

Ring in the New Year with a Refresher on the 7 Elements of an Effective Compliance Program

Did you know all Medicare Advantage Organizations (MAO) and Medicare Prescription Drug Plans (PDP), such as Anthem and its affiliated plans, are required to adopt and implement an effective compliance program? As an FDR, are you aware how these requirements impact you? This article will explore the compliance program requirements of Anthem and how they pertain to our FDRs.

As a Medicare health plan, Anthem and its FDRs must have an effective compliance program in place, which must include measures to prevent, detect and correct Part C or D program noncompliance as well as Fraud, Waste and Abuse (FWA). At a minimum, the compliance program must include 7 core requirements, commonly referred to as the *7 Elements of an Effective Compliance Program*. Please keep in mind that for a compliance program to be effective, it must be fully implemented with adequate resources and be tailored to the uniqueness of each organization's operations and circumstances.

So let's get this refresher session started!

7 Elements of an Effective Compliance Program

1. Written Policies, Procedures and Standards of Conduct

Medicare health plans are required to have written policies, procedures and standards of conduct in place. These documents must (i) articulate the organization's commitment to comply with all applicable Federal and State standards; (ii) describe compliance expectations as embodied in the standards of conduct; (iii) implement the operation of the compliance program; (iv) provide guidance to employees and others on how to deal with and report suspected, detected or reported compliance issues; (v) describe how compliance issues are investigated and resolved; and (vi) include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program (*i.e. reporting potential compliance issues*).

- **FDR Impact:** Anthem and its FDRs must distribute compliance policies, procedures and standards of conduct to all employees within 90 days of hire, when there are updates to the policies, and annually thereafter. FDRs can demonstrate compliance with this requirement by implementing Anthem's Standards of Ethical Business Conduct (SOEBC) and Medicare Compliance Plan or adopting similarly aligned standards and policies of your own.

Helpful Compliance Links...

To review regulatory references to monitoring requirements:



CMS Medicare Managed Care Manual Ch. 11



Medicare Managed Care Manual Ch. 21 & Prescription Drug Benefit Manual Ch. 9



CMS Medicare Learning Network



Element 1 Continued -

Anthem makes our SOEBC and Medicare Compliance Plan available to all FDRs at the start of each calendar year in our Kick-Off Packet, as an attachment to the annual FDR Monitoring Survey, at the time of onboarding for new FDRs, and throughout the year upon updates to the documents. FDRs must maintain, and be able to provide upon request, documentation to evidence written policies, procedures and standards of conduct are made available to all associates supporting Anthem's Medicare business (as described above).

2. Compliance Officer, Compliance Committee & High Level Oversight

Medicare health plans must designate a Compliance Officer and a Compliance Committee who report directly and are accountable to the organization's chief executive or other senior management. The compliance officer must be an employee of the organization and vested with the day-to-day operations of the compliance program. Both the compliance officer and compliance committee are required to make periodic reports directly to the organization's governing body to ensure it is knowledgeable and aware of the operation and activities of the compliance program. The governing body must exercise reasonable oversight of the implementation and effectiveness of the compliance program, including oversight of FDR compliance with Medicare requirement.

- **FDR Impact:** FDRs need to be aware of Anthem's Medicare Compliance Officer (*information noted below*), including how to contact and/or report potential compliance issues and/or concerns. Additionally, FDRs should have their own compliance officer or internal compliance contact who is knowledgeable with Medicare requirements and methods of reporting compliance and FWA issues. Finally, it is important for Anthem's FDRs to have knowledge of Anthem's Medicare Compliance Committee (MCC). The role of the Committee is to monitor and provide guidance on Anthem's Medicare plans, review major compliance issues, engage in oversight activities related to remediation of compliance risks, and identify areas for training and education of associates and FDRs. Additionally, Anthem has implemented an FDR Compliance Committee (FDR CC) which reports at least quarterly to the MCC. The FDR CC is an authorized sub-committee of the MCC and is responsible for overseeing FDR's supporting Anthem's Medicare and for providing regular updates and recommendations to the MCC on FDR matters.

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3. Effective Training and Education

Medicare health plans and FDRs must establish, implement and provide effective training and education for employees. Plan sponsors must ensure their employees and FDRs are aware of Medicare requirements related to their job function and/or services being provided. For all associates and FDRs supporting Anthem's Medicare business, General Compliance and FWA Training must occur within 90 days of hire and annually thereafter and meet CMS' training requirements.

- **FDR Impact:** FDR employees are required to complete both General Compliance Training and FWA Training within 90 days of hire and annually thereafter. FDRs must utilize CMS training material issued via the Medicare Learning Network (MLN) and be able to demonstrate its employees have fulfilled all training requirements. Supporting documentation must be retained for a minimum of 10 years and be

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made available to Anthem upon request. Support documentation could include employee training certifications, employee attestations, MLN web-based training certificates, or training sign-in sheets. More information related to CMS' training requirements can be found [here](#). Please note, FDRs who have met the FWA training certification requirements through enrollment into Medicare Parts A or B or through accreditation as a supplier of DMEPOS are deemed to have already met FWA education requirements. However, General Compliance training is still required.

4. Effective Lines of Communication

Medicare health plans must establish, implement and publicize effective lines of communication, ensuring confidentiality, between the compliance officer, members of the compliance committee, employees, managers, governing body, and FDRs. Such lines of communication must be accessible to all and allow compliance issues to be reported anonymously. Organizations must also adopt, widely publicize, and enforce a no-tolerance policy for retaliation or retribution against any employee or FDR who in good faith reports a suspected compliance issues or FWA.

- **FDR Impact:** FDRs must report compliance concerns and suspected or actual violations related to the Medicare program to Anthem using published methods (*noted on page 4*). FDRs should have multiple ways to report issues and at least one way to anonymously report issues internally. Anthem and its FDRs must publicize all methods available for reporting compliance concerns and issues, and their non-retaliation policy for reporting those concerns in good faith.

5. Well Publicized Disciplinary Standards

Medicare health plans must have well-publicized disciplinary standards through the implementation of procedures which encourage good faith participation in the compliance program by all affected individuals. These standards must include policies which (i) articulate expectations for reporting compliance issues and assist in their

resolution; (ii) identify noncompliance or unethical behavior; and (iii) provide for timely, consistent, and effective enforcement of the standards when noncompliance or unethical behavior is determined. To encourage good faith participation in the compliance program, Medicare plan sponsors must publicize disciplinary standards for employees and FDRs. The standards should include the duty and expectation to report issues or concerns.

- **FDR Impact:** FDRs should review and be familiar with Anthem's SOEBC and Medicare Compliance Plan to understand the expectations related to participating in Anthem's compliance program (including the oversight of FDRs through annual monitoring and auditing activities), complying with applicable laws and regulations, and identifying and reporting noncompliance. FDRs must have standards and policies in place to detail the compliance requirements for employees, including the methods for reporting compliance issues and FWA. Finally, FDRs are strongly encouraged to participate in Anthem's bi-annual FDR Oversight Trainings, which provide rotating compliance topics, CMS regulation and policy updates, FDR requirements and performance expectations, and question and answer sessions. For more information on our FDR Trainings, please reach out to the FDRSharedMailbox@anthem.com.

6. Effective System for Routine Monitoring and Identification of Compliance Risks

Medicare health plans must establish and implement an effective system for routine monitoring and identification of compliance risks. The system should include internal monitoring and audits to evaluate the health plan's compliance with CMS requirements and the overall effectiveness of the compliance program. Additionally, Medicare plan sponsors must develop and implement a strategy to monitor and audit its FDRs to ensure they are in compliance with all applicable laws and regulations, including CMS' compliance program requirements.

- **FDR Impact:** Anthem requires its FDRs to participate in our Medicare FDR Oversight

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Program, which includes routine monitoring and auditing processes to ensure compliance with Medicare program requirements. Through the FDR Oversight Program, Anthem requires FDRs to (i) submit an annual FDR Monitoring Survey, including supporting documentation to evidence compliance with CMS requirements; (ii) participate in FDR focused audits when selected; and (iii) correct all identified noncompliance issues and/or compliance gaps in a timely and effective manner.

Effective monitoring also includes the requirement for Anthem and its FDRs to ensure employees and subcontractors are not excluded from participating in Federal programs. FDR employees, and subcontractors, must be checked against both the Office of Inspector General's (OIG) List of Excluded Individuals and Entities and the General Service Administration's (GSA) Excluded Parties List System prior to hire or contracting and monthly thereafter. For more information on Exclusion Screening requirements, please see the article titled "Remember to Double Check! Reminders for Federal Exclusion Screenings" on page 6 of this newsletter.

Please note – CMS has discretionary authority to perform audits, including the right to audit, evaluate, or inspect any books, contracts, medical records, patient care documentation, and other records of sponsors or FDRs pertaining to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract or as the Secretary of Health and Human Services may deem necessary to enforce the contract. Anthem and its FDRs must retain records for a minimum of 10 years and be able to provide all records to CMS or its audit designee, and cooperate in allowing access as requested. Failure to do so may result in a referral of the sponsor and/or FDR to law enforcement and/or implementation of other corrective actions, including intermediate sanctioning.

7. Procedures and System for Prompt Response to Compliance Issues

Medicare health plans must establish and implement procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensuring ongoing compliance with CMS requirements.


- **FDR Impact:** FDRs must promptly remediate compliance issues and/or gaps identified during FDR monitoring and auditing processes, self-assessments or internal discovery. Additionally, FDRs must ensure corrective actions and steps taken to resolve issues are properly documented to demonstrate identified compliance issues were resolved. Information related to FDR compliance issues and/or gaps, as well as corrective actions, are reported to Anthem's Medicare leadership, including the Medicare Compliance Officer, Medicare Compliance Committee, and Audit Committee of the Board of Directors on a regular basis. It is critical FDRs remediate all identified issues in a timely and effective manner.

There are several ways to report violations:

- Anthem's Fraud Hotline: **1-866-847-8247**
- Anthem's Ethics and Compliance Helpline: **1-877-725-2702**
- Ethics & Compliance E-mail box: **ethicsandcompliance@anthem.com**
- Send a letter to: **Post Office Box 791, Indianapolis, IN 46206**
- You may report an issue to your Anthem contact (Business Owner) or directly to:
 - **Sarah Lorange, Vice President of Medicare Compliance**
Sarah.J.Lorange@anthem.com, 303-764-7277
700 Broadway, Denver, CO 80203
MedicareProgramsComplOfficer@anthem.com

**How to Report Compliance
and/or Fraud, Waste and
Abuse Issues**

** Anthem enforces a strict policy of non-retaliation. Retaliation against anyone who reports compliance issue in good faith is strictly prohibited, including reports made by contracted vendors (FDRs). If you see retaliation or believe it has occurred, you must report it.*



**The following article was featured as a “Y-Comply” newsletter article and published with the permission of the Health Care Compliance Association. This article is intended to help communication the value and purpose of compliance and ethics to the industry. We would like to pass this message onto our FDRs in an effort to reinforce the importance of fostering a culture of ethical and compliant decisions across the Anthem and FDR workplace.*

The Price is Right

Many of us enjoy watching television game shows. Some require knowledge and skill, while others are purely games of risk and guessing. It can be entertaining.

In business organizations, we have to be careful to know and understand the risks and certainly not guess, but more than that, to conduct due diligence. Due diligence is the care that a reasonable person exercises, and is a level of judgment, scrutiny, and caution a person takes to avoid harm to other persons or property. The outcome of not carrying out proper due diligence in an area of risk can carry a high price, which is not an entertaining prospect.

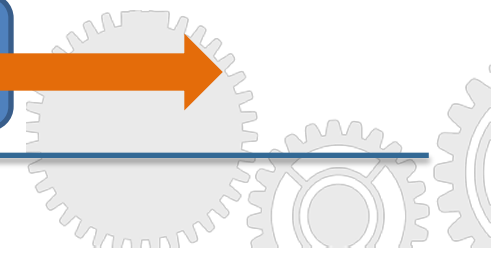
An area of risk where organizations need to exercise due diligence is in the area of screening individuals hired or contracted. The Federal Sentencing Guidelines (FSG) for Effective Compliance and Ethics programs addresses this risk and states: *“The organization shall use reasonable efforts not to include within the substantial authority personnel of the organization whom the organization knew, or should have known through the exercise of due diligence, has engaged in illegal activities or other conduct inconsistent with an effective compliance and ethics program.”* In plain and simple language that means companies need to use care to avoid hiring or contracting with those who are not trustworthy or honest.

A part of conducting due diligence is taking into consideration guidance provided, and the activities carried out, by enforcement agencies. For instance, organizations in the U.S. that participate in federal healthcare programs are required to screen employees and contractors to ensure they are not excluded from doing business with federal healthcare programs. The enforcement agency, the Office of Inspector General (OIG) of the Department of Health and Human Services, for many years has completed monthly updates to their database system of the names of those individuals and organizations excluded from participation with federal healthcare programs. We could then conclude that monthly screening by organizations would be a best practice.

The price of conducting screening more frequently may be of concern, but what about the potential cost of identifying an excluded individual or entity two, six, or 12 months after they were hired or contracted? The cost and consequences of addressing a finding caused by lack of diligence could be a much higher price to pay. What price might the company pay for a lost reputation with customers, business partners, or others?

Screening processes particularly impact professionals in the workplace that are involved in hiring, contracting, or purchasing, but we all have a responsibility to be aware of these types of requirements and risks. How organizations conduct screening has a direct correlation to the effectiveness of the compliance and ethics program, helps ensure a right organizational culture, and protects a good reputation.

Which screenings are required for FDRs? Turn the page for a refresher!





Remember to Double Check! Reminders for Federal Exclusion Screenings

“Sponsors shall not use federal funds to pay for services, equipment or drugs prescribed or provided by a provider, supplier, employee or FDR excluded by the DHHS OIG or GSA.” [Prescription Drug Benefit Manual Chapter 9 & Medicare Managed Care Manual Chapter 21, Section 50.6.8]

Anthem must ensure all our FDRs contracted to support Medicare business understand the Federal Exclusion Screening requirements and their accountability to maintain compliance. The following provides you with reminders on the required OIG and GSA exclusion screening process –

- **WHAT:** All FDRs must screen every employee **prior to hire and monthly thereafter** against **both** the OIG and GSA lists to ensure employees are not excluded or become excluded from participation in any Federal program.
 - **OIG’s List of Excluded Individuals and Entities (LEIE):** <https://exclusions.oig.hhs.gov/>
 - **GSA’s Excluded List:** <https://www.sam.gov/portal/SAM/#1#1>
- **WHO:** All FDR employees working on behalf of Anthem and its affiliates’ Medicare business (or any other Medicare, Medicaid, or Federal health care program work) must be screened. This includes temporary workers, interns, volunteers, contracted workers, and downstream contractors and vendors.
- **HOW:** FDRs need to be tracking and logging OIG and GSA screenings conducted prior to hire and throughout the year for each employee, including full name and the date in which the verification screening was completed against both OIG and GSA for each month. While a tracker spreadsheet is useful, you also need to maintain documentation to support the dates the employees were screened. Examples of supporting documentation include - screenshots from the OIG and GSA websites showing the results of the employee search, or output reports from a third-party vendor or human resources department. Please ensure the date of the search and the employee’s name are visible on your supporting documentation, as this information is critical to evidence the screening occurred.
 - If the FDR screening process identifies an employee or downstream as excluded from either the OIG or GSA federal exclusion lists, the first step should be to ensure the employee or entity being screened is one in the same with the individual or entity identified on the exclusion list. This can be done by comparing details, such as date of birth, state of residence, or social security numbers for the individual. Legal entity name, state of business, or employer identification numbers (EIN) can be reviewed for an identified downstream entity. If the extra verification steps confirm exclusion from federal programs, the individual or entity must not be hired. If subsequent monthly screenings identify and verify a current employee or contracted entity has been excluded, Anthem needs to be notified and the individual or entity must be removed from Medicare work immediately.
- **WHY:** By checking employees and contracted entities against federal exclusion lists, Anthem and its FDRs are doing their part to ensure Medicare payments are not being ultimately made to groups or individuals excluded from Medicare, Medicaid, or other Federal health care programs for engaging in misconduct related to health care fraud. It is important to remember exclusion checks are not only required by the Centers for Medicare & Medicaid Services (CMS) regulations, but also contractually required as an Anthem FDR.

If you have any questions on requirements or FDR expectations related to Federal Exclusion Screenings, please contact Anthem’s FDR Oversight Team: FDRSharedMailbox@anthem.com.



Questions from Readers



This section of the Quarterly FDR Newsletter focuses on common questions we receive from FDRs related to the FDR Oversight Program, the FDR Monitoring Survey, and CMS requirements. We realize a lot of our FDRs have similar questions, so we hope this section provides you with helpful information and useful tips! In this edition, we are focusing on some popular questions related to two (2) of Anthem's important contract exhibits – the **Medicare Regulatory Exhibit (MRE)** and **Business Associate Agreement (BAA)** -

1. What is a Medicare Regulatory Exhibit (MRE)? Anthem's MRE provides FDRs with the Medicare requirements and compliance expectations of all Anthem Medicare sub-contractors. The MRE is an exhibit typically attached to a FDR's contract* with Anthem, and specifies the Medicare laws and regulations in which all FDRs must maintain compliance. Additionally, the MRE details FDR oversight and monitoring requirements.

**FDR contracting is subject to agreements of both parties and may lead to variations of the material presented within this article. This information is intended to provide a high level overview of Anthem's contract exhibits applicable to the majority of FDRs.*

2. What is a Business Associate Agreement (BAA)? A BAA is a contract that must be established with a Business Associate before any Protected Health Information (PHI) can be disclosed to the Business Associate. Anthem may disclose PHI to its Business Associates to perform treatment, payment, and health care operations (including the mailing, transfer and printing of PHI) on a minimum necessary basis only if a BAA is in place.

- **What is Protected Health Information (PHI)?** PHI is any information about health status, provision of health care, or payment for health care that can be linked to an individual. This includes any part of a patient's medical record or payment history. Examples of PHI include name, address, phone number, credit card number, etc.
- **What is a Business Associate (BA)?** A BA is defined as an entity or person who performs a function or activity involving the use, exposure, or disclosure of PHI on Anthem's behalf. Examples of a BA include but are not limited to vendors, brokers, physician's consultants, Blue Cross and Blue Shield Association and Blue Plans, etc.

3. Who should I contact if my FDR contract with Anthem does not contain a required MRE or BAA? If you have any questions regarding Anthem's MRE and/or BAA, please reach out to the FDRSharedMailbox@anthem.com. The Anthem FDR Oversight Team will ensure you are put in contact with the appropriate Contracting/Procurement contacts.



HAPPY NEW YEAR!



It is hard to believe 2017 is upon us, time flies when you are having FDR fun! As we bring 2016 to a close and prepare for a new year, the Anthem FDR Oversight Team has a few important reminders for the New Year –

2017 Kick-Off Packet

Keep an eye out for Anthem's 2017 Medicare FDR Oversight Kick-Off Packet. We will be distributing it to all FDRs in January 2017 to ensure you have all the necessary tools and documents to make 2017 a success for FDR Oversight. The 2017 Kick-Off Packet will include the following items:

- Anthem's Standards of Ethical Business Conduct
- Anthem's 2017 Compliance Plan and Medicare Addendum
- CMS' General Compliance & FWA Training Information
- Anthem's FDR Oversight "Tools You Can Use" Kit

Audit Readiness

CMS has completed their 2016 audit cycle and plans to kick off their 2017 audit cycle bright and early in the New Year. So make sure you stay diligent on your organization's audit readiness activities. CMS places high priority and importance on FDR oversight, so it's critical all FDRs ensure they can demonstrate compliance will all Medicare Compliance program requirements.



Helpful Audit Resources:

- [CMS Medicare Managed Care Manual Chapter 21 & Prescription Drug Benefit Manual Chapter 9](#)
- [CMS Program Audit Protocols](#)

FDR Oversight Clinic

Are you a new Anthem Medicare FDR? Do you have questions on how to complete Anthem's FDR Monitoring Survey via the Ariba system? Are you wondering what type of documentation is needed to close out your open remediation items? If you have any questions surrounding Anthem's FDR Oversight Program, including our monitoring and auditing processes, please join us at an upcoming FDR Oversight Clinic. The Clinic is a monthly meeting hosted by the Anthem FDR Oversight Team where we provide an overview of the Oversight Program, review the monitoring process, and provide helpful information and tips related to Ariba, the web-based system we utilize to issue the annual FDR Monitoring Survey. Reach out to the FDRSharedMailbox@anthem.com, and we will send you the invitation for an upcoming Clinic!

Thank You!

Thank you for another successful year of administering Anthem's Medicare Advantage and Part D contracts, we could not do it without the support of our FDRs! We appreciate everyone's diligence and collaboration in maintaining compliance with CMS requirements. Your ongoing support and participation in Anthem's FDR Oversight Program allows us to safely and effectively serve our members. We look forward to a great 2017 – Happy New Year!!



Questions? Please send us an email: FDRSharedMailbox@anthem.com