

Overview

- To participate in the Medicare Shared Savings Program (Shared Savings Program), each ACO must have a compliance plan in accordance with [42 CFR § 425.300](#).
- Compliance plans are an ACO's first line of defense for preventing, detecting, and correcting noncompliance. If written effectively, a compliance plan should set compliance standards and assist the ACO in identifying risk, which may also reduce the potential for fraud, waste, and abuse (FWA).

IMPORTANT

- There is no template or specific format for the compliance plan; however, it must address all five required elements.
- Compliance plans should describe how the ACO will implement the five required elements.

The Five Required Elements of a Compliance Plan

1 A designated compliance official or individual who is not legal counsel to the ACO and reports directly to the ACO's governing body.

For this requirement, the ACO should consider and include, as appropriate:

- ✓ A clear statement that the compliance official does not serve as legal counsel to the ACO.
- ✓ A clear statement that the compliance official reports directly to the governing body.
- ✓ Details on how the compliance official reports to the governing body, how often, what the reporting entails, and how the reporting is documented.
- ✓ A description of the compliance official's place in the organizational structure, including to whom the compliance official reports.
- ✓ A job description for the compliance official that defines specific roles and responsibilities.

2 Mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance (e.g., internal risk assessment or audit processes).

For this requirement, the ACO should consider and include, as appropriate:

- ✓ A description of the mechanisms (e.g., systems, policies, or procedures) that are currently in place for identifying concerns and risks related to ACO compliance and provide details and specific examples.
 - Information on the system for receiving, recording, responding, and tracking compliance questions or reports of potential or actual noncompliance or FWA.
 - Provisions for evaluating the effectiveness of the reporting mechanisms (e.g., performance measures, etc.).
 - Provisions for an internal risk assessment or audit process that would monitor risk areas.
- ✓ A description of the actions the ACO takes to record and resolve issues, including actions taken to evaluate the effectiveness of issue management.
 - Provisions for evaluating any detected or reported violations.
- ✓ Details regarding to whom compliance issues are reported.
- ✓ A description of the policy of non-intimidation and non-retaliation for good faith participation in internal monitoring and reporting processes.
 - The compliance official shall be free to raise concerns to the governing body without fear of retaliation.
- ✓ A description of how the compliance officer responds to reported or suspected noncompliance and determines whether he or she believes a violation has occurred.
 - Details about how potential issues are resolved, such as who is responsible and the actions taken.

3 A method for employees or contractors of the ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to anonymously report suspected problems related to the ACO to the compliance officer.

For this requirement, the ACO should consider and include, as appropriate:

- ✓ An explanation of the method by which (e.g., a confidential compliance hotline, email address) noncompliance or suspected FWA can be reported anonymously.
- ✓ Details on how the method for anonymous reporting is advertised to ACO participants, ACO providers/suppliers, employees, and contractors.
- ✓ A statement that there is no retribution for reporting credible instances of improper or unlawful conduct.
- ✓ A statement that a failure to report suspected unethical or unlawful conduct is harmful to the integrity of the ACO and is a potential violation of the compliance plan.

4 Compliance training for the ACO, the ACO participants, and the ACO providers/suppliers.

For this requirement, the ACO should consider and include, as appropriate:

- ✓ A description of how the ACO ensures completion of compliance training for ACO employees and contractors and all ACO participants, and ACO providers/suppliers.
- ✓ Details on the topics covered within the training (e.g., what constitutes program violations, how to recognize violations, how to report compliance issues and possible violations).
- ✓ Details on the methods by which training is conducted (in-person sessions, newsletters, and other published material, etc.)
- ✓ A description of specialized training for individuals with specific job functions, if necessary.
- ✓ Information about how often the training is conducted.
- ✓ Information on the ACO's policy regarding formal training programs for new hires of the ACO's contractors, ACO participants, and ACO providers/suppliers, and refresher trainings thereafter.
- ✓ Details on whether the ACO retains its compliance training records and schedules.

5 A requirement for the ACO to report probable violations of law to an appropriate law enforcement agency.

For this requirement, the ACO should consider and include, as appropriate:

- ✓ A statement noting that the ACO is required to report violations and probable violations to an appropriate law enforcement agency.
- ✓ A description of how compliance issues are analyzed to determine whether they may be "probable violations of law."
- ✓ A description of the ACO's process for reporting probable violations of law to a law enforcement agency, including the steps the ACO should take to self-report violations to an appropriate government authority or law enforcement agency and the individuals responsible for self-reporting.
- ✓ Details on the roles and responsibilities that clearly state that the compliance official has the authority to report misconduct to CMS, its designee, and law enforcement.

Questions?

For additional questions or clarification, refer to [the OIG compliance guidelines](#) or contact SharedSavingsProgram@cms.hhs.gov.