



Compliance Training

January 2024





Contents of training

- Introduction
- Training Objectives
- Code of Conduct
- CVS Accountable Care Compliance Program
- Compliance with Laws and Regulations
- Fraud, Waste and Abuse
- How to Report Compliance Concerns
- ACO REACH Compliance Requirements
- Resources
- Compliance Acknowledgement

Introduction

Welcome to CVS Accountable Care Compliance training

CVS Accountable Care Organization, Inc. (“CVS Accountable Care™”) is committed to practicing business in an ethical and compliant manner.

As a CVS Accountable Care Participating or Preferred Provider, you will receive compliance training on an annual basis.

As part of your participation in the CMS ACO REACH model, you are required to complete the CVS Accountable Care Compliance training.

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Training Objectives

- Describe Standards of Conduct. The Code of Conduct explains the responsibilities and ethical standards expected from CVS Accountable Care providers
- Share the purpose and elements of the ACO REACH Compliance program
- Provide overview of compliance laws and regulations
- Define fraud, waste and abuse and provide examples
- Understand how to report fraud, waste, abuse and compliance concerns
- Provide overview of compliance with ACO REACH Participation Agreement requirements



Accountable Care Organization

What is an Accountable Care Organization (ACO)?

Accountable Care Organizations (ACOs) are groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high-quality care to the Medicare patients they serve. Coordinated care helps ensure that patients, especially the chronically ill, get the right care at the right time, with the goal of avoiding unnecessary duplication of services and preventing medical errors. When an ACO succeeds in both delivering high-quality care and spending health care dollars more wisely, it will share in the savings it achieves for the Medicare program.

ACO REACH Model

What is an ACO REACH model?

CMS created the ACO Realizing Equity, Access, and Community Health (ACO REACH) Model to achieve a three-part aim:

1. Improve overall care in a safe environment, equitable to all who seek it, and always available when needed.
2. Improve health accomplished through the practice of proactive, preventive medicine and care coordination.
3. Lower per-capita cost aimed at reducing the upward trend of medical costs associated with the Original Medicare population.

Standards of Conduct

Standards of Conduct are intended to help resolve ethics and compliance issues by providing the information, tools and resources necessary to make good decisions.

CVS Accountable Care follows the laws and regulations that govern our business, adhere to all company rules, and live our company values and purpose every day. The CVS Accountable Care team expects our Participant and Preferred Providers to follow similar standards.

The CVS Health Code of Conduct is a public document which can serve as a reference tool for our Participant Providers and Preferred Providers regarding standards of conduct.

A copy of the CVS Code of Conduct is available [**here**](#) (click link).

CVS Accountable Care Compliance Program



Guides CVS Accountable Care and our Participating and Preferred Providers (“Providers”) to comply with applicable laws, rules and regulations



Reinforces CVS Accountable Care’s commitment to compliance



Prevents, detects and resolves violations, both big and small, or any compliance concern or action which fails to meet Standards of Conduct

Elements of an ACO REACH Compliance Program

- A designated compliance official or individual (who is not legal counsel to the ACO) and reports directly to CVS Accountable Care's governing body
- Mechanisms for identifying and addressing compliance problems related to CVS Accountable Care's operations and performance
- A method for employees or contractors of CVS Accountable Care, its Providers, and other individuals or entities to anonymously report suspected problems related to the ACO REACH model
- Compliance training for CVS Accountable Care and its Providers
- A requirement for CVS Accountable Care to report probable violations of law to an appropriate law enforcement agency

Your Role in Compliance

Compliance is everyone's responsibility

Understand and adhere to laws, regulations and policies

Complete all required trainings on time

Protect patient confidentiality and privacy

Asks questions if you are unsure of a requirement

Participate, cooperate and be truthful during audits and investigations

Review and comply with the ACO REACH Participation Agreement requirements

Self-report to CVS Accountable Care Compliance team (CVSACO_Compliance@cvshealth.com) if your professional license has expired, been revoked and/or sanctioned, you are placed on any state or federal exclusion, debarment or sanction lists and/or convicted of a crime as defined by the Code of Conduct

ACO Reach Participation Agreement

(Double-click on the below to open the file)

Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
Seamless Care Models Group
7500 Security Blvd
Baltimore, MD 21244

Accountable Care Organization Realizing Equity, Access and Community Health (ACO REACH) Model
Second Amended and Restated Participation Agreement
(2022 Starters)

Last Modified: December 7, 2023

Compliance with Laws & Regulations

Compliance Laws and Regulations

CVS Accountable Care and its Providers must comply with all applicable laws, rules and regulations.

Anti-Kickback Statute (42 U.S.C. § 1320a-7b)

The Anti-Kickback Statute is a federal law that prohibits persons from directly or indirectly offering, providing or receiving kickbacks or bribes in exchange for goods or services covered by Medicare, Medicaid and other federally funded health care programs. These laws prohibit someone from knowingly or willfully offering, paying, seeking or receiving anything of value (“remuneration”) in return for referring an individual to a provider to receive services, or for recommending purchase of supplies or services that are reimbursable under a government health care program.

The Physician Self-Referral law [Stark Law] (42 U.S.C. § 1395nn)

The Stark Law (Physician Self- Referral) is a set of regulations that prohibits a physician from making referrals of a Medicare or Medicaid beneficiary to an entity for the provision of designated health services (“DHS”) in which the physician or their immediate family members has an ownership, investment, or financial interest or in which he or she has a compensation arrangement unless an exception applies.

Compliance Laws and Regulations

Federal False Claims Act (FCA) (31 U.S.C. § 3729 et seq.)

The federal False Claims Act (FCA) is a federal statute that covers fraud involving any federally funded contract or program, including the Medicare and Medicaid programs.

Under the FCA, any individual or organization that knowingly submits a claim he or she knows (or should know) is false and knowingly makes or uses, or causes to be made or used, a false record or statement to have a false claim paid or approved under any federally funded health care program, is subject to civil penalties. It also includes those cases in which any individual or organization obtains money to which they may not be entitled, and then uses false records or statements to retain the money, and instances where a provider retains overpayments.

Under the federal FCA, a person, provider, or entity is liable for up to triple damages and penalties for each false claim it knowingly submits or causes to be submitted to a federal program. Individuals and entities also can be excluded from participating in any federal health care program for non-compliance.

Civil Monetary Penalties Law (42 U.S.C. § 1320a-7a)

Under the Civil Money Penalties Law (CMPL), the Office of Inspector General (OIG) may impose civil money penalties, an assessment, and program exclusion for various forms of fraud and abuse involving the Medicare and Medicaid programs. Penalties range from \$2,000 to \$100,000 for each violation, depending on the specific misconduct involved.

Some examples of CMPL violations include:

- Violating Anti-Kickback statute
- Presenting a claim that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent

Fraud, Waste and Abuse

Participation in CVS Accountable Care requires Compliance & Fraud, Waste and Abuse Training for all employees, Provider partners or contractors of Providers associated with ACO REACH, within 90 days of hire/appointment and annually thereafter, or if changes are made to CMS requirements.

CVS Accountable Care Participating and Preferred providers must comply with fraud, waste and abuse laws.

Definitions

Fraud: Fraud is knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any health care benefit program; or to obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program. This violates criminal law.

Waste: Waste is over-utilization of services or other practices that, directly or indirectly, result in unnecessary costs to government programs like Medicare. Waste is generally not considered to be caused by criminally negligent actions but rather the misuse of resources. Examples include conducting excessive office visits or ordering excessive laboratory tests.

Abuse: Abuse includes actions that may, directly or indirectly, result in unnecessary costs to the federal health care program. Abuse involves payment for items or services when there is no legal entitlement and the provider has not knowingly and/or intentionally misrepresented facts to obtain payment.

Fraud, Waste and Abuse

Examples

Payments for excluded items: Receiving payment for services that are excluded by the plan or federal program

Billing for services that were never provided

Billing for a higher level of service than what was actually delivered

Billing for non-covered services or prescriptions as covered items

Enrolling beneficiaries without their knowledge or consent

Kickbacks, inducements or other illegal payments

Billing for nonexistent prescriptions or knowingly altering claim forms, medical records, or receipts to receive a higher payment

Unknowingly billing for brand name drugs when generics are dispensed

Penalties

Penalties for failure to comply with fraud, waste and abuse laws, include but are not limited to:

- Disciplinary action, up to and including termination
- Criminal convictions/fines (individually and at the corporate level)
- Civil monetary penalties
- Sanctions or loss of licensures
- Exclusion from participation in federal and state health care programs

How to report compliance concerns

If you identify actual or suspected fraud, waste or abuse, or have compliance concerns, it is your obligation to report it.

At any time, you may email the CVS Accountable Care compliance team at CVSACO_Compliance@CVSHealth.

You may also contact the CVS Health Ethics Line to report fraud, waste, or abuse or other compliance concerns. The Ethics Line is available 24 hours per day, 365 days per year, and reports can be made anonymously.

Toll-free Phone Number : 1-877-CVS-2040 (1-877-287-2040); TTY: 711

Email: Ethics.BusinessConduct@CVSHealth.com

Web: www.CVSHealth.com/ethicsline

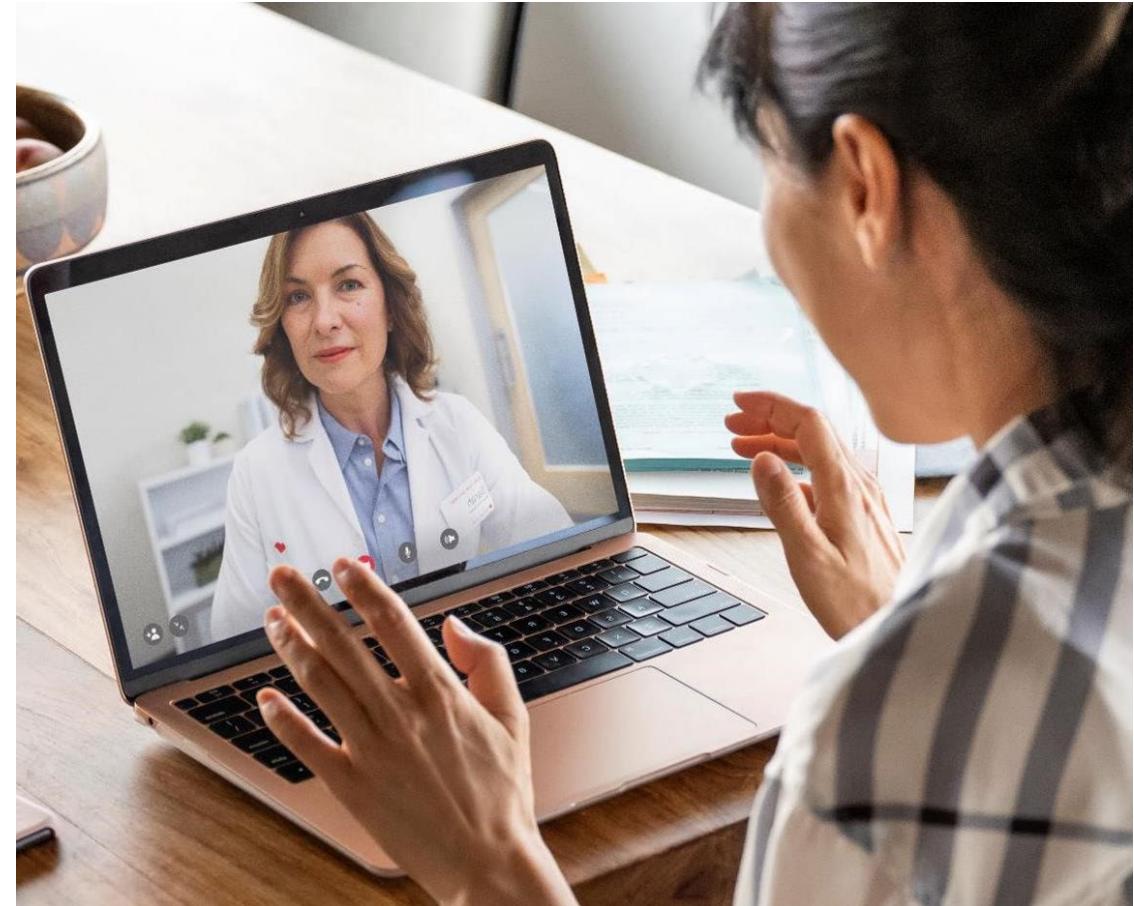
ACO REACH Compliance Requirements

ACO REACH Compliance Requirements

CVS Accountable Care providers must comply with the applicable terms of the ACO REACH Participation Agreement and the agreement between CVS Accountable Care and the Provider.

OIG/LEIE Exclusion Program

- CVS ACO must make certain that each provider has been properly screened against the HHS Office of Inspector General (OIG) Exclusion Database prior to start of Performance Year (PY) or hire. CVS Accountable Care will routinely check to ensure that new hires and current CVS Accountable Care providers are not on the government's exclusion lists.
- If an individual or entity has been identified as excluded from the OIG Exclusion Database or any state exclusion database, Federal and State funds cannot be used to support this person, or organization including any item or service they may have provided, ordered or prescribed whether directly or indirectly obtained and therefore cannot participate in Medicare, Medicaid and all other Federal health care programs.



A photograph of three women of African descent walking outdoors. The woman on the left is smiling and holding a water bottle. The woman in the center is laughing heartily. The woman on the right is looking towards the left. They are all wearing athletic attire. The background is a blurred outdoor setting.

Marketing Activities

Providers must conduct Marketing Activities, including Voluntary Alignment Activities, in accordance with the requirements described in the Participation Agreement.

ACO REACH Compliance Requirements

The Provider shall not:

- ✗ Conduct Marketing Activities before the contract start date or such other date specified by CMS.
- ✗ Discriminate or selectively target Beneficiaries based on race, ethnicity, national origin, religion, gender, sex, age, mental or physical disability, health status, receipt of health care, claims experience, medical history, genetic information, evidence of insurability, geographic location, or income.
- ✗ Conduct communication or Marketing Activities targeted to Beneficiaries enrolled in Medicare Advantage or any other Medicare managed care plan.
- ✗ Perform Marketing Activities outside the ACO REACH Service Area.
- ✗ Engage in activities that could mislead or confuse a Beneficiary regarding the ACO model, other models, Medicare Shared Savings Program, Medicare benefits, or the ACO.
- ✗ Claim the ACO is recommended or otherwise endorsed by CMS or that CMS recommends that the Beneficiary select a Provider as their main doctor, main provider, and/or the main place the Beneficiary receives care.
- ✗ Expressly state or imply that selecting an ACO REACH Provider as the Beneficiary's main doctor, main provider, and/or the main place the Beneficiary receives care removes a Beneficiary's freedom to choose to obtain health services from providers and suppliers who are not an ACO REACH Provider.

ACO REACH Compliance Requirements

The Provider shall not (continued):

- ✗ Use Marketing Materials or Activities through door-to-door solicitation, including:
 - Leaving information such as a leaflet/flyer at a residence
 - Using telephonic solicitation, including text messages and leaving voicemail messages
- ✗ Conduct Marketing Activities in restricted areas of a health care setting including but are not limited to, exam rooms, hospital patient rooms, treatment areas (where patients interact with a health care provider and his/her clinical team and receive treatment, including dialysis treatment facilities), and pharmacy counter areas (where patients interact with pharmacy providers and obtain medications).
- ✗ Perform health screenings at Marketing Events.
- ✗ Require attendees to provide their contact information as a prerequisite for attending a Marketing Event. For example, sign-in sheets must be labeled as optional.
- ✗ Conduct Marketing Activities that were part of an ACO REACH Marketing Plan that was rejected by CMS.

ACO REACH Compliance Requirements

The Provider shall:

- ✓ Only use Marketing Materials or engage in Marketing Activities that were reviewed and approved by CMS.
- ✓ Promptly discontinue use of any Marketing Materials and Marketing Activities rejected/disapproved by CMS
- ✓ Use Beneficiary contact information that was provided at a Marketing Event only for the purpose for which it was solicited.
- ✓ Comply with the applicable CMS ACO REACH requirements for any Marketing Activities conducted and Marketing Materials distributed as part of the Marketing Event.

The Provider may:

- Conduct Marketing Activities through unsolicited direct contact with Beneficiaries using conventional mail and other print media or email, provided that the Beneficiaries are given an opportunity to opt out of subsequent unsolicited contacts.
- Conduct Marketing Activities in common areas of a health care setting including but not limited to, common entryways, vestibules, waiting rooms, hospital or nursing home cafeterias, and community, recreational, or conference rooms.
- Distribute and display Marketing Materials in all areas of the health care setting, including both common areas and restricted areas, except as otherwise specified in the Participation Agreement.

ACO REACH Compliance Requirements

HIPAA Requirements

Have all of the appropriate administrative, technical, and physical safeguards in place before the Start Date to protect the privacy and security of protected health information (PHI).

Maintain the privacy and security of all Model-related information that identifies individual Beneficiaries in accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules and all relevant HIPAA Privacy and Security guidance applicable to the use and disclosure of PHI by covered entities and business associates, as well as other applicable federal and state laws and regulations.





Record Retention

- CMS has established a record retention period of at least 10 years for ACO REACH related records. CVS Accountable Care maintains, and requires all Participant Providers, Preferred Providers, and individuals and entities performing functions or services related to ACO Activities or Marketing Activities to maintain, such books, contracts, records, documents, and other evidence for a period of 10 years from the expiration or termination of the Agreement from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless:
 - CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies CVS Accountable Care at least 30 Days before the normal disposition date; or
 - There has been a termination, dispute, or allegation of fraud or similar fault against CVS Accountable Care, its Participant Providers, Preferred Providers, or other individuals or entities performing functions or services related to ACO Activities or Marketing Activities, in which case the records shall be maintained for an additional six years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

ACO REACH Compliance Requirements

Voluntary Alignment (VA)

- Beneficiaries can choose to align to an ACO by designating an ACO Participant Provider as the Beneficiary's primary clinician or main source of care. Voluntary alignment can be done through Electronic Voluntary Alignment or Signed Voluntary Alignment.
- Providers joining the ACO may not begin Voluntary Alignment activities until the start date of the relevant contract period (the Performance Year). Providers who are added and approved through the ad hoc additions process may begin to participate in approved Voluntary Alignment activities on their effective date.
- Providers are prohibited from completing a Voluntary Alignment Form or designating a clinician on MyMedicare.gov on a Beneficiary's behalf.
- Providers may 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 a Voluntary Alignment Form or a MyMedicare.gov.
- Providers must instruct Beneficiaries to contact the ACO for questions about how to make changes or how to designate a primary clinician.
- Beneficiaries can opt out of data sharing at any time by contacting Medicare and indicating their preference. Providers cannot contact Medicare for beneficiaries.
- Providers may not inhibit Beneficiaries from exercising their freedom to obtain health services from providers and suppliers who are not ACO Providers.

ACO REACH Compliance Requirements

Signed Voluntary Alignment (SVA)

- The process by which a Beneficiary may voluntarily align with an ACO by designating a Participant Provider as their primary clinician via a Voluntary Alignment (VA) Form provided by the ACO.
- Incomplete forms should be returned to the beneficiary to ensure the form has been properly dated, signed and includes the optional identifier field.
- If a VA paper form is returned to the provider's office, the signed forms and the envelopes that they are returned in, or an image of the envelope, must be kept and retained based on CMS record retention requirement.
- SVA forms from previous Performance Years, that are signed and dated after December 31, 2023, will no longer be considered a valid template in PY 2024. Providers should discard outdated SVA forms from previous Performance Years and only circulate the most current SVA form approved for use.
- Providers cannot make unsolicited phone calls or text to beneficiaries to discuss VA. Providers may only discuss VA on the phone call if a beneficiary proactively mentions the topic of VA. If the beneficiary initiates the VA discussion, the ACO or provider may provide answers.



Electronic Voluntary Alignment

- Electronic Voluntary Alignment is the process by which a Beneficiary may voluntarily align with an ACO by designating a Participant Provider as the Beneficiary's primary clinician on the MyMedicare.gov website.

ACO REACH Compliance Requirements

Notifications to CVS Accountable Care

- Provide timely notification to CVS Accountable Care of provider enrollment changes **within 30 calendar days** after the change.
- Provide timely notification to CVS Accountable Care **within 7 calendar days** of becoming aware of any provider sanctions or of being under investigation.
- Notify CVS Accountable Care of potential compliance issues or complaints that pertain to any aspect of the ACO REACH model. Notification to CVS Accountable Care must occur **within 7 calendar days** of identification of the issue by the Provider.

Examples:

- Potential issue of provider fraud, waste or abuse brought forth by a beneficiary
- Potential compliance issue brought forth by an individual provider involving ACO REACH and the anti-kickback statute
- Complaint about a CVS Accountable Care nurse brought forth by a caregiver, etc.

ACO REACH Compliance Requirements



Medicare Status

Maintain status as a Medicare-enrolled provider or supplier (as defined at 42 CFR § 400.202) that bills for items and services furnished to Beneficiaries under a Medicare billing number assigned to a TIN in accordance with applicable Medicare regulations.



Quality Measure Reporting

Cooperate with CVS Accountable Care in regard to quality measure reporting as described in Appendix D of the Participant Agreement. [I.e., Care Coordination/Patient Safety: Readmissions, Unplanned admissions, Days at home; Patient/Caregiver experience: CAHPS.]



Health Equity Plan & Activities

REACH ACOs are required to develop a detailed Health Equity Plan to address health disparities in service areas indicating a need.



Resources

For additional resources, you can visit:

- CMS: <http://www.cms.hhs.gov/>
- HHS/OIG: <http://oig.hhs.gov>



Compliance Training Acknowledgement

Congratulations!

- You have completed your annual CVS Accountable Care compliance training requirement.
- If you have any questions about this compliance training and/or other compliance matters, please contact your organization's compliance department.

