Compliance Plan and Policy Manual

Disclaimer: MSSP- Program Policies and Procedure Manual Content guidance and format created by the Wilems Resource Group in collaboration with the National Association of ACOs (NAACOS).

TABLE OF CONTENTS

Duty to Report Suspected Non-Compliance	
Education and Training	
Introduction	ET-001
Distribution of Compliance Plan, Code of Conduct and ACO Policies and Procedures and Related Certification	ET-002
Compliance Communications	ET-003
Compliance Monitoring and Oversight	
Introduction	CMO-001
Reporting Suspected Non-Compliance	CMO-002
Annual Compliance Reviews	CMO-003
Responding to Compliance Issues	
Reports of Suspected Compliance Program Violations: Confidentiality	RCI-001
Reports of Suspected Compliance Program Violations: Non-Retaliation	RCI-002
Reports of Suspected Compliance Program Violations: Investigation	RCI-003

Corrective and/or Disciplinary Action and Programmatic Corrections	RCI-004
Compliance Log	RCI-005
Development, Revision, and Approval of Code of Conduct and ACO Policies and Procedures	
Development of New Policies and Procedures	DRP-001
Development, Revision, and Approval of Code of Conduct and ACO Policies and Procedures	
Review and Revision of Existing Compliance Plan, Code of Conduct and Policies and Procedures	DRP-002
Development, Revision, and Approval of Code of Conduct and ACO Policies and Procedures	
Approval of New or Revised Compliance Plan, Code of Conduct and Policies and Procedures	DRP-003
Retiring Policies and Procedures	DRP-004
Dissemination of New or Revised Compliance Plan, Code of Conduct and Policies and Procedures	DRP-005
Record Retention	DRP-006
ACO Communications	
ACO Communications and Material Review	COM-001
ACO Governance and Public Reporting Requirements	COM-002

Privacy and Security Compliance	
Compliance with HIPAA and DUA Requirements	PVS-001

Fraud, Waste and Abuse (FWA) Compliance	
FWA Laws and Utilization of Waivers	FWA-001
Benefit Enhancements	FWA-002
Beneficiary Incentives	FWA-003
Operational Policies	
Beneficiary Engagement and Patient Centeredness	OPS-001
Care Coordination	OPS-002
Evidence Based Medicine	OPS-003
Internal Reporting on Cost and Quality	OPS-004
Participant and Provider/Supplier List Updates	OPS-005
Repayment Mechanism (Only for ACO's with downside risk)	OPS-006
Initial Beneficiary Notifications	OPS-007

ACO COMPLIANCE

CMS requires ACOs to have a compliance plan. [1] The compliance regime surrounding ACOs consists of many interconnected parts - acceptance into the program is just the beginning. CMS expects an effective compliance program, one that prevents and detects potential compliance issues proactively rather than reactively. Ideally, a compliance team will consist of a fully engaged and informed leadership team and ACO Governing Body. Finally, evidencing a "culture of compliance" with clear expectations of ethical and proper behavior best serves an ACO. [2]

As part of the NextGen Model, all ACOs must "agree, and must require its Next Generation Participants, Next Generation Professionals, Preferred Providers, and other individuals or entities performing functions or services related to ACO activities" to allow federal authorities to audit the ACO's activities. [3] Practically, then, documentation is essential for ACO compliance - the most compliant ACO in the United States must still be able to document its compliance if CMS disputes it.

[1] 42 C.F.R. § 425.300.

[2] The OIG provides detailed compliance program advice, including "best practices" at its website, www.oig.hhs.gov/compliance, including specific advice for separate types of entities. A review of both ACO specific and non-ACO specific compliance guidance posted here should regularly be undertaken to ensure a complete, up-to-date understanding of compliance requirements.

[3] 42 C.F.R. § 425.314.

Policy Number:	**CPG-001**
Subject:	**Compliance Program Generally**
Policy/Procedure:	**Definitions**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of CPG-001 is to define the terms used throughout the ACO's Policies and Procedures.

II. **Scope.** The defined terms apply throughout the entirety of the ACO's Policies and Procedures. All terms are defined in the singular but are applicable to the plural of the term as well.

III. **Definitions.**

A. The terms are defined as follows:

TERM	DEFINITION
Keystone ACO	Refers to Keystone Accountable Care Organization, LLC, a not-for-profit company.
ACO Activities	Activities related to promoting accountability for the quality, cost, and overall care for a population of attributed Medicare Fee-For-Service Beneficiaries, including managing and coordinating care, encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery; or carrying out any other obligation or duty of the ACO under the Medicare Shared Savings Program.
ACO Participant	An entity identified by a Medicare-enrolled billing TIN through which one or more ACO providers/suppliers bill Medicare, that alone or together with one or more other ACO participants compose an ACO, and that is included on the list of ACO participants that is required under 42 C.F.R. § 425.118.
ACO Provider /Supplier	An individual or entity that: (1) is a provider or supplier under Medicare regulations; (2) is enrolled in Medicare; (3) bills for items and services furnished to Medicare fee-for-service beneficiaries during the agreement period under a Medicare billing number assigned to the TIN of an ACO participant; and (4) is included on the list of ACO providers/suppliers that is required under 42 C.F.R. § 425.118.
ACO Related Individual	ACO officers, directors, employees, ACO Participant, ACO Provider/Supplier, or any other individual or entity providing functions or services related to ACO Activities.
Adverse Action	With respect to a professional license, registration, or certification, any negative finding, unfavorable decision or action by a licensing agency or entity, or any decision or action that could have a negative or unfavorable implication. This term includes but is not limited to: revocation; denial; fine; monitoring; probation; suspension; letter of concern; guidance; censure; reprimand; disciplinary action; restriction; counseling required; loss, voluntary or involuntary surrender; initiation of inquiry; and investigation or other proceeding that could lead to any of the actions listed.
Annual Compliance Review	The annual internal review of the Compliance Program conducted pursuant to CMO-003.

Beneficiary	Medicare Fee-For-Service beneficiary attributed to the ACO by CMS.
Compliance Communication	An ACO communication (e.g., newsletter) highlighting the ACO's Compliance Program and other relevant compliance and legal issues, as deemed appropriate by the ACO Compliance Officer.
Policies and Procedures	The ACO's Policies and Procedures.
Compliance Program	The ACO's program to ensure compliance with applicable federal and state laws and regulations, and to promote ethical and lawful conduct.
Confidential Compliance Reporting Tool	A tool by which any individual may confidentially and anonymously report suspected problems related to the ACO to the ACO Compliance Officer.
Compliance Log	A record that includes a summary of each compliance disclosure received by the ACO Compliance Officer by or through any means or method; the status of the respective internal reviews; and any corrective action taken in response.
Compliance Training	The ACO's annual compliance education and training programs.
GSA	United States General Services Administration.
Government Investigation or Legal Proceedings	Any ongoing investigation or legal proceeding known to the ACO that is conducted or brought by a Government entity or its agents involving allegations that the ACO has committed a crime or has engaged in fraudulent activities.
HHS-OIG	United States Department of Health and Human Services, Office of the Inspector General.
HIPAA	Health Insurance Portability and Accountability Act of 1996.
LEIE	HHS-OIG's List of Excluded Individuals and Entities, which may be accessed on the Internet at https://exclusions.oig.hhs.gov .
Medicare Shared Savings Program (MSSP)	Medicare Shared Savings Program, established under section 1899 of the Social Security Act.
Code of Conduct	The Keystone ACO Code of Conduct in compliance with laws and regulations in accordance to the Medicare Shared Savings Program rules and with high legal, moral, and ethical standards.
Taxpayer Identification Number (TIN)	A federal taxpayer identification number or employer identification number as defined by the Internal Revenue Service (IRS) in 26 C.F.R. § 301.6109-1.

Policy Number:	**CPG-002**
Subject:	**Compliance Program Generally**
Policy/Procedure:	**Compliance with Laws; Conflict of Authorities**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of CPG-002 is to explain that the ACO's Compliance Program supplements federal and state laws and regulations. CPG-002 applies to all ACO Related Individuals.

II. **Policy.** The ACO is committed to compliance with relevant federal and state statutory and regulatory requirements. The ACO's Compliance Program supplements all applicable laws and regulations. In case of inconsistencies, these legal authorities take precedence over the Compliance Program unless the Compliance Program imposes stricter requirements.

III. **Procedures.**

1. General

   A. Some of the ACO's Policies and Procedures that make up the ACO's Compliance Program summarize various government laws and regulations. Such ACO Policies and Procedures are not substitutes for the actual laws, regulations, or rules to which they relate. The ACO's Policies and Procedures supplement applicable laws, regulations, and rules (and do not modify or replace them).

   B. In the event of an inconsistency between any Compliance Policy and/or Procedure in the ACO Compliance Program and applicable laws, regulations, or rules, all ACO Related Individuals are to follow the applicable laws and regulations, unless the ACO's Compliance Policy or Procedure imposes stricter requirements.

2. Code of Conduct

   A. This Code of Conduct has been adopted by the Keystone ACO's Board of Managers as part of the ACO's Compliance Plan in order to provide standards by which all members, partners, participants, participant employees, managers and contractors will conduct themselves. The Keystone ACO is fully committed to conducting its activities in compliance with all federal, state and local laws and regulations and in conformance with the highest standards of business integrity. Individual conduct must be in a manner that protects and promotes integrity and enhances the ACO's ability to achieve its organizational mission. The Code of Conduct is intended to serve as a guide to help all to whom it applies make sound, ethical and legal decisions during their day-to-day activities to ensure we achieve the level of compliance required by law. The standards and principles contained in this Code of Conduct apply to all ACO members, partners, participants, participant employees, managers and contractors. The ACO Board of Managers fully embraces the concepts contained herein and has formally adopted this Code of Conduct as the policy of the ACO. It is a requirement of all members, partners, participants, participant employees, managers and

contractors to fully adhere to the Compliance Plan and Code of Conduct at all times. Failure to comply can have serious consequences for the ACO and for those who do not comply.

B. Compliance with Laws and Regulations. The Keystone ACO operates in accordance with high legal, moral, and ethical standards and with all applicable laws, regulations, and standards. The ACO will not tolerate false statements by employees to a government agency or other payer. Deliberate misstatements to government agencies or other payers will be grounds for disciplinary action. The ACO will not pay employees, physicians, or health care professionals for referral of clients, or accept payments for referrals we make. The ACO will ensure that all reports or other information required by any federal, state, or local government agency are filed timely, accurately, and in conformance with the applicable laws and regulations. The ACO will not engage, either directly or indirectly, in any corrupt business practice, including bribery, kick-backs or payoffs, intended to induce, influence, or reward favorable decisions of any client, contractor, vendor, government personnel, or anyone in a position to benefit us in any way.

C. The ACO will not hire or contract with any individual or entity that is currently excluded, suspended, debarred, or otherwise ineligible to participate in the federal health care programs or has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.

D. Conflicts of Interest. All employees will perform their duties on behalf of the ACO in a truthful and loyal manner. All employees and Managers will avoid any actions that may be reasonably construed to cause an actual or potential conflict of interest with their responsibilities. Billing and Coding Integrity. The ACO and its participants will require accurate bills, which include only services actually rendered, using billing codes that accurately describe the services, and are based on documented medical necessity. The ACO and its participants will take every reasonable precaution to ensure that billing and coding is accurate, timely, and in compliance with federal and state laws and regulations.

E. The ACO will not tolerate the submission of any claims that contain any kind of false, fraudulent, or inaccurate statements. It has adopted policies and procedures to prevent and detect fraud, waste and abuse that are incompliance with both federal and state law. Any employee who lawfully reports a concern is protected from retaliation by these same policies, as well as federal and state laws governing false claims.

F. Privacy and Security of Information. The ACO will take every precaution to ensure the confidentiality, integrity, and availability of the information it collects and uses for health care and business purposes. The confidentiality protection extends to all information, regardless of location or storage medium, and it applies to both paper and electronic-based information.

I. **Questions.** Any questions concerning CPG-002, or questions that are not specifically addressed by this Policy, should be directed to the ACO's Compliance Officer.

Policy Number:	**CPG-003**
Subject:	**Compliance Program Generally**
Policy/Procedure:	**Conflict of Interest Policy**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of CPG-003 is to explain the ACO's Conflict of Interest Policy.

II. **Policy.** The Keystone ACO is committed to ensuring that all Conflicts of Interest are reported, reviewed and handled as appropriate, and that failure to report a Conflict of Interest as required results in appropriate disciplinary action.

III. **Procedures.**

A. Definitions. For purposes of this Conflict-of-Interest Policy, the following definitions and rules of construction shall apply:

1. "Interested Person" shall mean a Manager, officer, or member of a committee of the Keystone Accountable Care Organization, LLC who has a direct or indirect Financial Interest.

2. " Interest" exists if an Interested Person has, directly or indirectly, through business, investment, or family: (i) an ownership or investment interest in any entity with which the ACO has entered into a transaction or arrangement; (ii) a compensation arrangement with the ACO or with any entity or individual with which the ACO has entered into a transaction or arrangement; or (iii) a potential ownership or investment interest in or compensation arrangement with, any entity or individual with which the ACO is negotiating a transaction or arrangement. Compensation includes direct and indirect remuneration and gifts or favors, which are substantial in nature.

B. The ACO shall cause all Interested Persons to disclose any Financial Interests and all material facts relating thereto.

C. The ACO Compliance Officer shall work with the ACO General Counsel to determine whether the Financial Interest of an Interested Person constitutes or results in a conflict of interest. No Interested Person shall attend a meeting at which such person's Financial Interest is discussed, nor shall any Interested Person be entitled to vote on any action relating to such person's Financial Interest.

D. In the event the ACO determines that a conflict of interest exists, it shall take such actions as it deems necessary to resolve the conflict of interest, including: (i) prohibiting the Interested Person from attending any meeting at which is discussed the transaction or arrangement that results in the conflict of interest; (ii) prohibiting the Interested Person from voting on any matter relating to the conflict of interest; (iii) appointing, if appropriate, a disinterested person or committee to investigate alternatives to the proposed transaction or arrangement; (iv) determining, by a simple majority vote of the disinterested individuals present at a meeting, whether the transaction or arrangement is in the ACO's best interest and for its own benefit; is fair and reasonable to the ACO; and, after exercising due diligence, whether the ACO can enter into a more advantageous transaction or arrangement with reasonable efforts under the circumstances; and (v) taking appropriate disciplinary action with respect to an

Interested Person who violates the ACO's Conflict of Interest Policy in order to protect the ACO's best interests.

E. The minutes of meetings of the Keystone ACO Board of Managers and all committees of the Keystone ACO shall include: (i) the names of all persons who have disclosed Financial Interests, the nature of the Financial Interest disclosed, and the Keystone ACO Compliance Committee determination of whether a conflict of interest existed; and (ii) the names of the persons who were present at the meeting for discussions and votes relating to the transaction or arrangement, the content of these discussions (including any alternatives to the proposed transaction or arrangement), and a record of the vote.

F. The ACO shall distribute this Conflict-of-Interest Policy to all Interested Persons as defined herein. The ACO shall obtain annually a signed statement from each such person certifying that the person: (i) received a copy of the Conflict-of-Interest Policy. (ii) has read and understands the policy; (iii) agrees to comply with the policy; and (iv) understands that the policy applies to all committees and subcommittees acting with the authority of the Keystone ACO Board of Managers.

G. **Remedial Action.** If the Keystone ACO Compliance officer or a committee has reasonable cause to believe a member has failed to disclose actual or possible conflicts of interest, it shall inform the member of the basis for such belief and afford the member an opportunity to explain the alleged failure to disclose. If, after hearing the member's response and after making further investigation as warranted by the circumstances, the Keystone ACO Compliance officer or committee determines that the member has failed to disclose an actual or possible conflict of interest, it shall take appropriate disciplinary and corrective action, which may include removing such member from the Keystone ACO Board of Managers or committee, as appropriate.

H. **Conflicts Committee.** The Keystone ACO Compliance Committee, as a "committee of the whole," shall act as a "conflicts committee" to carry out the requirements of this Conflict of Interest Policy, and to adopt and apply such other procedures as it deems necessary therefor.

IV. **Questions.** Any questions concerning CPG-003, or questions that are not specifically addressed by this Policy, should be directed to the ACO's Compliance Officer.

Policy Number:	**CPG-004**
Subject:	**Compliance Program Generally**
Policy/Procedure:	**Non-Discrimination Policy**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of CPG-004 is to outline the ACO's prohibition on discrimination on the basis of race, color, national origin, gender, age, mental or physical disability, health status, receipt of health care, claims experience, medical history, genetic information, evidence of insurability, geographic location, or income in its health programs or activities.

II. **Policy.** The ACO does not discriminate, and does not tolerate discrimination by ACO Related Individuals, on the basis of race, color, national origin, sex, age or disability in its health programs or activities.

III. **Procedures.**

A. The ACO will not, on the basis of race, color or national origin, gender, age, or mental or physical disability, health status, receipt of health care, claims experience, medical history, genetic information, evidence of insurability, geographic location, or income aid or perpetuate discrimination against any person by providing significant assistance to any entity or person that discriminates on the basis of race, color, or national origin in providing any aid, benefit or service to beneficiaries of the ACO.

B. ACO Related Individuals may not directly, or through contractual or other arrangements, utilize criteria or methods of administration that have the effect of subjecting individuals to discrimination on the basis of race, color, national origin, sex, age or disability, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program.

C. In determining the site or location of a facility, the ACO may not make selections that have the effect of excluding individuals from, denying them the benefits of, or subjecting them to discrimination under any programs.

D. The ACO **may** operate a sex specific health program or activity only if the ACO can demonstrate an exceedingly persuasive justification that the program is substantially related to the achievement of an important health-related or scientific objective.

E. The ACO ensures appropriate auxiliary aids and services are available including qualified interpreters for individuals with disabilities and information in alternative formats, free of charge and in a timely manner, when such aids and services are necessary to ensure an equal opportunity to participate.

F. The ACO ensures appropriate language assistance services, including translated documents and oral interpretations, are available free of charge and in a timely manner, when such services are necessary to provide meaningful access to individuals with limited English proficiency.

1. A qualified interpreter shall be offered to any individual with limited English proficiency when oral interpretation is a reasonable step to provide meaningful access for the individual.

2. A qualified translator shall be used when translating written content in paper or electronic form.
3. The ACO shall **not:**
    a. Require the individual to provide their own translator;
    b. Rely on an adult accompanying the individual to interpret or facilitate communication; **except** (i) in an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no qualified interpreter immediately available; or (ii) where the individual specifically requests that the adult interpret or facilitate communication, the adult agrees to provide such assistance, and reliance on that adult is appropriate under the circumstances;
    c. Rely on a minor child to interpret or facilitate communication; **except** in an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no qualified interpreter for the individual immediately available; **nor**
    d. Rely on staff other than qualified bilingual/multilingual staff.

G. **Questions.** Any questions concerning CPG-004, or questions that are not specifically addressed by this Policy, should be directed to the ACO's Compliance Officer.

Policy Number:	**CPG-005**
Subject:	**Compliance Program Generally**
Policy/Procedure:	**Beneficiary Discharge, Avoidance, and Referrals**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of CPG-005 is to outline the policies of the ACO when an ACO Participant or Provider/Supplier discharges a patient who is also an ACO Beneficiary.

II. **Policy.** It is the policy of the ACO to provide quality care to all Beneficiaries aligned with the ACO and to ensure that ACO Related Individuals do not avoid at-risk Beneficiaries.

III. **Procedures.**

A. The ACO provides services to all Beneficiaries attributed to the ACO based on the best interests and wishes of the Beneficiary, as well as the medical judgement of the provider.

1. No ACO Related Individual gives or receives remuneration in return for, or to induce, business or referrals.
2. All referrals are made based on the best interest and wishes of the Beneficiary as well as the medical judgement of the provider. While ACO Providers/Suppliers may refer a Beneficiary to another provider within the ACO, all referrals are voluntary and the Beneficiary is free to see any provider, regardless of their participation in the ACO.
3. All ACO Related Individuals are prohibited from taking any action to limit the ability of a Provider/Supplier to make decisions in the best interests of a Beneficiary, including the selection of devices, supplies and treatment used in the care of the Beneficiary.

B. ACO may not require that beneficiaries be referred only to ACO participants or providers/suppliers within the ACO or to any other provider or supplier, except that the prohibition does not apply to referrals made by employees or contractors who are operating within the scope of their employment or contractual arrangement to the employer or contracting entity, provided that the employees and contractors remain free to make referrals without restriction or limitation if:

1. The beneficiary expresses a preference for a different provider, practitioner or supplier; or
2. The referral is not in the beneficiary's best medical interests in the judgment of the referring party.

C. The ACO does not condition the participation of ACO Related Individuals on referrals of Federal health care program business that the individual knew or should have known is being (or would be) provided to Beneficiaries who are not assigned to the ACO.

D. ACO Related Individuals shall not, directly or indirectly, commit any act or omission, nor adopt any policy, that coerces or otherwise influences a Beneficiary's decision to complete or not complete Voluntary Alignment, including but not limited to the following:

    1. Offering anything of value to the Beneficiary; and
    2. Withholding or threatening to withhold medical services or limiting or threatening to limit access to care.

E. The ACO requires its Participants and Provider/Suppliers to make medically necessary covered services available to Beneficiaries in accordance with applicable laws, regulations and guidance.

    1. The ACO and its Participants and Providers/Suppliers shall not take any action to avoid treating at-risk Beneficiaries or to target certain Beneficiaries for services with the purposes of trying to ensure alignment in a future period.

F. If, at any time, the physician-patient relationship becomes non-beneficial it may be in the best interest of the Beneficiary to find a new provider. ACO Providers/Suppliers follow their practice policies for administrative discharge of patients and are responsible for ensuring compliance with all requirements of their practice in relation to those actions.

    1. The ACO will continue to be accountable for the care of any terminated Beneficiary until he or she is no longer attributed to the ACO based on the assignment methodology utilized by the Centers for Medicare and Medicaid Services (CMS).

G. No patient or Beneficiary shall be discharged based on their health status or risk to the ACO.

    1. If Compliance Monitoring and Oversight activities, or any Compliance Investigation, determine that an ACO Related Individual is avoiding at-risk Beneficiaries, they will be subject to disciplinary action up to and including termination of employment and/or any contractual relationship with the ACO.

IV. **Questions.** Any questions concerning CPG-005, or questions that are not specifically addressed by this Policy, should be directed to the ACO's Compliance Officer.

Policy Number:	**CO-001**
Subject:	**Compliance Officer**
Policy/Procedure:	**Introduction**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of the Compliance Officer and Committee (CO) Policies and Procedures is to outline (1) the duties and responsibilities of the ACO's Compliance Officer, and (2) the compliance duties and responsibilities of the ACO's Board of Managers.

II. **Policy.** The ACO shall maintain a Compliance Program overseen and implemented by the ACO Compliance Officer and assisted by the ACO compliance committee and administrative (Keystone ACO Chief Administrative Officer, Director, Practice Transformation Coordinators, Quality Manager, etc).

III. **Procedures.** ACO shall audit and document compliance with the CO Policies and Procedures. Such audit shall be conducted pursuant to the Compliance Monitoring and Oversight (CMO) Policies and Procedures. Relevant documentation, which may include electronic documentation, shall be maintained in Compliance Program files, consistent with the ACO's document retention policies but, in no case, for a period of less than ten years.

IV. **Questions.** Any questions concerning the CO Policies and Procedures, or questions that are not specifically addressed in the CO Policies and Procedures, should be directed to the ACO's Compliance Officer.

Policy Number:	**CO-002**
Subject:	**Compliance Officer**
Policy/Procedure:	**ACO Compliance Officer Duties and Responsibilities**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of CP-002 is to outline the duties and responsibilities, qualifications, and authority of the ACO Compliance Officer.

II. **Policy.** The ACO is committed to maintaining an effective compliance program for promoting compliance with the laws and regulations that govern operation of the organization. In furtherance of this commitment, the Keystone ACO Board of Managers has established the position of ACO Compliance Officer. The ACO Compliance Officer shall have the authority, qualifications, and skills necessary to meet the scope and objective of the ACO Compliance Program.

III. **Procedures.**

A. Appointment of the ACO Compliance Officer.

1. The Keystone ACO Board of Managers, in consultation with others as appropriate, shall appoint an ACO Compliance Officer.
2. The ACO Compliance Officer shall be a senior management level individual and may report for operational purposes to the Keystone ACO Chief Administrator Officer. The ACO Compliance Officer shall not be (nor be subordinate to) the ACO's General Counsel or the Chief Financial Officer.
3. When the ACO Compliance Officer is appointed, an announcement concerning the appointment shall be circulated to all ACO Related Individuals, along with the Compliance Officer's contact information.
4. The ACO Compliance Officer shall make regular, but at least bi-annual, reports to the ACO, The Keystone ACO Board of Managers.

B. Qualifications.

1. The ACO Compliance Officer shall have credentials and experience appropriate for (a) understanding the ACO's various business lines, and (b) executing the duties and responsibilities set forth in the Compliance Program.
2. The ACO Compliance Officer shall demonstrate high integrity, good judgment, assertiveness, an approachable demeanor, and elicit respect and trust from ACO Related Individuals.
3. The ACO Compliance Officer must have sufficient time to dedicate to the Compliance Officer position and its duties.
4. The ACO Compliance Officer may not serve as legal counsel to the ACO.

C. Authority of the ACO Compliance Officer.

1. The ACO Compliance Officer shall have authority to (1) review all ACO documents and other information relevant to compliance activities (including, but not limited to, medical records, contracts, personnel records, and company e-mails), and (2) interview all ACO Related Individuals, as necessary, to discharge his or her duties and responsibilities.
2. The ACO Compliance Officer shall have sufficient management authority, responsibility, and resources to permit the effective performance of his/her duties as outlined below.
3. The ACO Compliance Officer shall have the authority to report to the Keystone ACO Chief Administrative Officer and Keystone ACO Board of Managers regarding compliance matters at any time.
4. The ACO Compliance Officer shall have direct access to all other senior management and legal counsel (in-house or outside), as appropriate and necessary.
5. The ACO, as directed by the Keystone ACO Board of Managers or otherwise, may commission an independent review to verify any findings of the ACO Compliance Officer.

D. **Duties and Responsibilities.** The ACO Compliance Officer shall be responsible for the development, implementation, operation, monitoring, and maintenance of the ACO's Compliance Program. The ACO Compliance Officer may delegate certain aspects of his/her duties and responsibilities, provided the ACO Compliance Officer appropriately supervises any such delegee, and retains ultimate responsibility for each duty and responsibility. More specifically, the ACO Compliance Officer shall be responsible for:

1. Overseeing and monitoring the day-to-day implementation and operation of the ACO's Compliance Program, including the supervision of other ACO Related Individuals who assist with Compliance Program efforts.
2. Ensuring that adequate procedures are established to (1) monitor changes in the MSSP and other applicable Federal or State laws and regulations, that may affect existing contractual obligations or changes in electronic data transmission and storage of health information privacy and security requirements; and (2) inform the ACO Keystone ACO Chief Administrative Officer and Compliance Committee of such relevant changes in law or regulation.
3. Making reasonable efforts to stay abreast of current, relevant regulatory materials, publications, web sites, and guidance issued by government agencies, including the HHS or HHS-OIG, regarding the MSSP and other state or federal laws and regulations.
4. Reporting on a regular basis (and at least bi-annually) to the ACO Board of Managers or Subcommittee thereof, and reporting periodically, as necessary and appropriate, to the ACO's Chief Administrative Officer and legal counsel on compliance issues and the status of the ACO's Compliance Program, unless such reporting would compromise an ongoing investigation or other confidential information.

5. Developing written Policies and Procedures that are designed to: (a) implement the ACO's Compliance Program; (b) address existing and new compliance risk areas; and (c) ensure compliance with the MSSP and other applicable state and federal laws and regulations.
6. Periodically reviewing, updating, and amending the ACO Compliance Program, including Code of Conduct the ACO's Policies and Procedures, as appropriate.
7. Developing, coordinating, and appropriately documenting the ACO's compliance-related educational and training programs, and reviewing and updating such programs as necessary, but at least on an annual basis.
8. Seeking to ensure that ACO Related Individuals are aware of and comply with applicable laws and regulations and the ACO Compliance Program (including Code of Conduct the ACO's Policies and Procedures).
9. Coordinating with ACO Operations and/or ACO Participants, as appropriate, to ensure that ACO Related Individuals are screened against HHS-OIG's and GSA's excluded parties' lists, pursuant to the ACO's Hiring, Employment and Contracting Policies and Procedures.
10. Ensuring that ACO Related Individuals (a) have access to the ACO Compliance Plan, Code of Conduct and the ACO's Policies and Procedures, and (b) are otherwise appropriately informed of ACO's Compliance Program, upon hire or contracting.
11. Appropriately publicizing the existence of the mechanisms for reporting suspected instances of non-compliance
12. Coordinating any internal and external compliance reviews of the ACO's business operations and practices (and assisting with the same, as necessary and appropriate).
13. In coordination with legal counsel, and on an as-needed basis, reviewing any new ACO business arrangements involving federal or state health care programs to ensure that these arrangements comply with relevant laws and regulations, as applicable.
14. Responding appropriately to compliance questions and inquiries.
15. Ensuring that reported compliance concerns are appropriately entered into the ACO Compliance Log (pursuant to **RCI-005)** and addressed and documented.
16. Investigating suspected violations of applicable laws and regulations and taking corrective action, where appropriate, and coordinating with or through in-house or outside legal counsel, as appropriate, on such investigations.
17. Recommending, overseeing, and documenting disciplinary action and other remedial measures, where appropriate.
18. Consulting with in-house or outside legal counsel for legal advice and guidance, as appropriate.
19. Developing an annual Compliance Work Plan and presenting such Compliance Work Plan to the Keystone ACO Board of Managers.

20. Acting as compliance liaison between regulatory bodies and the ACO. This includes, but is not limited to, ensuring timely dissemination of important compliance communications from the Centers for Medicare and Medicaid Services (CMS).
21. Ensuring appropriate notice to CMS in the event of the following:
    a. Any significant change in eligibility or program requirements; within 30 days of the change
    b. Bankruptcy; within 5 days of petition filing.

Policy Number:	**HE-001**
Subject:	**Hiring, Employment, and Contracting**
Policy/Procedure:	**Screening Prospective ACO Related Individuals**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of HE-001 is to provide (1) a statement of the ACO's policy regarding screening of prospective ACO Related Individuals, and (2) procedures to ensure that the ACO's Participants are consistent with its stated policy.

II. **Policy.** The ACO will conduct (or arrange for others to conduct) relevant screening of all prospective ACO Related Individuals. Subject to legal restraints, ACO will not contract with or employ any person who: (1) is currently excluded, suspended, debarred or otherwise has become ineligible to participate in a federal health care program or in a federal procurement or non-procurement program; (2) has been charged with, or convicted of, a criminal offense related to the provision of health care items or services or health care fraud (including any criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a)), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible for participation in a federal health care program; or (3) who has a conflict of interest with the ACO. In addition, the ACO will not contract with or employ individuals who do not have current professional licenses, registration, certifications or degrees, or other academic credentials identified by the ACO as necessary to perform the relevant duties and responsibilities.

III. **Procedures.**

A. Screening of Prospective Individuals.

1. At the time that ACO enters into contracts with new Participants, Providers and Suppliers, Affiliates, and Vendors, they will be screened against the OIG/GSA List of Excluded Individuals. New Participants, Affiliate and Vendors and Directly Employed ACO Staff will be screened by the ACO, and Providers/Suppliers and other ACO related individuals who are employed by a Participant, Affiliate, or Vendor shall be screen by their Employing TIN.

    a. The HHS-OIG's List of Excluded Individuals and Entitles, which may be accessed on the Internet at https://exclusions.oig.hhs.gov; and

    b. The GSA's Excluded Parties List System, which may be accessed on the Internet at http://www.sam.gov/

    c. Before appointment, hiring or contracting, individuals the ACO, or the hiring Entity, shall require that the prospective ACO Related Individual disclose, as applicable, whether he or she:

        i. has been, at any time, debarred, excluded, suspended or otherwise deemed ineligible for participation in a federal health care program or in a federal procurement or non-procurement program;

        ii. has been convicted of committing any criminal offense, including any criminal offense relating to the provision of health care items or services or of health care fraud that falls within the ambit of 42 U.S.C.

§ 1320a-7(a) or that relates to federal procurement or non-procurement programs;

iii. is the subject of or otherwise part of any ongoing federal or state investigation;

iv. has any charges pending against him or her for violating any criminal law;

v. lacks a current professional license, registration or certificate, as required for the job position, or is not in good standing with, or has/had an Adverse Action (as defined in CPG-001) taken by any authorities granting such license, registration, or certification, as applicable; or

vi. has not earned the degrees or other academic credentials as represented to ACO in his/her employment application or contract.

d. In the event that the prospective ACO Related Individual discloses a matter set forth above, the prospective individual shall provide complete information with respect to the charge(s), conviction(s), prohibition(s), notices(s), investigation(s), or other matters at issue.

2. Screening by Contractors/Vendors.

a. The ACO shall require, by contract, that Contractors/Vendors certify, in writing, that they have properly reviewed and screened all personnel who have been assigned to work on an ACO engagement prior to actual placement and have determined, as appropriate (based, in part, on disclosures by the individuals themselves), that the Contractor/Vendor and such individuals have:

i. not been excluded, debarred, suspended, or otherwise made ineligible to participate in a federal health care program or in a federal procurement or non-procurement program;

ii. not been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a);

iii. not been charged with a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a) or 1320a-7(b)(1)-(3);

iv. not been proposed for exclusion from participation in a federal health care program or in a federal procurement or non-procurement program; and

v. not named on the HHS-OIG or GSA exclusion lists.

b. The ACO shall obtain and maintain sufficient documentation to evidence the Contractor/Vendor's completion of the screening obligations set forth in this Policy.

B. Hiring. The ACO shall not knowingly (1) appoint an officer or director (2) employ an individual, (3) contract with a Contractor, or (4) utilize an employee of a Contractor that:

1. Is currently debarred, excluded, suspended or otherwise deemed ineligible for participation in a federal health care program or in a federal procurement or non-procurement program;

2. Has been convicted of a criminal offense related to the provision of health care items or services or to health care fraud (including a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a));
3. Has been charged with committing a criminal offense related to the provision of health care items or services or health care fraud (including a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a));
4. Does not have a current professional license, registration, or certification, and/or is not in good standing with, and/or has had an Adverse Action taken by, the relevant state authorities that grant such license, registration, or certification, if such professional license, registration or certificate is required by the ACO to perform related duties and responsibilities; or
5. Has not earned the degrees or other academic credentials identified by the ACO as required for the particular position.

C. Access to CMS Systems: Keystone ACO Chief Administrative Officer has responsibility for the maintenance and authorization of user access to CMS Systems. In accordance with the ACO's Compliance with HIPAA and DUA Requirements Policy, access to data and systems should be limited to those who require the information in order to complete their responsibilities related to ACO Activities.

1. The ACO maintains all required contacts in ACO-MS, and updates the Contact Page within that system within 30 days of a change in ACO contacts.
2. The ACO ensures users are disassociated from the ACO's account within the CMS system when a change occurs as a result of termination or a change in responsibilities within the ACO leads to the individual no longer requiring access.

D. Documentation. The ACO shall document compliance with HE-001, and shall maintain such documentation in accordance with the ACO's document retention policies but, in no case, for a period of less than ten years.

Policy Number:	**HE-002**
Subject:	**Hiring, Employment, and Contracting**
Policy/Procedure:	**Screening Current ACO Related Individuals**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of HE-002 is to provide (1) a statement of the ACO's policy regarding screening current ACO Related Individuals, and (2) procedures to ensure that the ACO's practices are consistent with its stated policy.

II. **Policy.** The ACO will conduct (or arrange for others to conduct) relevant screening of current ACO Related Individuals. Upon receiving notice that an ACO Related Individual:

- Is currently excluded, suspended, debarred or otherwise has become ineligible to participate in a federal health care program or in a federal procurement or non-procurement program; or
- Has been convicted of a criminal offense related to the provision of health care items or services or to health care fraud (including any criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a)), but has not yet been excluded, debarred, suspended or otherwise declared ineligible for participation in a federal health care program,

The ACO may, subject to legal and/or contractual constraints, terminate the individual or entity's employment/engagement/participation with the ACO, but shall, at a minimum, remove such person or entity from (1) any responsibility for, or involvement with, the ACO's business operations related to federal health care programs, and (2) any position for which the individual's compensation is, or the items or services furnished, ordered or prescribed by such individual are, paid in whole or in part, directly or indirectly, by federal health care programs or otherwise with federal funds. The ACO may, subject to legal and contractual constraints, terminate an individual's employment/engagement/participation with the ACO upon learning that the individual does not have current professional licenses, registration, certifications or degrees, or other academic credentials identified by the ACO as necessary to perform relevant duties and responsibilities.

III. **Procedures.**

A. Screening of Current Individuals

1. The ACO or the hiring ACO participating employer will screen Participants, Providers and Suppliers, affiliates, and Vendors, annually at a minimum against the OIG/GSA List of Excluded Individuals. Participants, affiliates and Vendors and Directly Employed ACO Staff will be screened by the ACO, and Providers /Suppliers and other ACO related individuals who are employed by a Participant, Affiliate, or Vendor shall be screen by their Employing TIN.
2. The HHS-OIG's List of Excluded Individuals and Entities, which may be accessed on the Internet at https://exclusions.oig.hhs.gov; and
3. The GSA's Excluded Parties List System, which may be accessed on the Internet at http://www.sam.gov/.

a. The ACO shall require all ACO Related Individuals to disclose immediately to the ACO Compliance Officer:

i. any debarment, exclusion, suspension, or other event that makes the individual ineligible to participate in a federal health care program or in a federal procurement or non-procurement program; or

ii. any conviction of a criminal offense that falls within the ambit of 42 U. S.C. § 1320a-7(a).

4. Screening by current Contactors/Vendors

a. The ACO shall, by contract, require Contractors/Vendors to screen their personnel annually against the HHS-OIG and the GSA exclusion lists and certify periodically (but no less than annually) that they and their personnel working on an ACO engagement have not been:

i. debarred, excluded, suspended, or otherwise made ineligible for participation in federal health care programs or other federal procurement or non-procurement programs; or

ii. convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a).

b. Contractors/Vendors shall, by contract, be required to notify the ACO immediately if they, or their personnel working on an ACO engagement, are:

i. debarred, excluded, suspended, or otherwise made ineligible to participate in the federal health care program or in federal procurement or non-procurement programs; or

ii. convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a).

B. Termination or Other Corrective Action.

1. Subject to legal constraints and absent extenuating circumstances, the ACO shall not knowingly retain any ACO Related Individual that:

a. Is currently debarred, excluded, suspended, or has otherwise been deemed ineligible for participation in a federal health care program or a federal procurement or non-procurement program; or

b. Has been convicted of committing a criminal offense related to the provision of health care items or services or of health care fraud (including a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a)) but has not been excluded, debarred, suspended or other been made ineligible for a federal health care program.

2. Notwithstanding the foregoing, the ACO may decide to retain such individual if the circumstances warrant such determination, as decided by the ACO Compliance Committee and Board of Managers in consultation with the ACO Compliance Officer and the General Counsel.

3. If such a determination is made, the individual shall be immediately removed from (1) any responsibility for, or involvement with, the ACO's business operations related to federal health care programs, and (2) any position for which the individual's compensation is, or the items or services furnished, ordered or prescribed by such individual are, paid in whole or in part, directly or indirectly, by federal health care programs or otherwise with federal funds.
4. Subject to legal and contractual restraints, the ACO also may terminate the employment/engagement/participation of, or modify the job duties of, a person or entity that:

    a. Does not have a current professional license, registration, or certification as applicable, and/or is not in good standing with, and/or has had Adverse Action taken by, the relevant state authorities that grant such license, registration, or certification, as applicable, if such a qualification is required by the ACO to perform ACO-related duties or responsibilities; or

    b. Has not earned the degree or other academic credentials identified by the ACO as required for the particular position.

C. Documentation. The ACO shall document compliance with this Policy, consistent with the ACO's document retention policies but, in no case, for a period of less than ten years.

Policy Number:	**HE-003**
Subject:	**Hiring, Employment, and Contracting**
Policy/Procedure:	**Pending Charges Against ACO Related Individuals**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of HE-003 is to provide (1) a statement of the ACO's policy regarding pending charges against its ACO Related Individuals, and (2) procedures to ensure that the ACO's practices are consistent with its stated policy.

II. **Policy.** The ACO shall ensure that it appropriately addresses situations in which a current ACO Related Individual is charged with a criminal offense in a manner that is consistent with its Compliance Program Policies and Procedures, and applicable laws and regulations.

III. **Procedures.**

A. Action Pending Resolution of Charges.

1. If the ACO learns that: (1) a current ACO Related Individual has been charged with a criminal offense related to the provision of health care items or services or health care fraud (including any criminal offense that falls within the ambit of 42 U. S.C. § 1320a-7(a)); or (2) a federal agency has issued a notice proposing to debar, exclude, or otherwise deem the ACO Related Individual ineligible to participate in a federal health care program or a federal procurement or non-procurement program, then, pending resolution of the charges or proposed sanction:

    a. If the individual is in a position of responsibility for, or involvement with, the ACO's business operations related to federal health care programs, then the individual shall be removed from such responsibilities. At the ACO's discretion, and if deemed warranted, further actions may be taken, up to and including termination of employment, ACO participation, or any contract with the ACO pursuant to any applicable contract requirements.

    b. In any such case, the ACO will take reasonable steps to insure that the responsibilities of the individual or entity have not and shall not adversely affect the quality of services offered by the ACO.

    c. If an ACO Related Individual is not in a position that involves direct responsibility for, or involvement with, the ACO's business operations related to federal health care programs, then the individual or Contractor shall not be appointed to such a position unless and until such pending allegations are resolved in the individual's favor.

2. If the ACO learns that a state agency or authority has proposed to take an Adverse Action against a required professional license, certification, or registration of an ACO Related Individual then, pending resolution of the Adverse Action, the ACO shall take all necessary steps as required by applicable law or regulation, and may remove the person from his or her current position, as deemed appropriate.

B. Documentation. The ACO shall document compliance with HE-003, consistent with the ACO's document retention policies but, in no case, for a period of less than ten years.

Policy Number:	**HE-004**
Subject:	**Hiring, Employment, and Contracting**
Policy/Procedure:	**Duty to Report Suspected Non-Compliance**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of HE-004 is to provide (1) a statement of the ACO's policy regarding the duty to report suspected non-compliance with the ACO's Compliance Plan, Code of Conduct Policies and Procedures, and applicable laws and regulations, and (2) procedures to ensure that the ACO's practices are consistent with its stated policy.

II. **Policy.** All ACO Related Individuals are expected to adhere to all applicable laws and regulations, as well as to the ACO's Compliance Plan, Code of Conduct and Policies and Procedures.

III. **Procedures.**

A. Duty to Report. Each ACO Related Individual is required, as a condition of participation, employment or engagement, to report any practice that the individual believes in good faith does or may violate the ACO's Compliance Plan Code of Conduct, Policies and Procedures, or applicable laws and regulations. The procedures for reporting suspected non-compliance are set forth in **CMO-002**

B. Responding to Reports. The procedures for responding to such reports of suspected non-compliance are set forth in **RCI-001** & **RCI-003** . RCI-004 sets forth the procedures for determining the appropriate corrective action and/or discipline for (1) ACO Related Individuals who violate applicable laws and regulations, the Compliance Plan, Code of Conduct, the ACO's Policies and Procedures, or other applicable ACO requirements, and (2) supervisors who fail to detect or report such compliance violations.

C. Documentation. The documentation requirements for reports of suspected non-compliance are set forth in **RCI-005** .

Policy Number:	**ET-001**
Subject:	**Education and Training**
Policy/Procedure:	**Introduction**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of the Education and Training (ET) Policies and Procedures is to ensure that all ACO Related Individuals understand the ACO's commitment to compliance and the objectives and requirements of the ACO's Compliance Program.

II. **Policy.** The ACO shall ensure that all ACO Related Individuals receive effective education and training, so that they understand (1) the ACO's commitment to compliance and the objectives and requirements of the ACO's Compliance Program, and (2) the important role that each individual plays in achieving Compliance Program objectives.

III. **Procedures.**

A. Participation. The ACO requires each ACO Related Individual to complete General Compliance Training upon hire or contracting, and annually thereafter.

1. All ACO Related Individuals are required to participate in the ACO's Compliance Training as a condition of employment, participation, or contracting with the ACO.

B. **Delivery.** The Compliance Training may be presented in any manner that the ACO Compliance Officer determines to be effective. This may include, for example, in-person classroom-based training, live Web-conference (Webinar) training, Web-based self-study, or teleconference training. If the ACO uses computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to individuals receiving such training.

1. Unless otherwise decided by the Compliance Officer as stated above, Keystone ACO Participants Organizations, Affiliates and Contractors will be provided with updated education from the ACO via Computer Based Training (CBT) or PowerPoint Presentation each year for distribution to employed provider /suppliers, and ACO Related Individuals. Each participating Participants Organization, Affiliate and Contractor are responsible for ensuring the distribution and education of their ACO Related Individuals upon hire and annually as updated

C. **Content Development, Implementation and Review.** The ACO Compliance Officer shall be responsible for developing, implementing, regularly reviewing (at least annually), and updating the Compliance Training. This training includes, at a minimum, information on the following areas:

1. Privacy and Security: Including HIPAA/HITECH privacy requirements, State level privacy considerations and ACO specific privacy concerns, such as additional privacy requirements found in the Data Use Agreement signed between the ACO and the Centers for Medicare and Medicaid Services.

2. Fraud, Waste and Abuse: Including applicable federal and state FWA laws and the waivers available to the ACO under the Medicare Shared Savings Program .

3. An overview of the ACO Compliance Program (with a focus on any modifications or additions since the previous Compliance Training);
4. The ACO's strong and continuing commitment to compliance with all applicable MSSP and federal health care program laws and regulations (with a focus on new legal and regulatory developments);
5. A discussion of the ACO Compliance Plan, Conflict of Interest, Code of Conduct, Marketing Material Guidelines and Policies and Procedures, the requirement that they be followed, and the consequences if they are not;
6. The importance of asking questions and seeking the guidance of the ACO Compliance Officer when in doubt about the propriety of a particular practice;
7. The duty to report any practice or activity that the individual suspects violates or may violate any laws, regulations, the Compliance Plan, Code of Conduct, or the ACO's Policies and Procedures;
8. The methods that can be used to communicate reports of any practice that the employee suspects violates, or may violate, any laws, regulations, the Compliance Plan, Code of Conduct, or the ACO's Policies and Procedures;
9. The ACO's policy of striving to protect the identity of individuals who report a practice that the individual suspects violates or may violate any laws, regulations, the Compliance Plan, Code of Conduct, or the ACO's Policies and Procedures; and
10. The ACO's policy of non-retaliation with respect to good faith reports of any practice that the individual suspects violates, or may violate, any laws, regulations, the Compliance Plan, Code of Conduct, or the ACO's Policies and Procedures (where the individual was not involved in the practice at issue).

D. **Questions.** Any questions concerning the ET Policies and Procedures, or questions that are not specifically addressed in the ET Policies and Procedures, should be directed to the ACO's Compliance Officer.

E. **Audit/Documentation.** The ACO shall audit and document compliance with the ET Policies and Procedures. Such audit shall be conducted pursuant to the CMO Policies and Procedures. Relevant documentation, which may include electronic documentation, shall be maintained in the Compliance Program files consistent with the ACO's document retention policies but, in no case, for a period of less than ten years. Documentation shall include:

1. All materials used in connection with the Compliance Training (e.g., course descriptions and course materials) (whether conducted as an in-house training program, an external workshop, or using computer-based training methods); and
2. Sign-in sheets, attendance records, certifications, and/or any other documents used to reflect and confirm participation in the Compliance Training.
3. All ACO Administrative employees and Board of Managers will receive training regarding this Compliance Plan and the requirements imposed on the ACO under the law. All new employees in organizations comprising this ACO will receive such training upon hire as assigned by their employing ACO contracted organization.

4. Contractors such as those providers/suppliers who have entered into a participation agreement will be provided with a copy of this Compliance Plan and will be contractually committed to adhering to applicable laws and regulations. Such contractors will, however, be deemed to have met the education and training standards of the ACO if they certify that they have met the fraud, waste and abuse certification requirements required for enrollment in the Medicare Program.
5. Participating organizations will ensure that it Keystone ACO workforce members complete required compliance education. Completion of compliance education will be documented in according with existing systems used by participating organizations.

Policy Number:	**ET-002**
Subject:	**Education and Training**
Policy/Procedure:	**Distribution of Compliance Plan, Code of Conduct and ACO Policies and Procedures and Related Certification**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of ET-002 is to establish (1) a policy for distributing the ACO's Compliance Plan Code of Conduct and Policies and Procedures and for encouraging understanding and compliance with these authorities, and (2) procedures to ensure that the ACO's practices are consistent with its stated policies.

II. **Policy.** The ACO shall make available the Compliance Plan, Code of Conduct and the ACO's Policies and Procedures to all ACO Related Individuals.

III. **Procedures.**

A. The ACO's Compliance Plan, Code of Conduct and Policies and Procedures shall be made available, electronically and/or in hard copy, to all ACO Related Individuals upon hire or contracting, and upon request thereafter.

B. Upon Contracting or updating, electronic or hard copies of the Keystone ACO Compliance Manual will be distributed to ACO participant Provider/Suppler sites, Board of Managers and ACO employees.

C. Documentation. Copies of all certifications executed in accordance with ET-002, whether hard copy or electronic, shall be maintained, consistent with the ACO's document retention policies but, in no case, for a period of less than ten years.

Policy Number:	**ET-003**
Subject:	**Education and Training**
Policy/Procedure:	**Compliance Communications**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of ET-003 is to provide (1) a statement of ACO's policies regarding the development and distribution of Compliance Communications, and (2) procedures to ensure that ACO Participants and Provider/Suppliers are consistent with its stated policies.

II. **Policy.** The ACO Compliance Officer shall develop and distribute Compliance Communications (as defined in **CPG-001**) that support the Compliance Program and educate ACO Related Individuals about compliance matters.

III. **Procedures.**

A. Preparation. The ACO Compliance Officer shall be responsible for the development and distribution of Compliance Communications, either published separately or as part of other outreach communications. Members of the Compliance Committee, as well as any other individuals, divisions, or segments that the ACO Compliance Officer deems appropriate, shall provide assistance.

B. Content.

1. Compliance Communications shall contain educational information that the ACO Compliance Officer deems appropriate to highlight the ACO Compliance Program and compliance-related issues, such as

    a. changes to ACO's Compliance Program, if any;

    b. issues identified by the ACO Compliance Officer and/or the Compliance Committee as relevant to highlight or discuss;

    c. upcoming compliance training and education programs; and

    d. the ACO's compliance resources (e.g., links to the on-line version of the Compliance Plan, Code of Conduct, and Policies and Procedures, and the phone number of the Confidential Compliance Reporting Tool for use in reporting suspected non-compliance.)

2. Compliance Communications may contain any other information relating to compliance that is deemed appropriate by the ACO Compliance Officer.

C. Distribution.

1. Compliance Communications shall be made available to all ACO Related Individuals, as appropriate. The ACO Compliance Officer shall determine which individuals should be included in the Compliance Communications.

2. The ACO may use any appropriate format and distribution method for the Compliance Communications (e.g., paper, e-mail, intranet, and/or inclusion with other newsletters published by the ACO).

3. Archived copies of the Compliance Communications shall be available upon request.

D. Documentation. The ACO shall maintain in its Compliance Program files copies (electronic or hard copy) of all Compliance Communications issued pursuant to this ET-003, consistent with its document retention policies but, in no case, for a period of less than ten years.

Policy Number:	**CMO-001**
Subject:	**Compliance Monitoring and Oversight**
Policy/Procedure:	**Introduction**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of the Compliance Monitoring and Oversight (CMO) Policies and Procedures is to identify how the ACO, through its ACO Compliance Officer, shall monitor, audit, and make reports regarding the ACO's compliance with laws, regulations, the Compliance Plan, Code of Conduct and the ACO's Policies and Procedures.

II. **Policy.** The ACO shall develop, implement, and maintain an ongoing monitoring and auditing function to ensure the effective implementation of its Compliance Program and compliance with applicable laws and regulations.

III. **Procedures.**

A. **General Methods of Compliance Monitoring.** The ACO has developed a multi-faceted approach to ensuring compliance, which includes day-to-day monitoring, and conducting regular compliance reviews and periodic compliance audits (both current and retrospective).

B. **Questions Related to CMO Policies and Procedures.** Any questions concerning the CMO Policies and Procedures, or questions that are not specifically addressed in the CMO Policies and Procedures, should be directed to the ACO's Compliance Officer.

C. **Audit and Documentation.** The ACO shall audit and document compliance with the CMO Policies and Procedures. Relevant documentation, which may include electronic documentation, shall be maintained in the Keystone ACO Shared Drive, consistent with the ACO document retention policies but, in no case, for a period of less than ten years.

D. **Reporting to Law Enforcement Agencies.** The ACO shall timely report probable violations of law to an appropriate law enforcement entity, such as the HHS-OIG or CMS.

1. The Compliance Officer will work with the ACO’s legal counsel to determine whether the facts of the investigation constitute a probable violation of law requiring the ACO to report to an appropriate law enforcement agency.

    a. The Compliance Officer will, when possible, notify and consult with the appropriate individuals within any relevant ACO Participant prior to completing the necessary reporting process.

    b. If the ACO Compliance Officer and legal counsel do not agree on whether or not the facts of the investigation constitute a probable violation of law requiring the ACO to report to an appropriate law enforcement agency, the issue shall immediately be taken to the ACO’s Board of Managers.

Policy Number:	**CMO-002**
Subject:	**Compliance Monitoring and Oversight**
Policy/Procedure:	**Reporting Suspected Non-Compliance**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of CMO-002 is to provide (1) a statement of the ACO's policy with respect to reporting suspected instances of non-compliance, and (2) procedures to ensure that the ACO's practices are consistent with its stated policies.

II. **Policy.** ACO Related Individuals are required to report any suspected noncompliance with applicable laws or regulations, the Compliance Plan, Code of Conduct, Policies and Procedures, and/or any other applicable ACO requirements. The ACO shall provide the necessary infrastructure to facilitate such reporting, including a confidential reporting line that allows such individuals to report suspected incidences of non-compliance anonymously and without fear of retaliation.

III. **Procedures.**

A. Reporting Suspicions of Non-Compliance

1. Reporting Required. ACO Related Individuals must report any activity, practice, or arrangement that the individual in good faith believes violates or may violate any laws or regulations, the ACO Compliance Plan, Code of Conduct, Policies and Procedures, or other applicable MSSP requirements.
2. Manner of Reporting. ACO Related Individuals are encouraged to report suspected Compliance Program violations in any of the following ways:

    a. To the ACO Compliance Officer; Open communication with the Compliance Officer whose duty it is to ensure total compliance by the ACO. Please feel free to contact the Compliance Officer directly with questions or concerns. It is the policy of the ACO that good faith participation in the compliance program including the reporting of any suspected noncompliance or other issue will not result in retaliation against the participant. Individuals shall not be intimidated or retaliated against in response to their good faith adherence to this compliance program.

    b. To the individual's direct supervisor or another member of the ACO leadership (if this individual alone receives a report of a suspected Compliance Program violation, he/she must immediately report the suspected Compliance Program violations to the ACO Compliance Officer);

    c. To the Compliance web reporting form at http://www.mycompliancereport.com enter the company code KAC when prompted; and/or

    d. To the Confidential Compliance Hotline; (855-387-4424) by which any person (including any employee, member, manager or contractor) may report any issue on an anonymous basis.

        1. Individuals are encouraged to identify themselves when reporting, as it often is easier to assess the issues or concerns raised in a report

when there is the ability to ask the reporting individual follow-up questions. At no time with the individual been pressured or threatened to reveal themselves.

e. Each participating provider office must have on display in a common employee area the compliance hotline number and information on how to report a suspected violation

3. Form of Report.

   a. Reports of suspected Compliance Program violations may be made either in writing or orally.

   b. Written reports include reports made via regular mail or e-mail and sent to any of the individuals or locations listed in **Section III.A.2** above.

   c. Oral reports include, reports made in-person or via telephone. Oral reports may be made to the ACO's Confidential Compliance Reporting Tool, which shall be available Individuals do not need to provide their name when making a report, although they are encouraged to do so to facilitate any appropriate or necessary follow-up.

4. Anonymity. Reports (whether written or oral) may be made anonymously.

B. Documentation.

1. The ACO Compliance Officer, or his/her designee, shall maintain copies of any written reports submitted pursuant to **CMO-002** in the Compliance Program files, which include electronic files.

2. The ACO Compliance Officer, or his/her designee, shall document any oral reports submitted concerning suspected Compliance Program violations, and shall maintain such documentation in the Compliance Program files, which include electronic files.

3. Final copies of work papers, notes, and other documentation generated in connection with every written or verbal report submitted concerning suspected incidences of non-compliance shall be maintained in the Compliance Program files, which include electronic files.

4. The ACO Compliance Officer shall document follow-up action taken as a result of any reports submitted concerning suspected Compliance Program violations, and shall maintain related documentation in the Compliance Program files, which include electronic files, pursuant to **RCI-003** .

5. The ACO Compliance Officer shall, pursuant to **RCI-002**, keep confidential (to the extent possible) the identity of the person(s) who report suspected Compliance Program violations.

C. The ACO Compliance Officer shall inform the ACO Board of Managers as part of his or her regular reporting obligations, regarding any action taken in response to reported Compliance Program violations that have been verified through investigation pursuant to **RCI-003** to be compliance violations.

D. All documentation enumerated above, which may include electronic documentation, shall be maintained in the Compliance Program files, consistent with the ACO's document retention policies but, in no case, for a period of less than ten years.

Policy Number:	**CMO-003**
Subject:	**Compliance Monitoring and Oversight**
Policy/Procedure:	**Annual Compliance Reviews**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of CMO-003 is to provide (1) a statement of the ACO's policy with respect to conducting Annual Compliance Reviews of the Compliance Program, and (2) procedures to ensure that the ACO's practices are consistent with its stated policies.

II. **Policy.** The ACO shall conduct Annual Compliance Reviews of its Compliance Program to ensure that the Compliance Program is effective and that the ACO's business practices are consistent with its stated policies, and applicable laws and regulations.

III. **Procedures.**

A. Compliance Program Reviews.

1. Subject Matter Areas. The ACO Compliance Officer (with, as appropriate, the assistance of outside independent review consultants and counsel) shall develop a protocol for performing annual reviews of the Compliance Program. This protocol shall provide for reviews of at least the following areas:

a. Compliance with the following requirements of the MSSP in relation to the ACO's Compliance Program:

1. Identification of a designated compliance official or individual who is not legal counsel to the ACO and reports directly to the ACO's Board of Managers
2. Creation of mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance;
3. Development of a method for ACO Related Individuals to anonymously report suspected problems related to the ACO to the ACO Compliance Officer;
4. Completion of Compliance training for ACO Related Individuals; and
5. The requirement for the ACO to report probable violations of law to an appropriate law enforcement agency.

b. To the extent not covered above, any federal health care program risk areas that the ACO Compliance Officer determines, in his or her discretion, warrants review as part of the Annual Compliance Review process.

B. **Technique.** The protocol developed by the ACO Compliance Officer shall be based on available resources and the type of issue under review.

C. **Review Assistance.** The Annual Compliance Review shall be conducted under the supervision of the ACO Compliance Officer (with assistance of ACO Administrative Staff, the ACO compliance committee outside, independent review consultants and counsel, as necessary). In addition to, or in lieu of, internal reviewers, outside

independent review consultants and/or counsel may be used to assist in the Annual Compliance Review, where either the ACO Compliance Officer or the Compliance Committee determines that such assistance is necessary or appropriate.

D. **Reviewer Qualifications and Independence.**

1. The entity or individual(s) conducting the Annual Compliance Review (whether internal or external) shall be independent insofar as they must be able to review the ACO's practices and procedures and make objective, independent determinations as to the accuracy or effectiveness of those practices or procedures.
2. The reviewers shall have the qualifications and experience necessary to adequately identify potential issues related to the subject they are reviewing.
3. The reviewers shall have access to the resources and information necessary to conduct the Annual Compliance Review, including access to documents and ACO Related Individuals.

E. Documentation.

1. The reviewers shall prepare a report of their findings, which may include recommendations, suggestions, and/or any corrective actions to achieve compliance with the Compliance Plan, Code of Conduct and Policies and Procedures. This report shall be provided to the ACO Compliance Officer, who shall review and revise the report, as necessary. The ACO Compliance Officer shall then report on the Annual Compliance Review to the ACO Chief Administrative Officer and the Board of Managers as part of his or her regular reporting obligations.
2. Final copies of work papers, notes, and other documentation generated in connection with every Annual Compliance Review, and the findings and conclusions thereof, shall be maintained in the Compliance Program files, consistent with the ACO's document retention policies but, in no case, for a period of less than ten years.

    a. CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies Keystone ACO at least 30 days before the normal disposition date; or

    b. There has been a termination, dispute or allegation of fraud or similar fault against Keystone ACO, its members, partners, participants, participant employees, managers and contractors or other individuals performing services or functions related to Keystone ACO activities. In this case, Keystone ACO must retain its records for an additional 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

Policy Number:	**RCI-001**
Subject:	**Responding to Compliance Issues**
Policy/Procedure:	**Reports of Suspected Compliance Program Violations: Confidentiality**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of RCI-001 is to provide (1) a statement of the ACO's policy with respect to the confidentiality of reports of suspected non-compliance, and (2) procedures to ensure that ACO's practices are consistent with its stated policies.

II. **Policy.** ACO Related Individuals are required to report any suspected noncompliance with applicable laws or regulations, the ACO Compliance Plan, Code of Conduct, Policies and Procedures, other applicable ACO requirements. The ACO shall provide the necessary infrastructure to facilitate such reporting, including a Confidential Compliance Reporting Tool (pursuant to **CMO-002**) that allows individuals to report suspected non-compliance anonymously and without fear of retaliation.

III. **Procedures.**

A. **Response to Report.** Where an individual has made a good faith report of an activity or practice that the individual believes violates or may violate applicable laws or regulations, the Compliance Plan, Code of Conduct, Policies and Procedures, or other applicable ACO requirements, the ACO Compliance Officer shall:

1. Communicate the ACO's appreciation to the individual for making the report, as appropriate;
2. Strive to keep the identity of the reporting individual confidential; and
3. Inform the reporting individual (if known) that there may come a point in time where his or her identity may become known or may have to be revealed (e.g., if government authorities become involved in the investigation).
4. If at any time the reporting individual's name needs to be provided to other authorities for the investigation purposes, the Compliance Officer will notify the reporter prior to the release of their name.

B. **Documentation.** The ACO shall document compliance with **RCI-001.** Such documentation, which may include electronic documentation, shall be maintained in the ACO's Compliance Program files consistent with its document retention policies but, in no case, for a period of less than ten years.

C. Beneficiary Complaints and Grievances. Patient grievances will be investigated and resolved within five (5) calendar days of the filing date, unless the nature of the grievance requires additional time. If additional time is required, the responsible care manager or Keystone ACO staff member will notify the patient, employee, contractor of the Keystone ACO, Keystone ACO participants, Keystone ACO providers/suppliers and other individuals or entities no later than five calendar days after the filing date and provide the grievance filer with a date on which a response can be expected.

1. No patient, employee, contractor of the Keystone ACO, Keystone ACO participants, Keystone ACO providers/suppliers and other individuals or entities will be retaliated against or have their care impacted because they filed a complaint or grievance
2. If the patient's care is managed by a provider practice, the patient will follow that practice's complaint and grievance process.
3. Local or embedded care managers or Keystone ACO staff will assist patients with the grievance process applicable to the provider's practice.
4. Patients who have a concern may call 855-387-4424 (24/7) to report their concerns confidentially. Patients should state they have a concern related to the management of their care and provide details relating to their concern, including:
    1. Their contact information for follow-up and resolution;
    2. Where the care was received;
    3. The name of the provider who gave the service;
    4. When the service was received;
    5. A description of why the patient is dissatisfied with his or her service.
5. The Director of Operations or designee will contact patients to resolve their concerns.
6. Patients may choose to anonymously report their concerns; however, if not enough information is provided, our ability to effectively investigate a concern may be impacted.
7. The Director of Operations will document resolution of patient concerns and share these concerns with the ACO's Quality and Safety Committee and the Chief Compliance Officer. Such documentation will be maintained for a period of 10 years from the date of resolution.

D. Expedited Grievances. All expedited grievances will be resolved within 24 hours.

1. An expedited grievance includes a verbal or written complaint from a patient regarding a clinical issue of such an urgent nature that a delay in the review process might seriously jeopardize:
    a. An issue that poses an interruption in the ongoing immediate treatment and care of the patient.
    b. The member's ability to regain maximum functioning; or
    c. The life and/or health of the patient;
2. Examples of expedited grievances may include, but are not limited to:
    a. Patient is having pain and cannot reach the provider's office;
    b. Patient is unable to reach the provider's office to schedule an urgent appointment.
    c. Patient is out of medication due to a delay in delivery of medication;

3. All written complaints, and those verbal complaints alleging a serious concern, will be reported to the Director of Operations. The Director of Operations and/or the Quality and Safety Committee will provide direction and oversight for the resolution of such complaints.

Policy Number:	**RCI-002**
Subject:	**Responding to Compliance Issues**
Policy/Procedure:	**Reports of Suspected Compliance Program Violations: Non-Retaliation**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of RCI-002 is to provide (1) a statement of the ACO's policy regarding non-retaliation with respect to reports of suspected non-compliance, and (2) procedures to ensure that the ACO's practices are consistent with its stated policies.

II. **Policy.** ACO Related Individuals are required to report any suspected noncompliance with applicable laws and regulations, the Compliance Plan, Code of Conduct, Policies and Procedures, or other applicable ACO requirements. Individuals submitting such reports of noncompliance in good faith shall not be subject to retaliation or any form of harassment.

III. **Procedures.**

A. **General Rule.** When an individual has made a report (internally or externally) of an activity, practice, or arrangement that the individual in good faith believes violates or may violate laws or regulations, the ACO's Compliance Plan, Code of Conduct, Policies and Procedures, or other applicable ACO requirements:

1. The ACO shall in no way impede, prohibit, or dissuade the individual from reporting a suspected Compliance Program violations;
2. The ACO shall not retaliate or engage in retribution (including discharge, demotion, suspension, denial of promotion, or discrimination) against, or otherwise harass in any manner, the individual for making a report, provided such report was made in good faith and the individual was not involved in the misconduct at issue;
3. The ACO Compliance Officer periodically will make appropriate inquiry to determine whether those who report suspected Compliance Program violations were victims of retaliation conduct;
4. Any ACO Related Individual who is involved in any act of retaliation, retribution, or any form of harassment - either committing the act or condoning it - against a person who reports a compliance concern will be subject to disciplinary action, up to and including termination of participation in the ACO.

B. Self-Disclosure of Participation in Non-Compliance.

1. Notwithstanding its commitment not to retaliate for reporting known or suspected Compliance Program violations, the ACO shall take appropriate corrective and/or disciplinary action against any individual who violates the ACO's Compliance Plan, Policies and Procedures, Code of Conduct, or applicable laws or regulations, regardless of whether that individual reported such violation.

2. As set forth in **RCI-004,** however, the fact that the individual reported his or her own misconduct - and the truthfulness and completeness of that self-disclosure - may be a mitigating factor in determining the severity of any corrective and/or disciplinary action.
3. No corrective and/or disciplinary action shall be taken against any individual who mistakenly reported what he or she reasonably and in good faith believed to be an act of non-compliance or a Compliance Program violation. However, an individual may be subject to corrective and/or disciplinary action if it is determined that the report of wrongdoing or suspected Compliance Program violation was not made in good faith (e.g., was knowingly fabricated, distorted, exaggerated, or minimized in order to injure someone else, protect himself/herself, or for any other reason).
4. Any ACO Related Individual who misuses the Confidential Compliance Reporting Tool or attempts to interfere with efforts to investigate or address a possible compliance issue is subject to corrective and/or disciplinary action, up to and including termination of participation in the ACO.

C. **Documentation.** The ACO shall document compliance with RCI-002 and maintain such documentation consistent with the ACO's document retention policies but, in no case, for a period of less than ten years.

Policy Number:	**RCI-003**
Subject:	**Responding to Compliance Issues**
Policy/Procedure:	**Reports of Suspected Compliance Program Violations: Investigation**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of RCI-003 is to provide (1) a statement of the ACO's policy with respect to its investigation of reports of suspected non-compliance, and (2) procedures to ensure that the ACO's practices are consistent with its stated policies.

II. **Policy.** The ACO shall appropriately investigate reports of any suspected noncompliance with applicable laws or regulations, the Compliance Plan, Code of Conduct, Policies and Procedures, or other applicable ACO requirements, and document the findings of those investigations.

III. **Procedures.**

A. Preliminary Evaluation.

1. Upon receipt of a report concerning a compliance-related review, a Confidential Compliance Reporting Tool report, or other information suggesting a possible compliance issue, the ACO Compliance Officer (or his/her designee) shall record the information in the Compliance Log (as set forth in **RCI-005)**.
2. The ACO Compliance Officer (or his/her designee) must (a) make a preliminary, good faith inquiry into all reported allegations of non-compliance with applicable laws or regulations, the Compliance Plan, Code of Conduct, Policies and Procedures, or other applicable ACO requirements, and (b) determine whether further review is necessary. If the ACO Compliance Officer determines that no additional review is necessary, this decision shall be documented (with a brief explanation for the determination) in the Compliance Log.
3. For any disclosure that is sufficiently specific so that it (a) reasonably permits a determination of the appropriateness of the alleged improper practice, and (b) provides an opportunity for taking corrective action, the ACO Compliance Officer shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted, as set forth below.

B. Investigators.

1. The internal investigation of suspected non-compliance shall be initiated and overseen by the ACO Compliance Officer. The ACO Director of Operations and /or Compliance Committee shall be available to provide assistance to the ACO Compliance Officer, as needed.
2. Depending on the nature and severity of the suspected non-compliance, the ACO Compliance Officer may utilize outside legal counsel to assist in conducting an internal investigation.

C. **Investigation.** In conducting an internal investigation, investigators for the ACO shall, as necessary:

1. take steps to secure, and prevent the destruction of, documents and other evidence relevant to the investigation;
2. review relevant documents;
3. review all applicable policies, procedures, laws, and regulations;
4. interview persons with relevant information; and
5. take all reasonable and necessary steps to stop any ongoing misconduct.

D. Documentation.

1. Upon conclusion of the investigation, written documentation will be prepared by the ACO Compliance Officer (or his/her designee) that includes:
    a. the nature of the problem;
    b. the investigation scope and procedures;
    c. consistent with policy, the identity of the persons involved and the degree of culpability of said individuals; and
    d. any findings and recommended corrective actions, discipline, or programmatic corrections.
2. The ACO shall maintain written reports, copies of any work papers, interview notes, and any other key documents related to the investigation in Compliance Program files, consistent with the ACO's document retention policy but, in no case, for a period of less than ten years.
3. In connection with any internal investigation, the ACO shall maintain in a confidential and secure fashion any documents, whether electronic or hard copy, that are attorney-client communications or covered by the attorney work-product privilege. Any such documents should be appropriately labeled or stamped as attorney-client privileged or attorney work product and maintained consistent with the ACO's document retention policy but, in no case, for a period of less than ten years. However, failure to label such documents in this manner will not mean the documents are not protected under the attorney-client privilege or attorney work-product doctrine.

Policy Number:	**RCI-004**
Subject:	**Responding to Compliance Issues**
Policy/Procedure:	**Corrective and/or Disciplinary Action and Programmatic Corrections**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of RCI-004 is to provide (1) a statement of the ACO's policy governing corrective and disciplinary actions taken in response to identified non-compliance, as well as programmatic corrective actions, and (2) procedures to ensure that the ACO's practices are consistent with its stated policies.

II. **Policy.** The ACO shall take appropriate and consistent corrective action to address both programmatic deficiencies in its Compliance Program and instances of noncompliance by ACO Related Individuals. Any individual violating the ACO's Compliance Plan, Policies and Procedures, Code of Conduct, applicable laws or regulations, or other applicable ACO requirements shall be subject to discipline, as relevant and appropriate, up to and including termination.

III. **Procedures.**

A. Programmatic Corrective Actions. The ACO shall take appropriate action to correct internal operational or programmatic deficiencies that are identified by the ACO Compliance Officer in connection with the report prepared pursuant to **RCI-003** .

1. If the violation involves an ongoing activity or practice, then (a) the activity or practice shall be stopped, and (b) legal counsel shall be notified of the violation.
2. If the same or a similar violation could or might be prevented in the future by making changes to the ACO Policies and Procedures, Code of Conduct, or otherwise, such changes shall be considered, developed, instituted, and promptly communicated to all affected individuals.
3. In developing and implementing programmatic corrective actions, the ACO may consider and employ any other appropriate corrective action that may be needed.

B. Corrective Action and/or Disciplinary Action.

1. Any ACO Related Individual who has violated any applicable laws or regulation, the Compliance Plan, Code of Conduct, Policies and Procedures, and/or other applicable ACO requirements shall be subject to a corrective action plan and/or disciplined, as appropriate.
2. The ACO also may take corrective action and/or disciplinary action against individuals who fail to detect or report non-compliance on the part of individuals under their supervision. Failure to detect non-compliance means that the individual knew or reasonably should have known about the non-compliance, but failed to identify the relevant conduct as potentially violative of applicable laws or regulations, the Compliance Plan, Code of Conduct, Policies or Procedures and /or other applicable ACO requirements.

3. Corrective and/or disciplinary action of ACO Related Individuals may take one or more of the following forms:

    a. Compliance with all applicable laws and regulations is a requirement for all members, partners, participants, participant employees, managers and contractors. In addition, all are expected to adhere to the Code of Conduct and to follow the principles of this Compliance Plan. Also, as noted above, it is an expectation of all that they report compliance issues and identify noncompliance or unethical behavior. Failure to comply with this requirement can result in disciplinary actions.

    b. The type and severity of the action will depend on the particular facts and circumstances but
    serious deviations from these requirements can result in:

        1. termination of a participant from the ACO, termination of employment of an employee and possible termination of the relationship with a contractor.

        2. it is the policy of the ACO that it will institute timely, consistent and effective enforcement of the standards described in this Compliance Plan

4. When corrective and/or disciplinary action is appropriate, the severity of the action will depend on a variety of factors, including, but not limited to:

    a. The nature and severity of the violation

    b. Whether the violation was committed intentionally, recklessly, negligently, or accidentally;

    c. Whether the individual had previously violated any laws, regulations, the Compliance Plan, Code of Conduct, or Policies and Procedures;

    d. Whether the individual self-reported his or her non-compliance; and

    e. Whether (and the extent to which) the individual cooperated with the ACO in connection with its investigation of the non-compliance.

5. The determination of the appropriate disciplinary action for compliance or legal obligations will be made by the ACO Compliance Officer, in consultation with the ACO Chief Administrative Officer, the Compliance Committee
and the individual's supervisor, as appropriate.

C. Disclosure; Restitution.

1. If the ACO Compliance Officer believes that there has been a probable violation of applicable laws or regulations, the Compliance Plan, Code of Conduct, Policies and Procedures, or other applicable ACO requirements, the ACO shall determine whether the Company should:

    a. make a report to appropriate government authorities (including making a report to the HHS-OIG; and/or

    b. make a payment of any kind to the government or other entity or person (if a program overpayment has been determined); and/or

c. perform other types of remedial action (including disciplinary action). In making such a determination, the ACO may consult with outside counsel, as appropriate.

D. **Continual Monitoring and Follow-up Audits.** Any issue for which corrective action is taken, will be targeted for monitoring and reviewed in future audits of that division or segment, pursuant to **CMO-003.** Pertinent information learned during investigations will be incorporated into division/segment education and training, as appropriate.

E. **Documentation.** The ACO shall document any corrective and/or disciplinary actions taken pursuant to **RCI-004** and maintain such documentation, which may include electronic documentation, in the Compliance Program files consistent with its document retention policies but, in no case, for a period of less than ten years.

Policy Number:	**RCI-005**
Subject:	**Responding to Compliance Issues**
Policy/Procedure:	**Compliance Log**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of RCI-005 is to outline required maintenance of the Compliance Log (as defined in **CPG-001**).

II. **Policy.** It is the ACO's policy to respond to all compliance matters brought to the ACO Compliance Officer's attention and to maintain a Compliance Log of such matters. The Compliance Log is a record summary of compliance disclosures and shall be maintained by the ACO Compliance Officer (or his or her designee) in accordance with this Policy.

III. **Procedure.**

A. As set forth in **CMO-002,** the ACO provides ACO Related Individuals with various avenues to report any activity, practice, or arrangement that such individual believes, in good faith, violates or may violate any laws or regulations or the ACO's Compliance Plan, Code of Conduct, or Policies and Procedures.

B. The ACO Compliance Officer (or his/her designee) must maintain a Compliance Log of all suspected compliance violations, including, but not limited to, reports made in-person, via e-mail or other written form, or through the Confidential Compliance Reporting Tool.

C. The Compliance Log should, at a minimum, include for each suspected compliance violation the following:

1. The manner in which the suspected compliance violation was brought to the ACO's attention;
2. If applicable and known, the name of the person reporting the suspected compliance violation;
3. The names of all persons involved in the suspected compliance violation, to the extent such information is known;
4. A summary of the suspected compliance violation, including, but not limited to, the nature and type of allegation(s) made;
5. The results of any investigations;
6. Any notations regarding continued monitoring, if applicable;
7. A description of any corrective (or other) actions taken in response to the reported suspected compliance violation; and
8. The status of the suspected compliance violation, as updated from time-to-time to reflect current information.

D. The ACO Compliance Officer, or his/her designee, shall maintain all relevant documents and notes related to each Compliance Log entry, in accordance with the ACO's document retention policies but, in no case, for a period of less than ten years.

IV. **Documentation.** The ACO shall document compliance with **RCI-005.** Such documentation, which may include electronic documentation, shall be maintained in the ACO's Compliance Program files consistent with its document retention policies but, in no case, for a period of less than ten years.

1. CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies Keystone ACO at least 30 days before the normal disposition date; or
2. There has been a termination, dispute or allegation of fraud or similar fault against Keystone ACO, its members, partners, participants, participant employees, managers and contractors or other individuals performing services or functions related to Keystone ACO activities. In this case, Keystone ACO must retain its records for an additional 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

Policy Number:	**DRP-001**
Subject:	**Development, Revision, and Approval of Code of Conduct and ACO Policies and Procedures**
Policy/Procedure:	**Development of New Policies and Procedures**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of DRP-001 is to provide (1) a statement of the ACO's policy regarding the development of the ACO Policies and Procedures, and (2) procedures to ensure that the ACO's practices are consistent with its stated policies.

II. **Policy.** The ACO shall develop new Policies and Procedures as necessary in response to updates or changes to applicable laws, regulations and/or guidance, identification of compliance issues related to ACO Operations, or new processes implemented within the ACO.

III. **Procedures.**

A. Development of New Policies and Procedures.

1. New Policies and Procedures are developed by the relevant operational area or division of the ACO, in conjunction with the Compliance Officer.
2. In developing such Policies and Procedures, the Operational Leaders and ACO Compliance Officer shall consider (and incorporate):
    a. topics and standards designed to foster and maintain high ethical standards and fair and honest conduct.
    b. compliance guidance issued by HHS-OIG as fundamental to an effective ACO Compliance Program, as well as other authoritative sources of compliance guidance, such as the Federal Sentencing Guidelines.
3. The Policies and Procedures shall address any "risk" areas that are deemed relevant and appropriate to address by the ACO Compliance Officer, in conjunction with the Compliance Committee, in light of the ACO's business operations. In determining appropriate risk areas to address, the ACO Compliance Officer and the Compliance Committee shall consider any relevant CMS and HHS-OIG compliance program guidance, reports, and/or settlements, as well as any relevant "risk" areas identified by other agencies of federal or state government.
4. All Policies and Procedures should be clear and concise and follow the same general format.
5. New Policies and Procedures shall be discussed with the appropriate persons in the affected division(s).
6. Once developed, Policies and Procedures must be approved as set forth in **DRP-003.**

B. **Documentation.** The ACO shall document compliance with **DRP-001.** Such documentation, which may include electronic documentation, shall be maintained in the ACO's Compliance Program files consistent with its document retention policies but, in no case, for a period of less than ten years.

Policy Number:	**DRP-002**
Subject:	**Development, Revision, and Approval of Code of Conduct and ACO Policies and Procedures**
Policy/Procedure:	**Review and Revision of Existing Compliance Plan, Code of Conduct and Policies and Procedures**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of DRP-002 is to provide (1) a statement of the ACO's policies regarding the review and revision of the existing Compliance Plan, Code of Conduct and Policies and Procedures implementing the ACO's Compliance Program, and (2) procedures to ensure that the ACO's practices are consistent with its stated policies.

II. **Policy.** The ACO shall periodically, but no less than annually, review and revise, as appropriate, existing Compliance Program Documents, including the Compliance Plan, Code of Conduct and Policies and Procedures to ensure consistency of its practices with applicable laws and regulations.

III. **Procedures.**

A. Review of Compliance Plan, Code of Conduct and the ACOs Policies and Procedures.

1. The ACO Compliance Officer, in conjunction with the Compliance Committee and appropriate ACO Operational Leadership, shall review the Compliance Plan, Code of Conduct and all Policies and Procedures as necessary, but, at a minimum, once every twelve (12) months.
2. The ACO Compliance Officer shall modify and amend the Compliance Plan, Code of Conduct and/or Policies and Procedures, as appropriate, to reflect: (1) changes to the MSSP statute, regulation, or other program requirements; (2) changes in the nature or scope of the ACO's business (including the ACO's contractual obligations); and (3) indications that existing Policies or Procedures have been ineffective in preventing compliance violations or that new or additional Policies and Procedures would be more effective in preventing or avoiding the recurrence of misconduct.
    a. When updating operational policies and procedures, the Compliance Officer shall work with appropriate business owners and ACO Operational Leadership to ensure the effectiveness of edits made.
3. Where appropriate, the ACO Compliance Officer, in conjunction with the Compliance Committee and appropriate ACO Operational Leadership, shall propose revisions to the Compliance Plan, Code of Conduct and/or Policies and Procedures.
4. Proposed revisions shall be discussed with appropriate persons in the affected department(s).
5. Any revisions must be approved pursuant to **DRP-003.**

B. **Documentation.** The ACO Compliance Officer shall maintain copies in the Compliance Program files of all versions of the Compliance Plan, Code of Conduct and Policies and Procedures, consistent with the ACO's document retention policies but, in no case, for a period of less than ten years.

Policy Number:	**DRP-003**
Subject:	**Development, Revision, and Approval of Code of Conduct and ACO Policies and Procedures**
Policy/Procedure:	**Approval of New or Revised Compliance Plan, Code of Conduct and Policies and Procedures**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of DRP-003 is to provide (1) a statement of the ACO's policies regarding the approval of new and revised Compliance Program documents, including the Compliance Plan, Code of Conduct and Policies and Procedures, and (2) set forth procedures to ensure that the ACO's practices are consistent with its stated policies.

II. **Policy.** The ACO shall approve its Compliance Plan, Code of Conduct and Policies and Procedures developed pursuant to the Compliance Program to ensure consistency of its practices with applicable laws and regulations.

III. **Procedures.**

A. Approval of New/Revised Compliance Plan, Code of Conduct and Policies and Procedures.

1. Revisions to the Compliance Plan and Code of Conduct must be approved by the ACO Compliance Officer and the Compliance Committee
2. Revisions to existing Policies and Procedures may be made and implemented based on the approval of the Compliance Officer, as awaiting approval by the Board of Managers and/or Compliance Committee can lead to significant delays in ACO operational practices. Policies and Procedures are reviewed by the Compliance Committee annually.

B. **Documentation.** The ACO Compliance Officer shall maintain copies in the Compliance Program files of the approval required in Section III.A above, consistent with the ACO's document retention policies but, in no case, for a period of less than ten years.

Policy Number:	**DRP-004**
Subject:	**Development, Revision, and Approval of Code of Conduct and ACO Policies and Procedures**
Policy/Procedure:	**Retiring Policies and Procedures**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of DRP-004 is to provide (1) a statement of the ACO's policy regarding retiring Policies and Procedures implementing the ACO's Compliance Program, and (2) procedures to ensure that the ACO's practices are consistent with its stated policies.

II. **Policy.** The ACO shall retire its Policies and Procedures in a manner that ensures consistency of practices with applicable laws and regulations.

III. **Procedures.**

A. Retiring Policies and Procedures.

1. The ACO Compliance Officer, a member of the Board of Managers, Compliance Committee, and/or any ACO Related Individual may propose that a Policy and Procedure be retired.
2. In order for a Policy and Procedure to be retired, the ACO Compliance Officer and any appropriate Operational Leaders, must concur that the Policy and Procedure has become obsolete.
3. Retired Policies and Procedures shall not be destroyed, but shall be removed from current distribution and appropriately archived in the Compliance Program files consistent with the ACO's document retention policies but, in no case, for a period of less than ten years.
4. All ACO Related Individuals shall be notified when a Policy and Procedure is retired. If a new Policy and Procedure is put in its place, such document will be disseminated pursuant to **DRP-005.**

B. **Documentation.** The ACO shall document compliance with DRP-004. Such documentation, which may include electronic documentation, shall be maintained in the ACO's Compliance Program files consistent with its document retention policies but, in no case, for a period of less than ten years.

Policy Number:	**DRP-005**
Subject:	**Development, Revision, and Approval of Code of Conduct and ACO Policies and Procedures**
Policy/Procedure:	**Dissemination of New or Revised Compliance Plan, Code of Conduct and Policies and Procedures**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of DRP-005 is to provide (1) a statement of the ACO's policy regarding dissemination of new or revised Compliance Program Documents including the Compliance Plan, Code of Conduct and Policies and Procedures, and (2) procedures to ensure that the ACO's practices are consistent with its stated policies.

II. **Policy.** The ACO shall disseminate its Compliance Plan, Code of Conduct and Policies and Procedures to all ACO Related Individuals in a manner that ensures consistency of its practices with applicable laws and regulations.

III. **Procedures.**

A. Dissemination of New/Revised Compliance Plan, Code of Conduct and Policies and Procedures. The ACO shall disseminate any new or revised Compliance Plan, Code of Conduct and/or the ACO's Policies and Procedures pursuant to **ET-002** , electronically or by hard copy, within 30 calendar days of approval.

B. **Documentation.** The ACO shall document compliance with DRP-005. Such documentation, which may include electronic documentation, shall be maintained in the ACO's Compliance Program files consistent with its document retention policies but, in no case, for a period of less than ten years.

Policy Number:	**DRP-006**
Subject:	**Development, Revision, and Approval of Code of Conduct and ACO Policies and Procedures**
Policy/Procedure:	**Record Retention**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of DRP-006 is to provide a statement of the ACO's record retention policy.

II. **Policy.** It is the policy of the ACO to maintain all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, investigation, and inspection of the ACO's compliance with program requirements as required by the Medicare Shared Savings Program Final Rule.

III. **Procedures.**

A. The ACO requires all ACO Related Individuals to maintain all books, contracts, records, documents and other evidence (including data related to Medicare utilization and costs, quality performance measures, shared savings distributions and other financial arrangements related to ACO activities) sufficient to enable the audit, evaluation, inspection, or investigation of the ACO's compliance with the Medicare Shared Savings Program Final Rule, the agreement signed with the Centers for Medicare and Medicaid Services (CMS), the quality of services furnished to Beneficiaries, the ACO's right to and distribution of Shared Savings.

B. Each ACO Participant is responsible for maintaining the records associated with their practice. The ACO is responsible for maintaining the records of the ACO’s activities, including records regarding the scope of outcomes-based contracts held by the ACO and/or its Participants with non-Medicare purchasers.

1. The ACO shall maintain, and shall require Participants and Preferred Providers to maintain, records of all remuneration paid or received pursuant to participation in the ACO

C. CMS, DHHS, the Comptroller General, the Federal Government or their designees have the right to audit, inspect, investigate and evaluate any books, contracts, records, documents and other evidence of the ACO and any ACO Related Individual, in accordance with the Medicare Shared Savings Program Final Rule.

D. **Documentation.** All such books, contracts, records, documents and other evidence must be maintained for a period of 10 years from the final date of the agreement period or from the date of completion of any audit, evaluation or inspection, whichever is later, unless:

1. CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the ACO at least 30 calendar days before the normal disposition date; or

2. There has been a termination, dispute or allegation of fraud or similar fault against the ACO or an ACO Related Individual, in which case the ACO must retain records for an additional 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

Policy Number:	**COM-001**
Subject:	**ACO Communications**
Policy/Procedure:	**ACO Communications and Material Review**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of COM-001 is to identify the ACO's policy around communications outside of the ACO, as well as the approval process to ensure compliance with CMS requirements related to Marketing Materials as defined in the Medicare Shared Savings Program Final Rule.

II. **Policy.** It is the policy of the ACO to ensure that all general audience materials are compliant with any relevant regulatory requirements, and accurately reflect the opinions, position, and strategy of the ACO.

III. **Procedures.**

A. The ACO does not use and prohibits ACO Related Individuals from using ACO Related Marketing Materials or Activities until reviewed and approved in their entirety by the ACO Chief Administrative Officer and/or the Director of Operations.

1. Marketing Materials or Activities include, but are not limited to, general audience materials such as brochures, advertisements, outreach events, letters, web pages, mailings, social media, or other activities conducted by or on behalf of the ACO or its Participants or Providers/Suppliers, when used to educate, notify, or contact Beneficiaries or providers/suppliers regarding the Medicare Shared Savings Program

B. ACO Related Communications. Only certain specified individuals are authorized to communicate official ACO policy or to make any public statement on behalf of the ACO.

1. A "public statement" is defined as any statement made to anyone other than a person receiving care from a Participant or Provider/Supplier, whether such statement is made orally, in writing, via email or other electronic communication or through social media.

a. A "public statement" does not include any complaint or report made in good to any government agency or law enforcement personnel.

2. For purposes of this policy, "social media" includes all means of communicating or posting information or content of any sort on the Internet, including to one's own or someone else's web log or blog, journal or diary, personal website, social networking or affinity website, web bulletin board or chat room, whether or not associated or affiliated with the ACO.

3. Only the Chair and Vice Chair of the Board of Managers, and the of the ACO are authorized to make public statements on behalf of the ACO. No other individuals are authorized to make such statements.

4. All requests for public statements on behalf of the ACO, and all opportunities or responsibilities to make public statements on behalf of the ACO, should be referred to one of the above listed individuals.

C. The ACO Chief Administrative Officer and/or the Director of Operations will review any materials to be used as a public statement and, if necessary, submit it to CMS via the ACO-MS Marketing portal for review for compliance within the MSSP regulations. Depending on the subject matter, ACO Board of Managers Approval may also be requested before releasing for publication.

D. Any materials which meet the definition of ACO Related Marketing Materials or Activities, will be submitted to the Centers for Medicare and Medicaid Services (CMS) in accordance with the requirements of the MSSP Final Rule.

1. Any changes to existing materials will trigger an additional review by ACO Chief Administrative Officer and/or the Director of Operations.

E. Any template materials provided by CMS may be utilized by the ACO immediately upon filing with CMS. These template materials may not be changed in any way.

F. The ACO and any ACO Related Individuals will obtain prior approval from Compliance for the publication or release of any press release, external reports or statistical/analytical material that materially and substantially references the ACO's participation in the MSSP or the ACO's financial arrangement with CMS. Examples of such reports include, but are not limited to: papers, articles, professional publications, speeches and testimony.

1. All external reports and statistical/analytical material that are subject to this section must include the following statement on the first page: "The statements contained in this document are solely those of the authors and do not necessarily reflect the view or policies of CMS. The authors assume responsibility for the accuracy and completeness of the information contained in this document."

G. Voluntary Alignment Communications. ACO Related Individuals may directly communicate with Beneficiaries regarding Voluntary Alignment.

1. The ACO uses template language developed by CMS for Voluntary Alignment communications. Template language and Fact Sheets are used without modification.

2. Materials will be submitted to Compliance as required and will not offer gifts, cash, or other remuneration as inducements for:

    a. Completing Voluntary Alignment, or

    b. Receiving items or services from, or remaining in, an ACO or with ACO Providers/Suppliers in a particular ACO or receiving items or services from ACO participants or ACO providers/supplier

3. ACO Related Individuals may answer questions from Beneficiaries regarding Voluntary Alignment but may not complete the online form on behalf of any Beneficiary.

4. If a Beneficiary has a question about how to make a change to their Voluntary Alignment selection, they should be directed to call the 1-800-MEDICARE or visit MyMedicare.gov, Medicare.gov

H. ACO Communications may not contain inaccurate or misleading information, including but not limited to:

1. Language suggesting that beneficiaries are required to see providers only within the ACO or are in any way prohibited from seeing providers outside of the ACO.
2. Language suggesting that beneficiaries enroll or are participating in ACOs. Language should be clear that it is the provider, not the beneficiary, which is participating in the ACO.
3. Language suggesting that CMS endorses one ACO over another.
4. Language suggesting a Shared Savings Program ACO is in any way superior to other ACOs or other types of ACOs, or that the providers participating in the MSSP ACO are superior to other providers participating in other ACOs or CMS initiatives.

I. ACO Communications must not be used in a discriminatory manner and should adhered to Federal Plain Language Guidelines where possible.

J. The ACO Chief Administrative Officer or Director of Operations, or his or her designee, shall maintain a log of all material approvals and a library of all written and electronic materials in accordance with **DRP-006** and the MSSP Final Rule.

IV. **Questions.** Any questions concerning the ACO Communications (COM) Policies and Procedures, or questions that are not specifically addressed in the COM Policies and Procedures, should be directed to the ACO Compliance Officer.

Policy Number:	**COM-002**
Subject:	**ACO Communications**
Policy/Procedure:	**ACO Governance and Public Reporting Requirements**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of the COM-002 is to outline and define the ACO's Public Reporting Requirements as defined by the MSSP Final Rule and the Public Reporting Guidance released by the Centers for Medicare and Medicaid Services (CMS).

II. **Policy.** It is the policy of the ACO to promote transparency within the Medicare Shared Savings Program by ensuring compliance with all Public Reporting requirements put in place by CMS.

III. **Procedures.**

A. The ACO will maintain a publicly accessible website. The website will be reviewed and updated as necessary to ensure all information posted on the website is current. The website will include reporting of, at a minimum, the following:

1. Organizational information, including ACO Name and location, ACO Primary Contact name, phone number, and email address; list of all ACO Participants by Legal Business Name with D/B/A name in paratheses; and identification of all joint ventures between ACO professionals and hospitals.
2. Governing Body information, including members' names, positions, voting power, membership types, and associated ACO participant LBNs. Any change to the ACO's Governing Body will also be updated in ACO-MS within 30 days, as required.
3. Key ACO Clinical and Administrative Leadership, including the names of the current ACO Executive, Medical Director, Compliance Officer, and Quality Assurance/Improvement Officer.
    a. Any change to leadership will be updated in ACO-MS Contacts subtab within 30 days, as required.
4. Associated Committees and Committee Leadership, including the committee name, leader's name, and leader's committee position.
5. Types of ACO Participants, or Combinations of Participants, that Formed the ACO.
6. Shared Savings and Shared Losses Information, including the dollar amount for all completed performance years by agreement period; the percentage of shared savings distribution invested in infrastructure, redesigned care processes and other resources to coordinate care and improve quality; and percentage distributed among ACO participants.
7. Quality Performance Results, including the results for the most performance recent year available and the measures listed in the Public Reporting Guidance issued by CMS.

a. The ACO will not publicly share or report cell sizes <11 or any combination of information that would allow cell sizes of <11 to be calculated.

8. Documentation of the ACO's utilization of any Payment Rule Waivers, the Pre-Participation Waiver, or the Participation Waiver available to the ACO as a result of its participation in the MSSP.

B. The ACO's website is a Marketing Material for purposes of compliance review. All changes must be submitted to Compliance for review and approval prior to use on the website, except:

1. ACO Chief Administrative Officer and/or Director of Operations may update the list of ACO Participants as needed without submitting those changes for approval.

C. All updates to required public reporting shall be made within 30 days of the effective date of the change. For purposes of:

1. Adding a Participant, the effective date will be the date the notice is received from CMS;
2. Removing a Participant, the effective date will be the date when the individual's or entity's agreement with the ACO to participate in the MSSP terminates.

D. ACO Participants are responsible for ensuring that CMS is notified when a Provider /Supplier is no longer billing under the ACO Participant TIN, or when a new Provider /Supplier is added to practice. Such notification shall be submitted to CMS within 30 days of the effective date. It is the responsibility of the Participant and the Provider /Supplier to ensure that the Provider/Supplier's billing information listed in the Provider Enrollment, Chain and Ownership System (PECOS) is also updated.

Policy Number:	**PVS-001**
Subject:	**Privacy and Security Compliance**
Policy/Procedure:	**Compliance with HIPAA and DUA Requirements**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of the Privacy and Security (PVS) Policies and Procedures is to outline the ACOs policies for ensuring compliance with all privacy requirements.

II. **Policy.** It is the policy of the ACO to maintain the privacy and security of all ACO related information in accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules, the Data Use Agreement (DUA) signed between the ACO and the Centers for Medicare and Medicaid Services (CMS), all relevant HIPAA Privacy and Security guidance applicable to the use and disclosure of protected health information, as well as applicable state laws and regulations.

III. **Procedures.** The ACO requires that all ACO related activities comply with all elements of applicable federal and state laws, regulations, and standards governing privacy of Health Care information. In accordance with the HIPAA and the Privacy Rules; the Health Information Technology for Economic and Clinical Health (HITECH) Act, part of the American Recovery and Reinvestment Act (ARRA) of 2009, Gramm-Leach-Bliley Act (GLBA), and the Data Use Agreement signed with the CMS.

A. The ACO is the Business Associate of each ACO Participant. Any data shared by the ACO will be done only in accordance with the Business Associate Agreement signed by each ACO Participant.

B. The Compliance Officer is responsible for ensuring compliance with this privacy policy, and utilizes the ACO's Monitoring & Oversight program to ensure that the ACO is compliant with all applicable privacy regulations and standards.

C. The ACO requires all Relevant Individuals to use the best practices listed below in an effort to protect Beneficiaries? personally identifiable information (PII), protected health information (PHI), and other sensitive data:

1. Avoid sharing PII, PHI or sensitive data by email. If data must be emailed, it is sent as an encrypted file and the password is sent to the recipient by phone or fax.

2. Passwords for encrypted files are not sent via email.

3. Passwords are not shared.

D. Privacy concerns are reported to the Compliance Officer and investigated according to the ACO's RCI Policies. The report, investigation and any follow-up activities are documented in the Compliance Log, as required by RCI-005.

E. The Compliance Officer is responsible for reporting violations as required by the regulations, and in accordance with the ACO's CMO 001 policy regarding reporting to law enforcement.

1. In the event of any breach of personally identifiable information from the CMS data files, loss of these data or disclosure to any unauthorized persons, the Compliance Officer will report to the CMS Action Desk within one hour and cooperate in the federal security incident process.
2. The ACO shall take reasonable steps to mitigate, to the extent practicable, any harmful effect (that is known to the ACO) of a use or disclosure of PHI by the ACO in violation of an agreement with an ACO Participant, or the ACO's Data Use Agreement with the ACO.

F. As part of its participation in the Medicare Shared Savings Program, the ACO has signed a Data Use Agreement (DUA) with the Centers for Medicare and Medicaid Services (CMS). The ACO will only share data in accordance with the terms of that agreement.

1. Data is not physically moved, transmitted, or disclosed in any way from or by the site indicated in the DUA without written approval from CMS unless such movement, transmission or disclosure is required by a law.
2. If the ACO needs to send information covered by the DUA outside of the ACO, the ACO will ensure that the receiving entity agrees to abide by the terms of the DUA through the use of a Data Use Acknowledgement Form prior to sharing any data files received from CMS as part of the Shared Savings Program. This form will capture, at a minimum, the following data elements to ensure the ability of the ACO to respond to CMS in the event of an audit:

    a. The legal name and full address of the entity;
    b. The individual within the entity ultimately responsible for ensuring compliance with the requirements of the DUA;
    c. The date the ACO began sharing data with the entity;
    d. The date the ACO stopped sharing data with the entity; and
    e. Upon termination of the arrangement, a certification by the individual identified in paragraph ii above, that all data has been destroyed or returned to the ACO.

G. The ACO has designated a Custodian of the CMS data files who is responsible for the observance of all conditions of use and for the establishment and maintenance of security arrangements as specified in the DUA to prevent unauthorized use. The ACO shall notify CMS within 15 days of any change of custodianship.

1. All individuals identified as an ACO Contact in ACO-MS are deemed by CMS to be ACO Custodians, and are thus responsible for ensuring the ACO's Compliance with all requirements of the Data Use Agreement signed by the ACO.

H. Availability of PHI for Amendment: Within fifteen (15) business days of receipt of a written request from an ACO Participant for the amendment of an Individual's PHI maintained by the ACO, the ACO shall provide such information for amendment and incorporate any such amendments in the PHI as required by 45 C.F.R. §164.526. If the ACO receives a request for amendment to PHI directly from an Individual, the ACO shall forward such request to the ACO Participant or Provider/Supplier within ten (10) business days.

I. Accounting of Disclosures: Within thirty (30) business days of written notice by an ACO Participant or Provider/Supplier that it has received a request for an accounting of disclosures of PHI (other than disclosures to which an exception to the accounting requirement applies), the ACO shall make available such information as is in the ACO's possession and is required for the ACO Participant to make the accounting required by 45 C.F.R. §164.528.

J. Each ACO Related Individual is required to complete Compliance Training, including HIPPA and Privacy training, upon hire or contracting and at least annually thereafter. The ACO Chief Administrative Officer, Director of Operations, or Assigned ACO Administrative Staff is responsible to distribute the compliance training materials to each Participating Organization, ACO Affiliate, and Contractor for distribution and education of their employees. The participating or contracted employer is responsible for maintaining records of ACO Compliance Training for their employees including ensuring the appropriate documentation of training completions and retention of training records.

K. Requests to add vendors or contractors to the Data Use Agreement with CMS are submitted to the ACO Chief Administrative Officer. Once approval is received, the ACO Chief Administrative Officer provides notification to the appropriate individual within the ACO to allow for the sharing of data as necessary.

L. All data requests, uses and disclosures are limited to the minimum necessary to achieve the purposes of the ACO and the MSSP.

IV. **Reporting.** The Compliance Officer reports on any privacy issues to the Board of Managers at least bi-annually.

History

Policy Number:	**FWA-001**
Subject:	**Fraud, Waste and Abuse (FWA) Compliance**
Policy/Procedure:	**FWA Laws and Utilization of Waivers**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of FWA-001 is to outline the processes used by the ACO to ensure compliance with all Fraud, Waste and Abuse (FWA) laws and regulations, and appropriate use and documentation of any FWA waivers.

II. **Policy.** It is the policy of the ACO to ensure that all ACO Related Individuals act in accordance with all applicable Fraud, Waste and Abuse laws, and to ensure proper compliance with the five Medicare Shared Savings Program FWA Waivers created by the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG). These waivers are known as the:

A. ACO Pre-Participation Waiver

B. ACO Participation Waiver

C. Shared Savings Distribution Waiver

D. Compliance with Physician Self-Referral (Stark) Law Waiver

E. Patient Incentives Waiver

III. **Procedures.** The ACO requires that all ACO Related Individuals complete Compliance training upon hire or contracting and on an annual basis thereafter. The training emphasizes the ACO's commitment to making compliance with Federal and State requirements a top priority, including but not limited to training related to Fraud, Waste and Abuse (FWA) laws.

A. The Chief Administrative Officer and/or Director of Operations is responsible for ensuring compliance with the FWA laws and utilizes the ACO's Monitoring & Oversight program to actively manage that requirement.

B. The ACO Chief Administrative Officer and/or the Director of Operations will evaluate new initiatives for compliance within the MSSP regulations and work directly with the appropriate individuals to revise or omit any procedures that are outside of the law.

C. If any of the waivers are to be utilized, Chief Administrative Officer and/or Director of Operations will work with the business owner to document their use. This documentation will include, but may not be limited to:

1. Details around the program including any payments to be made;
2. Purposes of the program and their relationship to the three-part-aim of the MSSP; and
3. Approval of the use of a waiver by the Board of Managers

D. This documentation will be maintained in accordance with DRP-006. The Chief Administrative Officer will work with the Director of Operations to ensure any public disclosure requirements are met once utilization of the waiver has been approved.

E. The Chief Administrative Officer and/or Director of Operations will maintain a log of any waivers utilized by the ACO.

Policy Number:	**FWA-002**
Subject:	**Fraud, Waste and Abuse (FWA) Compliance**
Policy/Procedure:	**Benefit Enhancements**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of FWA-002 is to detail the ACO's policy and processes to ensure compliance with the Medicare Shared Savings Program Final Rule requirements related to the provision of certain payment rule waivers, also known as Benefit Enhancements.

II. **Policy.** It is the policy of the ACO to abide by all rules and regulations set forth by the Centers for Medicare and Medicaid Services (CMS) in regard to the Benefit Enhancements available to the ACO under the Medicare Shared Savings Program.

III. **Procedures.**

A. The ACO shall take all necessary steps to ensure compliance with the rules of any and all applicable Benefit Enhancements it opts to employ. The ACO may elect to provide one or more Benefit Enhancements for a Performance Year and must submit a certification of that Benefit Enhancement each year. The available Benefit Enhancements are:

1. 3-Day SNF Rule Waiver
2. Telehealth Services Payment Waiver.

B. 3-Day SNF Rule Waiver : allows Skilled Nursing Facility (SNF) Services furnished by Eligible SNFs to be covered under Medicare Part A for Eligible Beneficiaries who are admitted to the SNF without a prior inpatient hospital stay ("Direct SNF Admission") or who are discharged from a hospital to the SNF after an inpatient hospital stay of fewer than three days, as long as other coverage requirements for such services are satisfied

1. In order to be eligible to receive services under these Benefit Enhancements, the Beneficiary must be assigned to the ACO, and: the beneficiary must have been included in the preliminary prospective assignment list, or a quarterly update prior to the SNF services being provided.

a. Not be residing in a SNF or long-term care facility at the time of admission.
b. Be medically stable;
c. Have confirmed diagnoses;
d. Not require inpatient hospitalization or treatment; and
e. Have a skilled nursing or rehabilitation need that is identified by the evaluating physician or other practitioner and cannot be provided as an outpatient; and
f. Have been evaluated by a physician or other practitioner licensed to perform the evaluation within three days prior to admission

2. The ACO has a written agreement in place with each eligible SNF to partner with the ACO for purposes of this Benefit Enhancement.

3. The items or services are not Medicare-covered items or services for the beneficiary on the date the in-kind item or service is furnished to the beneficiary.

C. Telehealth Services Payment Waiver: Under this Benefit Enhancement, the home of the beneficiary is treated as an originating site under section 1834(m)(4)(c)(ii) of the Act if the following requirements are met:

1. The Beneficiary is prospectively assigned to the ACO for the relevant Performance Year.
2. The physician or practitioner who furnishes the service must bill under the TIN of an ACO Participant.
3. The Originating Site complies with applicable State licensing requirements.
4. The ACO ensures that the services are appropriate for the Originating Site. Services that are typically furnished in an inpatient setting may not be furnished as a telehealth service when the Originating Site is the Beneficiary's home.

D. Responsibility for Denied Claims: In the event that CMS denies a claim under one of the Benefit Enhancements:

1. CMS may, in some limited circumstances make payment but recoup the payment from the ACO, payable as Other Monies Owed for the Performance Year. In most cases, CMS will make no payment.
2. The ACO shall ensure that the individual or entity that provided the Services does not charge the Beneficiary for the expenses incurred for such services;
3. The ACO shall ensure that the individual or entity that provided the Services returns to the Beneficiary any monies collected from the Beneficiary; and
4. The ACO shall indemnify and hold the Beneficiary harmless for payment of any such services provided to the Beneficiary.

E. Access to Up-to-Date Beneficiary Rosters: Compliance with the Benefit Enhancement requirements cannot be ensured if Participants, Provider/Suppliers, and SNF Affiliates do not have access to the most up-to-date information regarding Beneficiary alignment to the ACO. Without this information, the Participant or Provider/Supplier may inadvertently refer an ineligible beneficiary or file an inappropriate claim under one of the Enhancements. As a result, the ACO has established appropriate procedures to ensure that Participants and Provider/Suppliers have access to the most up-to-date information regarding Beneficiary alignment to the ACO.

1. ACO Administration, Care Coordinators who work directly with Providers/Supplier are provided access to the most recently Beneficiary Assignment file from CMS via a secure MFT file that is password protected. This file is updated within 7 days of receipt from CMS by the ACO Administrative Staff. SNF Affiliate Staff have access to a secure password protected database which provided a searchable field to identify ACO Beneficiaries on the most recent Beneficiary Assignment file from CMS. The back-up method for validation should any of the secure electronic documents be temporarily inaccessible, is for the Participants, Provider /Suppliers, and SNF Affiliates to directly contact the ACO Administration team for a verbal conformation of ACO alignment.

Policy Number:	**FWA-003**
Subject:	**Fraud, Waste and Abuse (FWA) Compliance**
Policy/Procedure:	**Beneficiary Incentives**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of FWA-003 is to detail the ACO's policy and processes to ensure compliance with the Medicare Shared Savings Program Final Rule requirements related to the provision of beneficiary incentives.

II. **Policy.** It is the policy of the ACO to ensure compliance with state and federal regulations prohibiting the ACO, its Participants, Providers/Suppliers, and other individuals or entities performing functions or services related to the ACO's activities from providing any remuneration to Beneficiaries as inducements for receiving, or continuing to receive, items or services.

III. **Procedures.**

A. The ACO, its Participants, Providers/Suppliers, and other individuals or entities performing functions or services related to the ACO's activities are prohibited from providing gifts or other remuneration to beneficiaries as inducements for

1. Receiving items or services from, or remaining in, an ACO or with ACO providers /suppliers in a particular ACO; or
2. Receiving items or services from ACO participants or ACO providers/suppliers.

B. The ACO may provide in-kind items or services to beneficiaries only if:

1. There is a reasonable connection between the items and services and the medical care of the beneficiary;
2. The items or services are preventive care items or services or advance a clinical goal for the beneficiary, including adherence to a treatment regime, adherence to a drug regime, adherence to a follow-up care plan, or management of a chronic disease or condition; and
3. The items or services are not Medicare-covered items or services for the beneficiary on the date the in-kind item or service is furnished to the beneficiary.

C. No one acting on behalf of the ACO or an ACO Participant or Provider/Supplier may, directly or indirectly, commit any act or omission, nor adopt any policy, that coerces or otherwise influences a Beneficiary's decision to complete or not complete Voluntary Alignment, including but not limited to the following:

1. Offering anything of value to the Beneficiary; or
2. Withholding or threatening to withhold medical services or limiting or threatening to limit access to care.

D. All plans for Marketing Materials and Activities related to rewards and incentives must be submitted to the Chief Administrative Office. ACO Chief Administrative Office shall then work with the Director of Operations for approval of the material and/or activity.

Policy Number:	**OPS-001**
Subject:	**Operational Policies**
Policy/Procedure:	**Beneficiary Engagement and Patient Centeredness**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of OPS-001 is to describe the ACO's focus on patient centeredness and policies related to beneficiary engagement.

II. **Policy.** It is the policy of the ACO to promote patient centeredness and to promote define, establish, implement, evaluate and periodically update processes to promote beneficiary engagement. This policy is promoted by the Board of Managers and is integrated into practice by the leadership and management of the ACO in accordance with Section 425.112 of the Medicare Shared Savings Program Final Rule.

III. **Procedures.**

A. The ACO's focus on patient centeredness is promoted by the Board of Managers and integrated into practice within the ACO's operational activities by ACO leadership. The ACO's individualized care program promotes improved outcomes for all ACO Beneficiaries.

1. Patient centeredness is a focus of the ACO beginning with the Medical Director and the Participant CMOs, Analytics and Innovation Committee, Quality and Safety Committee and the Care Coordination team working together in the following.

    1. Take a population health approach to improving care including Medical Home and evidence-based medicine protocols
    2. Focus on workflows and care redesign to improve care coordination
    3. Leverage the existing robust system of care to serve our patients
    4. Patient-centered approach including the Patient Centered Medical Home Model and care coordinator services including RNs, Social Workers and Community Health Assistants
    5. Emphasis on quality
    6. Access to specialty and advanced care
    7. Local physicians and hospitals
    8. Demonstrate good stewardship of Medicare's scarce resources

B. The ACO's Beneficiary Engagement program is designed to encourage the beneficiary to take an active role in his/her health care.

1. The ACO will use both claims-based cost, utilization and HCC codes along with Electronic Health Record (EHR) data to evaluate the previous, and current status of the ACO's Beneficiaries. This information will be used to provide education, support and care coordination to the Beneficiaries to better engage them to take

an active role in their care.

2. The ACO's Chief Medical Officers will work with the various ACO committees, Administration, IT, and Provider/Suppliers to create effective communication tools and protocols and monitor the ACO quality results (CAHPS survey results) along with claims and EHR data to evaluate communication effectiveness.

    a. Communications used as part of the Beneficiary Engagement Program will meet requirements for marketing materials as outlined by COM-001.

3. The ACO works with Beneficiary representatives as appropriate, and in accordance with the beneficiary representative requirements set forth in 42 CFR Section 425.106.

    a. ACO Providers will be educated on CAHPS scoring on the beneficiaries' perception of their current state of shared decision making with providers. The ACO will provide best practice information to providers on how to better include the patient and assure they are part of the shared decision-making process.

4. Beneficiaries are ensured access to their health information and to ACO providers.

    a. The ACO will not limit access to care for any provider.

    b. The ACO will encourage Beneficiaries to receive the appropriate preventative care and care for chronic conditions to ensure the best quality of life. The ACO will assist as needed by providing care coordination services for acute, post-acute, transitions-of-care, and chronic disease support, as well as access to specialist when necessary.

    c. The ACO providers will utilize all forms of communication that meets individual beneficiary needs including, educational materials, tele-communication, and secure portal/email/fax.

C. The ACO contracts with a CMS approved third party contractor to complete Patient Experience of Care Surveys each year as required by 42 CFR Section 425.500. The results of this survey are reported to the ACO Quality and Safety Committee and utilized by the ACO as a tool to determine the effectiveness of the ACO's Beneficiary Engagement Program.

D. Continued Improvement. The ACO utilizes internal assessments to continuously monitor and improve ACO care practices as required by 42 CFR Section 425.112.

    1. Monitoring of ACO claims, EMR, Quality and CAHPS reporting are reviewed for areas of needed improvement.

    2. Areas of opportunity are discussed with the ACO CMO and Committees to create improvement plans and to develop project criteria.

E. Enforcement. ACO Participants and Provider/Suppliers are required to follow all applicable ACO policies. Failure to comply with ACO processes, including cooperation in Beneficiary Engagement and Care Coordination activities, will result in remedial and /or disciplinary actions as appropriate in accordance with RCI-004.

Policy Number:	**OPS-002**
Subject:	**Operational Policies**
Policy/Procedure:	**Care Coordination**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of OPS-002 is to provide a description of the ACO's Care Coordination Program as required by the Medicare Shared Savings Program Final Rule.

II. **Policy.** It is the policy of the ACO to maintain a care coordination program to meet the needs of the ACO population, including but not limited to chronic disease management, transition of care and high, rising and low risk management programs for beneficiaries attributed to the ACO.

III. **Procedures.**

A. The ACO will provide access to care coordinators for ACO Beneficiaries involving transitions of care in Primary Care, Specialty, Acute and Post-Acute settings as they are made aware of care coordination needs via various methods, including but not limited to, EHR reports, Health Information Exchange (HIE) reporting, Claims data, beneficiary or provider notification.

1. Beneficiaries identified to have a TOC need will be assess for needed assistance. If needed, a care coordinator will be assigned to assist them with the transition between primary and specialty care to assure they are cared for in the most expedient and efficient way possible. Care coordinators are also assigned to ACO hospitals to assist in beneficiary's transition to the most appropriate post-acute care setting that will best meet their care needs.

B. Care Coordination programs and protocols including best practice care and evidence-based medicine which are approved by the ACO Medical Director and ACO Committees which, shall be used in conjunction with data analysis and care coordination implementation plans to promote improved outcomes for, at a minimum, the ACO's high-risk and multiple chronic condition beneficiaries to ensure the unique needs of each beneficiary are met.

C. The ACO will utilize the care coordination team including Nurses, Social Workers and Community Health Assistants to evaluate Beneficiary social determinants of health and assisting to connect the beneficiary to the appropriate community resources.

D. **Use of Enabling Technologies.** The ACO encourages and promotes the use of enabling technologies for improving care coordination for beneficiaries. These technologies include but are not limited to;

1. Near real-time reporting via Electronic Health Record and Health Information Exchange systems to identify care coordination needs in TOC and Disease Management
2. Bluetooth medical devise monitoring to assist with disease exacerbation monitoring.
3. Patient Portal messaging and screening

4. Telephonic outreach for chronic condition and TOC monitoring

E. The ACO utilizes reports developed in accordance with the ACO's Internal Reporting on Cost and Quality Metrics Policy to identify high-risk and multiple chronic condition beneficiaries. These reports also allow the ACO to identify additional target populations that would benefit from the individualized care plans provided during care coordination, and the additional assistance of available community resources.

    1. The ACO shall not use data to avoid at-risk beneficiaries. Use of data is for identification of those beneficiaries who are most in need of care coordination services, and who are most likely to benefit from those services. Care Coordination activities are not denied based on a beneficiary's classification as "at-risk".

    2. Beneficiaries will be provided Care Coordination Services if need for services are identified, this may include
    but is not limited to; acute or chronic disease status, social determinant of health needs, and agreement to participate. Individual assessment plans are in place to evaluate the timing of opening or closing a care coordination episode as well as ongoing disease management services. Beneficiaries may be excluded from care coordination services if they refuse such services.

F. The ACO does not require Beneficiaries to be referred within the ACO or to any other provider or supplier

    1. Exception: Referrals made by employees or contractors who are operating within the scope of their employment or contractual arrangement to the employer or contracting entity, provided that the employees and contractors remain free to make referrals without restriction or limitation if:

        a. The beneficiary expresses a preference for a different provider, practitioner or supplier; or

        b. The referral is not in the beneficiary's best medical interests in the judgment of the referring party.

G. The ACO partners with long-term and post-acute care providers, both inside and outside the ACO, to improve care coordination for assigned beneficiaries.

    1. The ACO care coordinators communicate with long-term and post-acute staff to assist in beneficiary transition of care to and from the facilities to assure the appropriate level and type of care is available and provided.

    2. ACO Care Coordinators assist beneficiaries in transitions of care from post-acute back to their primary care providers for smooth transitions and to assist in coordinating ongoing need including chronic disease monitoring.

H. **Enforcement.** ACO Participants and Provider/Suppliers are required to follow all applicable ACO policies. Failure to comply with ACO processes, including cooperation in Beneficiary Engagement and Care Coordination activities, will result in remedial and /or disciplinary actions as appropriate in accordance with RCI-004.

Policy Number:	**OPS-003**
Subject:	**Operational Policies**
Policy/Procedure:	**Evidence Based Medicine**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of OPS-003 is to provide a description of the ACO's commitment to the use and promotion of evidence-based medicine.

II. **Policy.** It is the policy of the ACO to encourage and promote the use of evidence-based medicine by all ACO Related Individuals and to utilize these standards in the management of appropriate clinical guidelines.

III. **Procedures.**

A. The ACOs promotion of evidence based clinical guidelines is critical to achieving positive healthcare outcomes, minimizing unwarranted practice variation and promoting cost-effective utilization for a diverse beneficiary population; including identification of high-risk Beneficiaries, multiple chronic condition Beneficiaries, and additional target populations who would benefit from care coordination.

B. The ACO's Chief Medical Officer has responsibility for ongoing clinical practice guideline review and approval for promoting the use of evidence-based medicine (EBM) across the ACO.

1. The Chief Medical Officer and the Analytics and Innovations Committee reviews clinical literature, evaluates the unique health needs and resources of the ACO's service area, gathers specialty specific best practice information, and solicits expert input whenever the body of available research literature is not conclusive.

2. The Chief Medical Officer and the Analytics and Innovations Committee determines which guidelines should be implemented within the ACO based on those diagnoses with significant potential for the ACO to achieve quality improvements.

C. Guideline recommendations made by the ACO's Analytics and Innovations Committee are shared with ACO Participants and Provider/Suppliers as well as the Care Coordination Team. Guidelines are then implemented and utilized as appropriate based on the clinical decision making of the provider, the individual circumstances of each Beneficiary and in accordance with the OPS-002.

D. The ACO's approach to EBM involves the effective use of information technology and empowering both providers and staff to take responsibility for providing optimal evidence-based guideline care for every beneficiary.

1. The ACO Providers/Suppliers and care coordinators use EHR technology including best practice alerts, registry reports, pharmacy alerts, etc. to evaluate beneficiaries for the use of evidence-base care pathways, preventative medicine and pharmaceutical treatment guidelines where appropriate. Treatments are evaluated on an individual bases once potential improvement opportunities are identified by reporting.

E. At no time shall the ACO's evidence-based medicine standards or guidelines be used to influence or remove the ability of the provider to make clinical decisions based on the individual circumstances, preferences or best interests of the beneficiary.

F. **Enforcement.** ACO Participants and Provider/Suppliers are required to follow all applicable ACO policies. Failure to comply with ACO processes, including utilization of evidence-based medicine standards and guidelines, will result in remedial and/or disciplinary actions as appropriate in accordance with RCI-004.

Policy Number:	**OPS-004**
Subject:	**Operational Policies**
Policy/Procedure:	**Internal Reporting on Cost and Quality**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of OPS-004 to provide details around the ACO's processes for internally reporting on cost and quality metrics to ensure success in the Medicare Shared Savings Program.

II. **Policy.** It is the policy of the ACO to maintain an infrastructure for reporting and management of quality and cost metrics to improve beneficiary outcomes and monitor the performance of ACO Participants and Provider/Suppliers as required by Section 425.112 of the Medicare Shared Savings Program Final Rule.

III. **Procedures.**

1. The ACO's Analytics and Innovations Committee is charged with reviewing and updating the ACO's infrastructure for internal reporting of quality and cost metrics.
2. The ACO utilizes standardized, nationally recognized performance measures to assess cost and quality performance. The ACO utilizes internal reports on cost and quality metrics to identify target populations that would benefit from care coordination and individualized care plans, as described in the ACO's Coordination of Care Policy. Minimum performance thresholds for each critical cost and quality metric are established and Evidence Based Medical Guidelines are approved by the Chief Medical Officer as a benchmark for performance.
3. The ACO's Analytics and Innovations and Quality and Safety Committee reviews reports as appropriate and make suggestions based on the clinical and operational goals of the ACO, ACO progress in achieving cost and quality metrics, and CMS requirements.
4. Recommendations for performance measures and Evidence Based Medical Guidelines may be recommended to the Analytics and Innovations and Quality and Safety Committee by any ACO Related Individual.
5. Reports are provided Quarterly which allow for recognition of individual providers and for intervention for providers who need improvement in their quality or cost profiles.
    1. Claims based reports are provided quarterly via the ACO's Secure Analytics platform, and as distributed by ACO Administrative Staff during Medical Home and Provider Office Staff meetings.
    2. Annual Quality reporting results are compiled to include high level to provider level data and are distributed to providers via ACO Administrative Staff during Medical Home and Provider Office Staff meetings. Quality improvement plans for poor performers can be individualized by Participant, Office, and/or individual provider/supplier.
    3. Regular reporting includes:
        a. Cost and Utilization reporting updated quarterly;

b. Total, Acute, ED and Post-Acute cost of care at the Participant, Office and Provider/Supplier levels.

c. Admission, Readmission, ED and Acute Care Sensitive Condition Admissions/1000 rates at the Participant, Office and Provider/Supplier levels.

4. Quality reports include performance per measure at the participant office and site level and are produced annually after data collection is completed for annual CMS reporting requirements.

    a. Ad hoc reporting is compiled by participants utilizing EMR data.

    b. Claims based quality measures are evaluated utilizing the ACO reports found in the MSSP ACO Portal.

5. The ACO utilizes these reports to monitor ongoing performance, to work with the Chief Medical Officer on distribution and education of improvement plans and achieved successes, and to provider administrative support in the development and implementation of improvement plans.

6. The ACO Chief Administrative Officer and/or the Director of Operations in conjunction with the Chief Medical Officer and Participant Administration provide follow-up to the ACO providers/suppliers.

6. The ACO shall not use data to avoid at-risk beneficiaries. Data is used to identify opportunities for the ACO to meet the goals of improved health, improved quality and lower costs.

7. Quality Reporting. The ACO shall completely and accurately report quality measures for each Performance Year. Participants are required to cooperate in quality measure reporting.
   The ACO is responsible for procuring a CMS-approved vendor to conduct the CAHPS or other patient experience survey results are transmitted to CMS by a date and in a form and manner established by CMS.

Enforcement. ACO Participants and Provider/Suppliers are required to follow all applicable ACO policies. Failure to comply with ACO processes, including cooperation with the care coordination program and evidence-based medicine initiatives, will result in remedial and/or disciplinary actions as appropriate in accordance with RCI-004

Policy Number:	**OPS-005**
Subject:	**Operational Policies**
Policy/Procedure:	**Participant and Provider/Supplier List Updates**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of OPS-005 is to detail the ACO's policy and processes to ensure compliance with the Medicare Shared Savings Program Final Rule requirements that the ACO maintain, update and submit to CMS an accurate and complete list identifying each ACO Participant and Provider/Supplier.

II. **Policy.** The ACO shall maintain processes to ensure that the ACO is able to maintain, update and submit to CMS an accurate and complete list identifying each ACO Participant and Provider/Supplier within 30 Days of any addition or deletion.

III. **Procedures.**

A. During the term of the Participation Agreement, the ACO may add or remove ACO Participants and/or Providers/Supplier.

B. The ACO must notify CMS within 30 days of any addition or removal of ACO Participants and/or Providers/Supplier.

C. The ACO must notify CMS within 30 days of any significant change. A "significant change" occurs when the ACO is no longer able to meet the eligibility or program requirements of the Medicare Shared Savings Program Examples of a "significant change" include, but are not limited to:

1. A provider or supplier is no longer enrolled in Medicare

2. A provider or supplier has reassigned its billing to a Participant TIN after the ACO has certified it's ACO Provider/Supplier List.

D. Medicare Revalidation. All ACO Participants and Provider/Suppliers are required to maintain their status as a Medicare enrolled entity. This includes the requirement to complete the Medicare Revalidation process.

1. The ACO will monitor the CMS Medicare Revalidation Webpage for due dates.

2. Participants are required to notify the ACO Executive Director within 15 days if a Provider/Supplier is no longer Medicare enrolled.

3. **Participants Changes.**

a. Changes to the ACO Participants is decided by the Board of Managers. New Participants who are approved for inclusion in the ACO by the Board of Manager are required to sign the approved participating agreement and DUA accordingly. The signed Participation agreement along with the participant TIN and Legal Business Name, is submitted to CMS for final approval for participation in accordance with MSSP Guidelines.

b. Participant additions and deletions are submitted for approval based on timelines established by CMS each year and are only effective at the end of each Performance Year.

c. Terminations are effective as of December 31st of the current Performance Year.

    1. At any time after the first Performance Year of this Agreement, either party may terminate this Agreement by providing thirty (30) days' written notice to the other party of its intent to terminate this Agreement.

    2. Additions are effective as of January 1st of the subsequent Performance Year.

d. Upon CMS approval of a new Participant, the ACO will determine whether any changes to the Board of Managers are required to ensure compliance with the Shared Governance requirements found in the Final Rule at 42 CFR Section 425.106. Changes are implemented as required in the governing documents of the ACO.

e. The ACO Participant is responsible for:

    1. Notifying the ACO if the Participant or a Provider/Supplier is no longer Medicare enrolled

    2. Notifying all provider/suppliers within the Participant TIN of the TIN's involvement (or termination of involvement) with the ACO, and

    3. Ensuring that all signs and materials are added/removed from participating practice locations upon the effective date of the addition /termination.

    4. The ACO Chief Administrative Officer and/or Director of Operations is responsible to assure the ACO's Public Disclosure is updated with any additions/deletions within 30 days of the effective date

    5. Notifying the ACO if their intent to terminate their agreement at least 30 days prior to proposed termination date.

E. **Providers/Suppliers.** When a Provider/Supplier is added or removed from the ACO, the change must be noted.

1. The Participant must log in to PECOS and make the appropriate changes within 30 days.

2. ACO Participants are required to send the ACO a list of new provider/suppliers with their start dates and a list of terminating provider/suppliers with their termination date each month, buy the end of the month.

3. The Participant list changes will be placed on the MSSP Bulk Upload Provider /Supplier template and uploaded to the ACO-MS portal on a monthly basis. by the ACO Director of Operations

4. Effective date of Provider/Supplier Changes. If a request is sent timely to CMS (within 30 days of the change), the addition of an individual or entity to the ACO Provider/Supplier List is effective on the date specified in the notice furnished to CMS, but no earlier than 30 days before the date of notice.

    a. If the ACO fails to submit timely notice to CMS, the update is effective on the date of notice.

    b. The deletion of an individual or entity from the ACO Provider/Supplier List is effective on the date the individual or entity ceased to be a Medicare enrolled provider or supplier that bills for items or services it furnishes to Medicare Fee-For-Service beneficiaries under a billing number assigned to the TIN of an ACO Participant.

F. The ACO does not condition the participation of ACO Related Individuals in the ACO on referrals of Federal health care program business that the ACO Related Individual knew or should have known is being (or would be) provided to beneficiaries who are not assigned to the ACO.

Policy Number:	**OPS-006**
Subject:	**Operational Policies**
Policy/Procedure:	**Repayment Mechanism (Only for ACO's with downside risk)**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of OPS-006 is to detail the ACO's policy and processes to ensure compliance with the Medicare Shared Savings Program Final Rule requirements related to the maintenance of an appropriate Repayment Mechanism.

II. **Policy.** It is the policy of the ACO to ensure it has the ability to repay all shared losses for which it may be liable under a two-sided risk, or down-side risk model, in accordance with Section 425.204 of the Medicare Shared Savings Program Final Rule.

III. **Procedures.**

A. The ACO will, for the duration of the ACO's participation under a two-sided model plus 12 months following, maintain one or more of the following repayment mechanisms in an amount specified by CMS:

1. An escrow account with an insured institution;
2. A surety bond from a company included on the U.S. Department of Treasury's List of Certified Companies;
3. A line of credit at an insured institution (as evidenced by a Letter of credit that the Medicare program can draw upon).

B. The repayment mechanism must either cover:

1. The entire duration of the ACOs participation under a two-sided risk model plus 23 months following the conclusion of the agreement period.
2. A term of at least the first two performance years in which the ACO is participating under a two-sided model and provides for automatic, annual 12-month extensions such that the repayment mechanism will eventually remain in effect for the duration of the agreement period plus 12 months following the conclusion of the agreement period.

C. The ACO must demonstrate the adequacy of this repayment mechanism prior to the start of each performance year in which it is participating in a two-sided model.

D. In the event that the repayment mechanism is used to repay any portion of shared losses owed to CMS, the ACO will replenish the amount of funds available within 90 days.

Policy Number:	**OPS-007**
Subject:	**Operational Policies**
Policy/Procedure:	**Initial Beneficiary Notifications**
Version Number:	**1**
Version Date:	**01/02/2025**

I. **Purpose.** The purpose of OPS-007 is to detail the ACO's policy and processes related to the requirement to provide initial Beneficiary notifications.

II. **Policy.** It is the policy of the ACO to provide notification to Beneficiaries at the point of care that their Providers/Suppliers are participating in the Shared Savings Program and of the opportunity to decline claims data sharing under 42 CFR §425.312 and 425.708.

III. **Procedures.**

A. For ACO's with Prospective Assignment: The ACO ensures that Medicare Fee-For-Service Beneficiaries aligned to the ACO are notified during the Agreement Period in which the Beneficiary is aligned to the ACO. The notice must explain the following:

1. That each ACO participant and its ACO providers/suppliers are participating in the Shared Savings Program.
2. The opportunity to and method by which the Beneficiary can decline claims data sharing under §425.708 of the Final Rule.
3. The Beneficiary's ability to identify or change identification of the provider he or she designated for purposes of voluntary alignment and instructions on the process by which this may be completed.

B. This notification is carried out through the following methods:

1. Posters & Written Notices:

a. The ACO uses template language developed by CMS for the posters and written notices described in this policy. Template language is used without modification and the templates are submitted to CMS, as required, but do not require the five day "file and use" waiting period described in the ACO's policy titled: ACO Communications and Material Review

b. Posters and Brochures are distributed by ACO administration staff to all ACO participant facilities. Upon completion of site distribution staff notifies ACO administration that all sites meet compliance.

c. Compliance Manuals are distributed to ACO participant facilities. via electronic email distribution. The sites will also be made aware that a copy of the compliance manual can be found on the Keystone ACO website at http://www. keystoneaco.org/

d. ACOs electing prospective assignment must provide each prospectively assigned beneficiary with a standardized written notice at least once during an agreement period via USPS mail/email/patient portal.

1. Beneficiary notification letters will be mailed to beneficiaries using the most recent address noted in their medical record.
2. Returned letters with corrected addresses will be remailed or provided via email/patient portal.

e. Following the provision of the standardized written notice a Beneficiary, the ACO will provide a verbal or written follow-up communication to the Beneficiary. This follow-up must occur no later than 180 days from the date the notice was provided.

1. The ACO maintains a record of all beneficiaries receiving the follow-up communication, the date, and how the communication was made. These records are available to CMS upon request.

f. These notifications state that the ACO may have requested Beneficiary identifiable claims data about the Beneficiary for purposes of its care coordination and quality improvement work, and inform the Beneficiary how to decline having his or her claims information shared with the ACO in the form and manner specified by CMS.

g. Beneficiary requests to decline claims data sharing will remain in effect unless and until a Beneficiary subsequently contacts CMS to amend that request to permit claims data sharing with the ACO.

h. The opportunity to decline having claims data shared with an ACO does not apply to the information CMS provides to ACOs under 42 CFR §425.702(c).

i. CMS does not share Beneficiary identifiable claims data related to the diagnosis and treatment of alcohol and substance abuse without the explicit written consent of the Beneficiary.

j. The ACO maintains records related to the beneficiary notification process in accordance with the ACO’s Record Retention Policy.

[1] 42 C.F.R. 425.300.

[2] The OIG provides detailed compliance program advice, including "best practices" at its website, www.oig.hhs.gov/compliance , including specific advice for separate types of entities. A review of both ACO specific and non-ACO specific compliance guidance posted here should regularly be undertaken to ensure a complete, up-to-date understanding of compliance requirements.

[3] 42 C.F.R. 425.314.

[4] Established under Section 3022 of the ACA, amending Title 18 of the Social Security Act by adding Section 1899, et seq.

[5] 76 Fed. Reg. 19528 (April 7, 2011), 76 Fed. Reg. 67802 (Nov. 2, 2011), 79 Fed. Reg. 72760 (Dec. 8, 2014), 80 Fed. Reg. 32692 (June 9, 2015), and 81 Fed. Reg. 37950 (June 6, 2016).

[6] Located at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html?redirect=/sharedsavingsprogram/ .