chapter 21 – Compliance Program Guidelines and Prescription Drug Benefit Manual Chapter 9 - Compliance Program Guidelines

- [mc86c21.pdf \(cms.gov\)](#)

U.S. Department of Health and Human Services Office of Inspector General, General Compliance Program Guidance

- [HHS-OIG General Compliance Program Guidance | November 2023](#)

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