



Building Blocks & Checking Box(es)

COMPLIANCE ACROSS CMS VALUE-BASED MODELS

Agenda

- Welcome
 - Housekeeping
 - Compliance Updates for CMS
 - Compliance Manual Access
 - Q+A
-

Brian Hammer



**Vice President
Membership and
Business Services
NAACOS**

Brian Hammer, MS, MBA, FACHE is the vice president of membership and business services for the National Association of ACOs. As part of the executive team, Brian leads all activities developing relationships with new and existing ACOs contracting with CMS and commercial payers. Brian also oversees the procurement of strategic business partnerships benefiting ACOs. Before NAACOS, Brian's considerable experience in both the hospital arena and in the out-patient ambulatory setting proved beneficial to Meridian Health System as his work strategized primary care physician alignment through practice acquisition and recruitment initiatives. Most notably, he delivered a successful ACO recruitment campaign yielding over 10,000 beneficiary lives. Prior to his hospital role, Brian was successful in the pharmaceutical space winning multiple national awards for companies such as Johnson & Johnson and Takeda Pharmaceuticals. Brian graduated top of his program for his Master of Science in Health Administration degree at St. Joseph's University. He also holds his MBA from Syracuse University, and his Bachelor of Science in Business Administration from Drexel University. He is a visiting adjunct professor at Monmouth University, is a Fellow of the American College of Healthcare Executives, and volunteers as a mentor to healthcare MBA students.

Email: bhammer@naacos.com

Kimberly Busenbark



CEO
Wilems Resource Group

After beginning her career in Medicare Advantage compliance, Kimberly began working with ACOs during the first wave of the Medicare Shared Savings Program. She has served as the Compliance Officer for more than 40 ACOs since 2012. In 2015 she began Wilems Resource Group, which has continued to grow and has helped organizations across the country remain compliant and be successful within the Medicare Shared Savings Program, Next Generation ACO Model, and the Direct Contracting Model.

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.

Email: kwilems@wilemsrg.com

How to Survive a Virtual Compliance Session



- Find your comfy pants, make a warm beverage
- Put your favorite show on in the background, be sure to mute your mic
- Laugh if Kimberly makes a joke, be sure to unmute your mic
- Interrupt me - please ask questions, make comments
- Doodle on your checklist
- Help Us! Join the discussion!**

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

Next Generation ACO Model Compliance Program Requirements

Next Generation Model 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

Direct Contracting Model Compliance Program Requirements

Direct Contracting Entities are required to have a Compliance Program containing the following 5 elements:



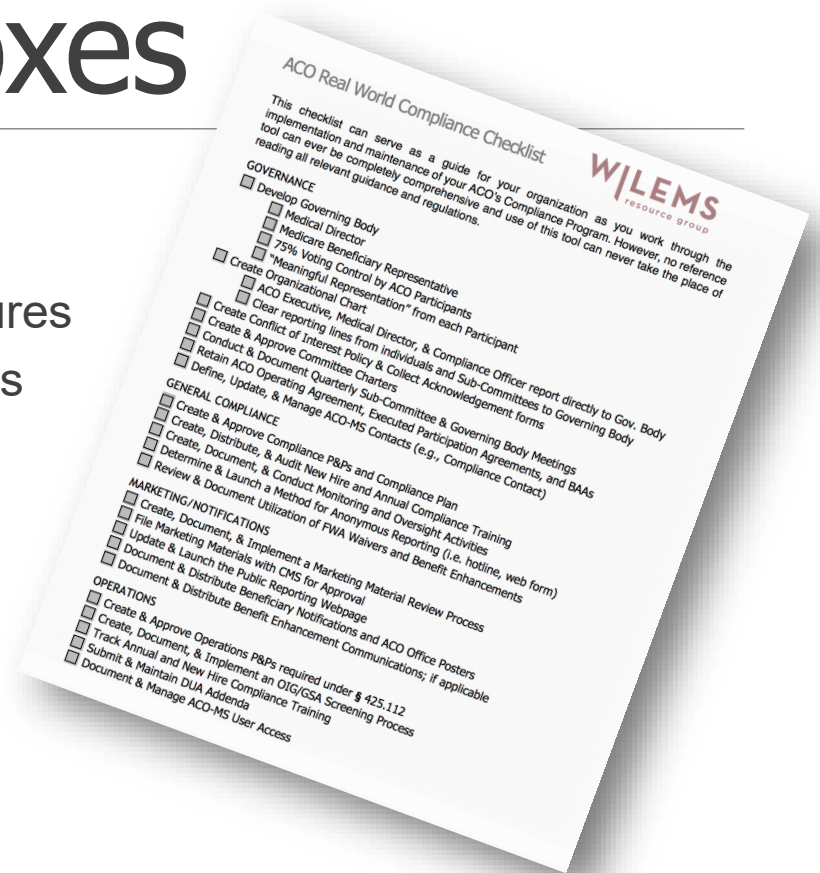
* CMS has shared a requirement that the Compliance Official have 2 years of Compliance Experience. This was not included in the Implementation Period Participation Agreement.

So, that's it right?

- Major Program Differences – Compliance Specific
- Practical Guidance
- Available Resources
- CYA** – Cover Your Audit

Checking 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



Complianc

e We're not
happy `till`

You're not
happy

Effective Compliance



- ❑ Collaborates with Operations to develop compliant strategies for success
- ❑ Works with Participants to identify economies across compliance requirements
- ❑ Oversees compliance with operational processes and regulatory guidance
- ❑ Serves as a liaison between CMS and the organization
- ❑ Balances risk, practice requirements, and financial burden
- ❑ Brainstorms with leadership and operational teams to get to “yes”
- ❑ Applies common sense to regulatory requirements
- ❑ Prepares for successful audit response

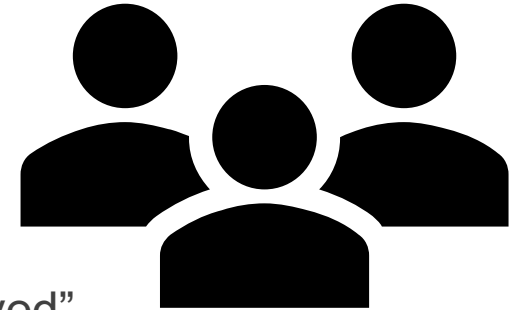
Major Program Differences: Governance

❑ 75% vs 25% Participant Representation

- Shared Savings Program and NextGen ACOs must have at least 75% Participant Representation
- DCEs need only 25% Participant Representation

❑ Medicare Beneficiary and Consumer Advocate Representatives

- Medicare Beneficiary: does not have to be aligned, must be “served”
- Consumer Advocate: someone with professional experience or training as a consumer advocate



Governance: What You Need to Know

- ❖ May appeal to CMS for alternative methods of engagement if you cannot meet these standards, (i.e. Corporate Practice of Medicine).
- ❑ 75% vs 25% Participant Representation
 - “Participant” or “Designated Representative”
 - Need to ensure transparency and participant engagement either way
 - **CYA**: Make sure your P&Ps are clear to prevent future changes disrupting your compliance
 - **CYA**: Make sure your Public Disclosure is clear
 - It’s an “at least” requirement
- ❑ Medicare Beneficiary and Consumer Advocate Representatives
 - Can be the same person
 - No guidance on what, specifically, is required

Major Program Differences: Notifications

❑ Beneficiary Notification Requirements

- Shared Savings Program: Office poster on display and written notice prior to or at the first office visit
- NextGen & Direct Contracting: written notice by a CMS-specified date during each Performance Year
- Direct Contracting:
 - Language translation requirements - “primary language of at least 5% of the individuals in the DCE Service Area”

❑ Participant, TIN Exec & Preferred Provider Notification Requirements

- Only required in NextGen and Direct Contracting
- Deadlines are extremely rigid: at least 7 days prior to submission of list



Notifications: What You Need to Know

❖ CMS WILL AUDIT THESE PROCESSES

❑ Beneficiary Notification Requirements

- **CYA:** Send it anyway you want – IF you can ensure documentation at the Beneficiary Level
- Save everything
- Have a plan to close gaps
- **CYA:** Document everything in P&Ps

❑ Participant, TIN Exec & Preferred Provider Notification Requirements

- E-mail is the most common
- Include the Participation Agreement to check two boxes at once
- **CYA:** Make sure you can document at the individual level for audit purposes
- **CYA:** Document plan for notifications in P&Ps

While We Are On The Subject...

- ❑ Paper-Based Voluntary Alignment
 - CMS will approve your plan – just watch out for Cherry Picking
 - **CYA**: Save everything
 - No. Really. Everything.
 - Save the envelopes for returned Voluntary Alignment Forms
 - **CYA**: Document everything in your P&Ps
 - Be prepared to submit your Beneficiary lists to CMS
 - Direct Contracting: Don't forget your translation requirements!

Major Program Differences: Marketing Materials

- ❑ Marketing Materials is defined very broadly in all three – anything used to “educate, solicit, notify or contact”
 - Shared Savings Program definition includes provider facing materials
 - Direct Contracting has additional requirements and limitations:
 - Specifically includes “materials”, “activities”, and “events”
 - Has specific limitations and prohibitions on “in-person” and “door to door” type activities, as well as what can be provided “in-office”
- ❑ CMS Approval Timeframes
 - Shared Savings Program is 5-day file and use
 - NextGen and Direct Contracting have 10-day file and use
 - CMS can disapprove at any time
- ❑ Direct Contracting 5% Translation Requirements

Marketing Compliance: What You Need to Know

❑ Operations

- Translation requirements can be met by printing front and back to save money
- Know when to “trust” the file and use timeframes

❑ Oversight

- Really understand the definition of what requires CMS Approval
- Identify internal review process and decision point

❑ Tracking & Archiving

- **CYA:** Create a Material Log and a Tracking Process
- ❖ Added bonus: Version Control

Major Program Differences: Alternative Payment Mechanism

- ❑ Population Based Payments (PBP) & All-Inclusive PBP (AIPBP)
 - Must notify and educate around intended participation
 - Participants and Preferred Providers can decide whether to participate each Performance Year
 - Each TIN must agree on the percentage
 - Must collect Written Confirmation for each Participant/Preferred Provider:
 - Next Generation ACO Model: Population-Based Payments Fee Reduction Agreement
 - Next Generation ACO Model: All-Inclusive Population-Based Payments Fee Reduction Agreement

Major Program Differences: Capitation & Advanced Payments

❑ Capitation

- Total Care Capitation: Every TIN/NPI on Participant List
- Primary Care Capitation: Each TIN/NPI Combo may decide whether to participate
- Preferred Providers can pick either way
- Must collect Direct Contracting Model: DC Capitation Payment Mechanism Fee Reduction Agreement
 - Must include specified percentage of reduction

❑ Advanced Payments

- Does not require participation of entire TIN
- Must collect Direct Contracting Model: Advanced Payment Fee Reduction Agreement

Capitation & Advanced Payments: What You Need to Know

❑ Practical Tips:

- Forms can be signed by the TIN Executive but must include a list of NPIs who have affirmatively agreed
- Notice and Educate requirements are not met solely by completion of the Consent Form
- Participation must be completely voluntary
- Consent must be signed prior to submission of Annual List

❑ **CYA:** CMS will confirm completion of the specified documentation

- Build QA into your Annual List Submission Process to ensure each required element is in place

Major Program Differences: Shared Savings Program & NextGen Waivers

- ❑ Pre-Participation Waiver
- ❑ Participation Waiver
- ❑ Physical Self-Referral (Stark) Law Waiver
- ❑ Shared Savings Distribution Waiver
- ❑ Beneficiary Inducement Waiver
 - NextGen requires documentation at the Beneficiary level
 - Different than the Beneficiary Incentive Program (BIP) available under the Shared Savings Program

Major Program Differences: Direct Contracting Waivers

Direct Contracting Implementation Period Waiver

- ❑ Limited in Scope - only waives Stark and Anti-Kickback (not Gainsharing CMP)
 - Cannot provide or receive inducements for referrals for non-aligned beneficiaries

- ❑ Must be “start up” in nature

- ❑ Interoperability requirement for any exchange of health IT

We expect to see waivers aligned with Shared Savings Program and NextGen for the Performance Year.

Waivers: What You Need to Know

- ❑ Use of a waiver does not require CMS approval
 - That's not necessarily a good thing!

- ❑ Bona-fide determination
 - More than a “rubber-stamp”
 - **CYA:** Watch your dates
 - **CYA:** Waiver Checklist – capture compliance and approval in one document
 - Document how it is “related to the purposes” of the model
 - Remove financial terms to meet public disclosure requirements

- ❑ Always watch for the *appearance* of Cherry-Picking

- ❑ No State Laws waived

Major Program Differences: Benefit Enhancements

- ❖ Benefit Enhancements (not Waivers) – do require CMS approval
 - ❑ Direct Contracting does not have any Benefit Enhancements available during the Implementation Period. Expectation is that the Benefit Enhancements will match NextGen during the Performance Year.
 - ❑ NextGen
 - 3-Day SNF Rule Waiver
 - Telehealth Expansion
 - Post-Discharge Home Visits
 - Chronic Disease Management Reward
 - Cost Sharing Support for Part B Services
 - Care Management Home Visits
 - ❑ Shared Savings Program
 - 3-Day SNF Rule Waiver
 - Telehealth Services

Benefit Enhancements: What You Need to Know

- ❖ **CYA:** Be prepared for an audit on all elements
 - ❑ Use the approved Implementation Plan to build the P&P
 - How will you ensure Beneficiary Eligibility? May go beyond alignment.
 - ❑ Maintain Oversight of the required elements for each Benefit Enhancement
 - Build into P&P
 - Build into Quarterly Compliance Monitoring
 - Report up to Quality/Clinical Committee and/or Governing Body
 - ❑ Pay attention to Termination requirements

Major Program Differences: Data Usage

- ❑ Documenting Compliance with CMS Data Usage Requirements
 - Shared Savings Program – still signs a Data Use Agreement (DUA); no longer requires DUA Addendum
 - NextGen and Direct Contracting – Data Use Acknowledgement Form as part of Participation Agreement

- ❑ Requirements are largely the same
 - NextGen and Direct Contracting specifically allow for sharing of beneficiary data with any provider in a treatment relationship with the beneficiary
 - Under Shared Savings Program DUA, CMS Data cannot be shared outside of the ACO, ACO Participants or ACO Provider/Suppliers
 - Cell Suppression and de-identified data sharing limits are in place for all three models

Data Compliance: What You Need to Know

- ❖ In all models, the organization is responsible for documenting compliance with Data Usage Requirements.
 - ❑ **CYA** : Decide how the organization is going to document downstream compliance
 - Should be a discussion between Legal and Compliance:
 - Business Associate Agreements
 - CMS Data Acknowledgement Form
 - Data Logs
 - ❑ **CYA** : Detail requirements in the P&Ps
 - ❑ **CYA**: Add cell suppression requirements to Marketing Oversight your

[Additional Guidance](#) – WRG White Paper: Data Use Agreement Simplification

Feeling Overwhelmed?

There are several resources available to help you navigate compliance.

❑ CMS Communications

- Spotlights & Newsletters are a great way to avoid missing deadlines and identifying holes in P&Ps
- Utilize your CMS Coordinator – especially in Direct Contracting!
- FAQs and other communications – usually released in the Spotlights/Newsletters

❑ NAACOs Compliance Manuals

- Template Policies & Procedures covering requirements specific to each model

❑ NAACOS Online Library

- Includes archives of all Newsletters and Spotlights
- Model specific insights and information
- Listserv



❑ Wilems Resource Group

- White Papers and Checklists: www.wilemsrg.com/resources
- Newsletter: It's free. It's quarterly. It's not lame. Sign up [here!](#)

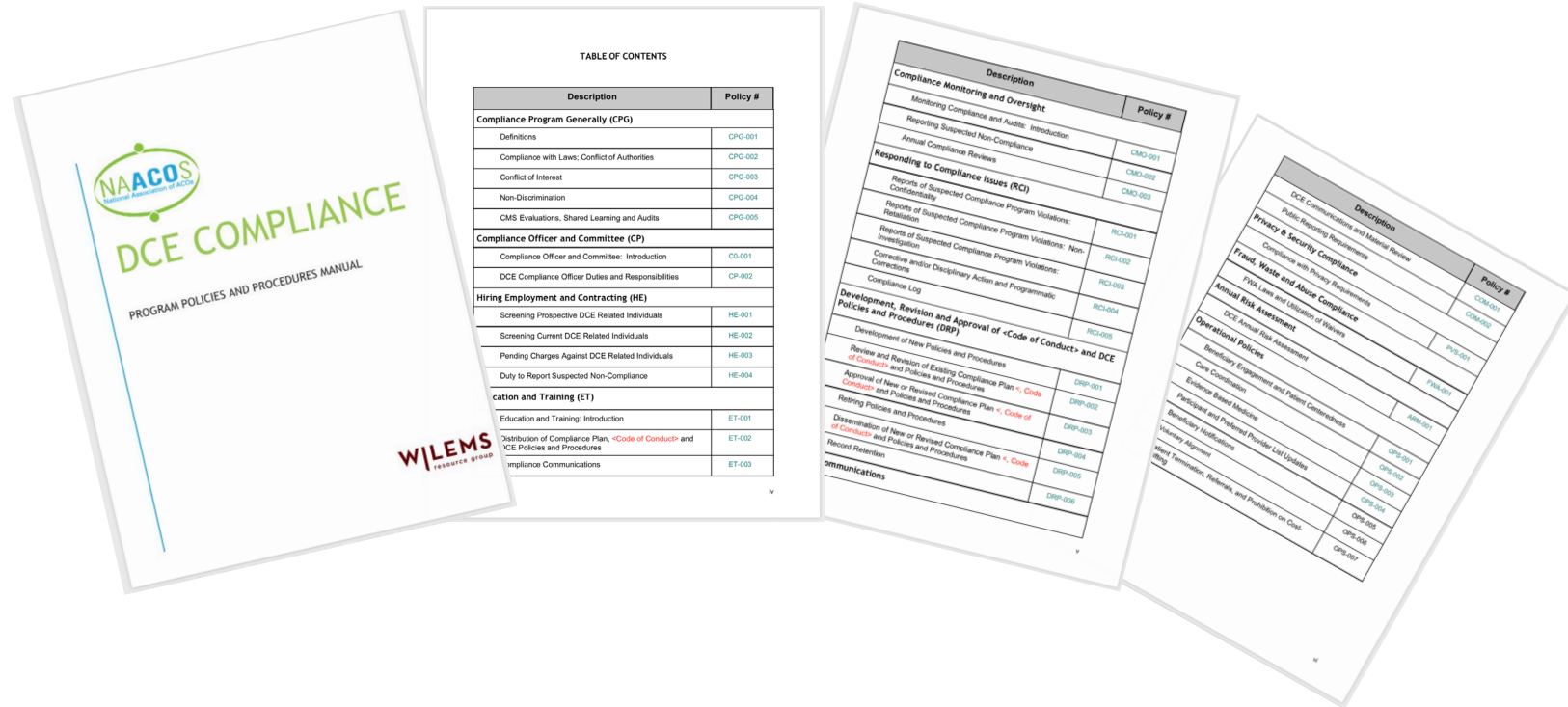
NAACOS ACO Compliance Manuals

- ❑ NextGen and Shared Savings Program ACOs are required to meet many state and federal regulatory requirements.
- ❑ The NAACOS Compliance Manuals provide template policies to help your ACO's leadership determine the best "next steps" for the ACO and implement procedures to ensure compliance with program requirements.
- ❑ The Compliance Manual includes:
 - Fully editable foundational policy templates
 - Version control and policy record retention capabilities
 - Important steps to consider when forming policies & procedures
 - Easy to use functionality
 - And more!
- ❖ ACO Compliance Manuals are reviewed and revised as new regulatory updates and recommendations are released by CMS - you only have to update based your internal processes!

Learn more: <https://www.naacos.com/compliance-manual>

NEW Direct Contracting Compliance Manual

- ❑ The NEW Direct Contracting Model Compliance Manual is coming soon!
- ❑ The robust set of template policies will help your DCE implement procedures to ensure compliance with model requirements.



Learn more: <https://www.naacos.com/compliance-manual>

Compliance Manual Pricing

	First Year	Yearly Renewal
NAACOS MEMBERS	\$450	\$200
NON-MEMBERS	\$900	\$500

PURCHASE THE COMPLIANCE MANUAL ONLINE AT <https://www.naacos.com/compliance-manual>

Still Feeling Overwhelmed?

I'm here now. Take advantage.

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”.