



Answers to Frequently Asked Questions

What are the Centers for Medicare & Medicaid Services' (CMS) requirements for Medicare Advantage Organizations (MAOs) and Part D Plan Sponsors in regard to compliance programs?

Federal law requires MAOs and Prescription Drug Plan (PDP) Sponsors (such as Florida Blue) to implement an effective compliance program that meets the regulatory requirements set forth at 42 C.F.R. §§422.503(b)(4)(vi) and 423.504(b)(4)(vi). An MAO or PDP Sponsor must:

- Create a Compliance Plan that incorporates measures to detect, prevent, and correct fraud, waste and abuse;
- Create a Compliance Plan that must include training, education and effective lines of communication;
- Apply such training, education and communication requirements to all entities that provide benefits or services under MAO or PDP programs; and
- Produce proof (e.g., attestations and copies of training logs) from first-tier, downstream and related entities to show compliance with these requirements.

What does CMS mean by first tier, downstream, and related entities (FDRs)?

- **First Tier Entity:** 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 Medicare Advantage (MA) program or Part D program. (See 42 C.F.R. § 423.501)
- **Downstream Entity:** 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 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)
- **Related Entity:** 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)

What are considered some of the functions and/or activities of an FDR?

Sponsors may enter into contracts with FDRs to provide administrative or health care services for enrollees on behalf of the sponsor. The **sponsor maintains ultimate responsibility** for fulfilling the terms and conditions of its contract with CMS, and for meeting the Medicare program requirements. Below are examples of functions that relate to the sponsor's Medicare Parts C and D contracts:

- Sales and marketing;
- Utilization management;
- Quality improvement;
- Application processing;
- Enrollment, disenrollment, membership functions;
- Claims administration, processing and coverage adjudication;
- Appeals and grievances;
- Licensing and credentialing;
- Pharmacy benefit management;

- Hotline operations;
- Customer service;
- Bid preparation;
- Outbound enrollment verification;
- Provider network management;
- Processing of pharmacy claims at the point of sale;
- Negotiating 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; and
- Health care services.

If I am an FDR that has met the fraud, waste, and abuse certification requirements through enrollment into the Medicare program, am I still required to complete the MA-PDP Fraud, Waste and Abuse (FWA) training?

No. FDRs that have met the fraud, waste, and abuse certification requirements through enrollment into the Medicare program are deemed to have met the training and educational requirements for fraud, waste, and abuse. The same does not apply to general compliance training, which still requires completion.

What is the required frequency of general compliance and FWA training?

At a minimum, general compliance and FWA training must be received within 90 days of initial hiring and annually thereafter.

What are the required elements of an effective compliance plan if I/my organization is a network provider or provides services (includes vendors and providers) for Florida Blue's MA and/or Part D networks?

An effective compliance program must include measures that prevent, detect, and correct non-compliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements:

1. Written policies, procedures, and standards of conduct that:

- Articulate the organization's commitment to comply with all applicable Federal and State standards;
- Describe compliance expectations as embodied in the standards of conduct;
- Implement the operation of the compliance program;
- Provide guidance to employees and others on dealing with potential compliance issues;
- Identify how to communicate compliance issues to appropriate compliance personnel;
- Describe how potential suspected, detected or reported compliance issues are investigated and resolved by the sponsor; and
- Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials.

2. Compliance Officer, Compliance Committee and High Level Oversight

- The sponsor must designate a compliance officer and a compliance committee who reports directly and are accountable to the sponsor's chief executive or other senior management.
- The compliance officer, vested with the day-to-day operations of the compliance program, must be an employee of the sponsor, parent organization or corporate affiliate. The compliance officer may not be an employee of an FDR.
- The compliance officer and the compliance committee must periodically report directly to the governing body on the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program.

- The sponsor's governing body must be knowledgeable about the content and operation of the compliance program and must exercise reasonable oversight with respect to the implementation and effectiveness of the compliance program.

3. Effective Training and Education

- The sponsor must establish, implement and provide effective training and education for its employees, including the CEO, senior administrators or managers, and for the governing body members, and FDRs.
- The training and education must occur at least annually and be made a part of the orientation for new employees, including the chief executive and senior administrators or managers, governing body members, and FDRs.
- The sponsor's employees (including temporary workers and volunteers), and governing body members, must, at a minimum, receive general compliance training within 90 days of initial hiring, and annually thereafter.
- Sponsors must ensure that general compliance information is communicated to their FDRs.
- The sponsor's employees (including temporary workers and volunteers), and governing body members, as well as FDRs' employees who have involvement in the administration or delivery of Parts C and D benefits must, at a minimum, receive FWA training within 90 days of initial hiring (or contracting in the case of FDRs), and annually thereafter.

NOTE: FDRs who have met the FWA certification requirements through enrollment into the Medicare program or accreditation as a Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) are deemed to have met the training and educational requirements for fraud, waste and abuse. The same does not apply to general compliance training, which still requires completion.

4. Effective Lines of Communication

- The sponsor must establish and implement effective lines of communication, ensuring confidentiality between the compliance officer, members of the compliance committee, the sponsor's employees, managers and governing body, and the sponsor's FDRs.
- Sponsors must have an effective way to communicate information from the compliance officer to others.
- Sponsors must have a system in place to receive, record, respond to and track compliance questions or reports of suspected or detected noncompliance or potential FWA from employees, members of the governing body, enrollees and FDRs and their employees.
- Sponsors must make the reporting mechanisms user friendly, easy to access and navigate, and available 24 hours a day for employees, members of the governing body, and FDRs.
- Sponsors must educate their enrollees about identification and reporting potential FWA.

5. Well-publicized Disciplinary Standards

- The sponsor must have well-publicized disciplinary standards through the implementation of procedures that encourage good faith participation in the compliance program by all affected individuals. These standards must include policies that:
 - Articulate expectations for reporting compliance issues and assist in their resolution;
 - Identify noncompliance or unethical behavior; and
 - Provide for timely, consistent, and effective enforcement of the standards when noncompliance or unethical behavior is determined.

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

- The sponsor must establish and implement an effective system for routine monitoring and identification of compliance risks.
- Sponsors must undertake monitoring and auditing to test and confirm compliance with Medicare regulations, sub-regulatory guidance, contractual agreements, and all applicable Federal and State laws, as well as internal policies and procedures to protect against Medicare program noncompliance and potential FWA.
- Sponsors must establish and implement policies and procedures to conduct a formal baseline assessment of the sponsor's major compliance and FWA risk areas, such as through a risk assessment.

- Sponsors must audit their operational areas and those of their first tier entities.

7. Procedures and System for Prompt Response to Compliance Issues

- The sponsor 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 ensure ongoing compliance with CMS requirements.
- If the sponsor discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.
- The sponsor must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation referenced in paragraph (b)(4)(vi)(G)(1) of this section¹.
- The sponsor should have procedures to voluntarily self-report potential fraud or misconduct related to the MA program to CMS or its designee (such as the NBI MEDIC).

What are the definitions of fraud, waste and abuse (FWA)?

Fraud: 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).

Examples include:

- Billing for services that were never rendered
- Billing for services at a higher rate than is actually justified
- Deliberately misrepresenting services, resulting in unnecessary cost to the Medicare program, improper payments to providers or overpayments

Waste: over-utilization 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.

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 that are medically unnecessary. Abuse involves payment for items or services where 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.

What should I/my organization do if I/it become(s) aware of or suspect FWA?

Everyone has the right and responsibility to report possible FWA. Issues or concerns of FWA can be reported to:

- Your organization's compliance officer or compliance hotline;
- The compliance officer or compliance helpline of the applicable Plan Sponsor(s) with whom you participate or directly to their Special Investigation Unit (SIU)
 - GuideWell's² helplines:
 - Compass helpline- (800) 477-3736 x56300
 - SIU- (800) 678-8355;
- The Medicare Drug Integrity Contractor (MEDIC) Health Integrity (877) 772-3379; and
- (800) MEDICARE or (800) 633-4227.

Why should I/my organization review a copy of GuideWell's Code of Conduct?

In order to communicate the sponsor's compliance expectations for FDRs, sponsor should ensure that Standards of Conduct and policies and procedures are distributed to FDRs' employees¹. Sponsors may make their Standards of Conduct and policies and procedures available to their FDRs. Alternatively, the sponsor may ensure that the FDR has comparable policies and procedures and standards of conduct of their own, that, at a minimum, comply with the elements described at 42 CFR §§ 422.503.(b)(4)(vi)(A), 423.504(b)(4)(vi)(A).

Should I/my organization conduct federal debarment and exclusion screening?

Yes. Sponsors and FDRs with federal contracts are prohibited from conducting business with anyone who has been debarred, excluded or are otherwise ineligible to participate in federal programs. Entities and individuals should be screened against the Office of Inspector General (OIG) List of Excluded Individuals and Entities (LEIE) and the General Services Administration (GSA) Excluded Parties List (EPLS) prior to hiring or contracting and monthly thereafter. Additional information can be found at:

- OIG: <http://exclusions.oig.hhs.gov>
- GSA: <http://sam.gov>

Where can I/my organization get more information about CMS requirements?

Visit <https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Guidance.html> to obtain additional information regarding CMS requirements.

¹ *Centers for Medicare & Medicaid Services Medicare Managed Care Manual, Chapter 21 – Compliance Program Guidelines (Rev. 108, Issued: 01-11-13).*

² *GuideWell, a not-for-profit mutual holding corporation with a family of companies offering a broad range of health solutions to businesses and consumers that help people and communities achieve better health. The four operating companies of GuideWell include: Health Insurance Company, GuideWell Health, GuideWell Connect and GuideWell Source.*