Prepping for Shared Savings Program Compliance

Performance Year 2025

WILEMS
resource group

Housekeeping

- Speakers will present for approximately 45 minutes
- Q&A will take the remainder of time
- Webinar is being recorded
- Slides and recording will be available on the NAACOS website within 24 hours.

Kimberly Busenbark

o After beginning her career in Medicare Advantage compliance, Kimberly began working with ACOs during the first wave of the Medicare Shared Savings Program and started Wilems Resource Group in 2015. Since then, WRG has continued to grow, and has helped more than 80 ACOs across the country remain compliant and be successful within CMS value-based models and programs.

o Kimberly is a graduate of Texas A&M University, where she received a Bachelor's of Business Administration in Marketing and Management, and of The University of Houston Law Center, where she received her Juris Doctorate before being admitted to the State Bar of Texas.

o Email: kwilems@wilemsrg.com

Questions & Answers

o To ask a question:

- To submit a written question, you can write in the Questions tab on your dashboard at any time.

- To ask a live question, you can use the "raise hand" feature on your dashboard. Please make sure you are dialed in on a telephone and have connected using the audio pin so that we can unmute your line. Your name will be called when it is your turn to ask a question.

How to Survive a Virtual Compliance Session

o Find your comfy pants and refill your coffee

o Laugh if Kimberly makes a joke, be sure to unmute your mic

o Try not to get too paranoid

o Please ask questions or make comments

o Doodle on your checklist

o **Help us! Join the discussion!**

BEFORE

AFTER

Shared Savings Program Compliance Program Requirements

Medicare Shared Savings Program ACOs are required to have a Compliance Program containing the following 5 elements:

Compliance Official

Mechanisms for Identifying Issues

Compliance Training

Method for Anonymous Reporting

Requirement for Reporting Violations of Law

Element 2: Mechanisms for Identifying Issues

CHECK COMPLIANCE BOXES

- ❑ Creation of a Formal Compliance Plan
- ❑ Adoption of Compliance and Operations Policies & Procedures
- ❑ Effective Annual Compliance Training for Related Individuals
- ❑ Anonymous Reporting – Hotline or Online Tool
- ❑ Data Use Requirements
- ❑ Marketing Material Compliance
- ❑ Development of a Monitoring and Oversight Program
- ❑ Annual Reviews and Updates

ACO Real World Compliance Checklist — WILEMS resource group

This checklist can serve as a guide for your organization as you work through the implementation and maintenance of your ACO's Compliance Program. However, no reference tool can ever be completely comprehensive and use of this tool can never take the place of reading all relevant guidance and regulations.

GOVERNANCE
- ❑ Develop Governing Body
  - ❑ Medical Director
  - ❑ Medicare Beneficiary Representative
  - ❑ 75% Voting Control by ACO Participants
  - ❑ "Meaningful Representation" from each Participant
- ❑ Create Organizational Chart
  - ❑ ACO Executive, Medical Director, & Compliance Officer report directly to Gov. Body
  - ❑ Clear reporting lines from individuals and Sub-Committees to Governing Body
- ❑ Create Conflict of Interest Policy & Collect Acknowledgement forms
- ❑ Create & Approve Committee Charters
- ❑ Conduct & Document Quarterly Sub-Committee & Governing Body Meetings
- ❑ Retain ACO Operating Agreement, Executed Participation Agreements, and BAAs
- ❑ Define, Update, & Manage ACO-MS Contacts (e.g., Compliance Contact)

GENERAL COMPLIANCE
- ❑ Create & Approve Compliance P&Ps and Compliance Plan
- ❑ Create, Distribute, & Audit New Hire and Annual Compliance Training
- ❑ Create, Document, & Conduct Monitoring and Oversight Activities
- ❑ Determine & Launch a Method for Anonymous Reporting (i.e. hotline, web form)
- ❑ Review & Document Utilization of FWA Waivers and Benefit Enhancements

MARKETING/NOTIFICATIONS
- ❑ Create, Document, & Implement a Marketing Material Review Process
- ❑ File Marketing Materials with CMS for Approval
- ❑ Update & Launch the Public Reporting Webpage
- ❑ Document & Distribute Beneficiary Notifications and ACO Office Posters
- ❑ Document & Distribute Benefit Enhancement Communications; if applicable

OPERATIONS
- ❑ Create & Approve Operations P&Ps required under § 425.112
- ❑ Create, Document, & Implement an OIG/GSA Screening Process
- ❑ Track Annual and New Hire Compliance Training
- ❑ Submit & Maintain DUA Addenda
- ❑ Document & Manage ACO-MS User Access

Review of Compliance Documents

- ❑ Compliance Plan – Summary Document approved by Governing Body Annually
- ❑ Committee Charters
- ❑ Data Use Documentation
- ❑ Compliance Work Plan – deliverables and due dates
- ❑ Compliance Monitoring Plan – detailed plan for the ACO's Monitoring Program

- ❑ Policies & Procedures – Detailed documents demonstrating compliance with each required element
  - o Key Policy Updates for PY25:
    - Privacy Reporting
      - o Clarifying reporting requirements in the event of a break
    - Evidence Based Medicine
      - o Updates to CEHRT requirements
    - Beneficiary Notifications:
      - o Remove requirement for Follow-Up Notification at the next office visit

Building a PY25 Monitoring Program

- ❑ Beneficiary Notification & Follow-Up Process
- ❑ Governance & Leadership Requirements
- ❑ Compliance with Policies & Procedures
- ❑ Compliance Training
- ❑ Data Compliance
- ❑ Marketing Material Compliance
- ❑ Public Reporting – new tool available to autofill template
- ❑ Waivers and/or AIP if applicable
- ❑ Testing Anonymous Reporting Tool
- ❑ CEHRT Usage

PY25 Red Flags, Changes & What to Do About Them

o Governance & Leadership
o Beneficiary Notifications
o CEHRT Usage
o Provider Materials

Red Flag: Governance & Leadership

Ensure the Governing Body meets all requirements:

- ❑ Ultimate Authority
  - At least quarterly meetings
- ❑ 75% control by Participants
  - Meaningful Participation
  - Duty of Loyalty
- ❑ Transparent Governing Process
  - Availability of Minutes & Record Retention
- ❑ Conflict of Interest policy, including resolution process
  - Annual attestation of conflicts prior to the start of the Performance Year

- ❑ Medical Director and Executive with experience and authority with no conflicts of interest
  - Governing Body must have authority for approval/removal of Executive
  - Medical Director does not have to be a Provider/Supplier in the ACO but must be a:
    - Board Certified and Licensed in a State in which the ACO operates
    - Physically present in a clinic or office of the ACO

Cover Your Audit: Governance and Leadership

- CMS increased oversight of Governance and Leadership in SSP and ACO REACH for PY2024
- Do not forget Governing Body members when setting up exclusion screening and training processes
    - Consider in-person training for Governing Body
- Monitor for COI completions in Q4 each year
- Ensure minutes are kept for each meeting to prove compliance with the following:
    - Beneficiary involvement
    - "Ultimate Authority" requirement
    - Reporting by Compliance Officer
    - Meaningful representation

Cover Your Audit: Governance and Leadership

- Policies and Procedures can help ensure requirements are not forgotten when changes are made
  - Include requirements to update ACO-MS and public disclosure within 30 days
  - Cannot send a change request if one is open, so collect and submit all at once

- Ensure Bylaws and P&Ps clearly document authority, reporting requirements and transparency

Update: Beneficiary Notifications

❑ Follow-up Communication

- Verbal or written communication
- Must occur **no later than** ~~the *earlier*~~ of:
  - ~~The next primary care visit or~~
  - 180 days from the date the standardized written notice was provided
- Must retain record of beneficiaries receiving the follow-up communication, and the form and manner in which the communication was made.

Update: Beneficiary Notifications

❑ Office poster on display
  - Must be placed in "all facilities" ~~not just those where "beneficiaries receive primary care services"~~

❑ Written Notification: Alignment methodology matters
  ➢ Preliminary Prospective:
    - Any Bene who received a primary care service during the assignment window
    - At or before 1st visit
  ➢ Prospective
    - Aligned Beneficiaries
    - During the PY in which they are aligned

Cover Your Audit: Beneficiary Notifications

- Document 2 attempts for each Beneficiary

- Confirm Office Posters on Display

- Prepare ACO-Related Individuals before Beneficiary Notifications are distributed

- Build record keeping at the individual-level for notifications and follow-up

  - Initial attempt methodology and date

  - Second attempt methodology and date

- Be particularly careful with in-office processes

- Monitor regularly in the ACO's quarterly monitoring plan

Update: CEHRT Usage

- ❏ Beginning in PY25:
  - ❏ Tracks A – D: must ensure 50% of providers are using CEHRT systems
  - ❏ Track E & Enhanced: must ensure 100% of providers are using CEHRT systems in compliance with BASE Requirements
- ❏ How to Monitor – Request Screenshots of:
  - • Product and Version Number in Use
  - • Provider Name shown in system (select sample from provider/supplier list)
    - • Tie in with Roster Management Oversight
  - • The product ONC Number which can be found here: https://chpl.healthit.gov/#/search

Base Electronic Health Record (EHR) Definition

The Base Electronic Health Record (EHR) definition provides a baseline assurance that certified health IT has been developed to possess, at a minimum, a key set of capabilities as outlined below.

Base EHR Definition – Certification Criteria Required to Satisfy the Definition	
Base EHR Capabilities	**Certification Criteria Final Rule Compliance Date**
Includes patient demographic and clinical health information	Patient demographics and observations § 170.315(a)(5) Implantable device list § 170.315(a)(14)
Capacity to provide clinical decision support	Clinical decision support § 170.315(a)(9) (expires January 1, 2025) or Decision support interventions § 170.315(b)(11)
Capacity to support physician order entry	Computerized provider order entry § 170.315(a)(1), (2) or (3)
Capacity to capture and query information relevant to health care quality	Clinical quality measures – record and export § 170.315(c)(1)
Capacity to exchange electronic health information with, and integrate such information from other sources	• Transitions of care § 170.315(b)(1) • Application access – patient selection § 170.315(g)(7) • Application access – all data request § 170.315(g)(9) • Standardized API for patient and population services § 170.315(g)(10) • Direct Project § 170.315(h)(1) or Direct Project, Edge Protocol, and XDR/XDM § 170.315(h)(2)
The requirements of the Base EHR Definition can be met using one Certified Health IT Module or a combination of Certified Health IT Modules.	

Red Flag Provider Materials

❑ Marketing Material definition in Shared Savings Program is extremely broad

❑ PY2025 Marketing Toolkit emphasized Provider materials and suggests CMS audits of those materials may be forthcoming.

❑ How to Monitor
   ❑ Ongoing: Marketing Log & Library
   ❑ At least annually: Confirm materials in use with relevant Operational Areas

Marketing materials and activities include, but are not limited to, general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, Web pages, data sharing opt out letters, mailings, social media, or other activities conducted by or on behalf of the ACO, or by ACO participants, or ACO providers/suppliers participating in the ACO, when used to educate, solicit, notify, or contact Medicare beneficiaries or ***providers and suppliers*** regarding the Shared Savings Program.

Feeling Overwhelmed?

There are several resources available to help you navigate compliance.

❑ **NAACOs** **Compliance Manual:** template policies & procedures covering requirements specific to the Shared Savings Program

❑ **CMS Communications**
- Spotlights are a great way to avoid missing deadlines and identifying holes in P&Ps
- Utilize your CMS
- FAQs and other communications – usually released in the Spotlights/Newsletters

❑ **NAACOS Online Library**

❑ **Wilems Resource Group:**
- Free resources online at wilemsrg.com
- Quarterly newsletter
- LinkedIn

Final Comments

The webinar recording and slides will be available at https://www.naacos.com/on-demand-webinars within 24-hours. THANK YOU!

Kimberly is ready to answer your questions!

Colleen Hayes/NBC/GettyImages

Disclaimer: This is not Kimberly Busenbark of Wilems Resource Group. This is Leslie Knope of Parks & Rec who we like to believe was speaking about compliance when she eloquently said, "one person's annoying is another's inspiring and heroic".

Contact Us

NAACOS

Elizabeth Holder

support@naacos.com

202.640.1850

Wilems Resource Group, LLC

Kimberly Busenbark

kwilems@wilemsrg.com

713.829.0882