



Building Blocks & Checking Box(es)

COMPLIANCE ACROSS CMS VALUE-BASED MODELS



Housekeeping



- Speakers will present for approximately 45 minutes
- Q&A will take the remainder of time
 - You can submit written questions using the Questions tab on your dashboard to the right of your screen at any time during the webinar
 - During the Q&A session, you can use the “raise hand” feature on your dashboard to ask a live question
- Webinar is being recorded
 - Slides and recording will be available on the NAACOS website within 24 hours. You will receive an email when they are available

Brian Hammer



BRIAN HAMMER
bhammer@naacos.com

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.

Kimberly Busenbark



After beginning her career in Medicare Advantage compliance, Kimberly began working with ACOs during the first wave of the Medicare Shared Savings Program and spent the first three years of the program as the ACO Compliance Officer for Collaborative Health Systems' 35 Shared Savings Program ACOs. During this time, she was responsible for the implementation and oversight of the compliance program for each of the ACOs. Kimberly started Wilems Resource Group in 2015. Since then, WRG has continued to grow, and has helped ACOs and DCEs across the country remain compliant and be successful within the Medicare Shared Savings Program, the Next Generation ACO Model and, the Global and Professional 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

Global & Professional Direct Contracting Model Compliance Program Requirements

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



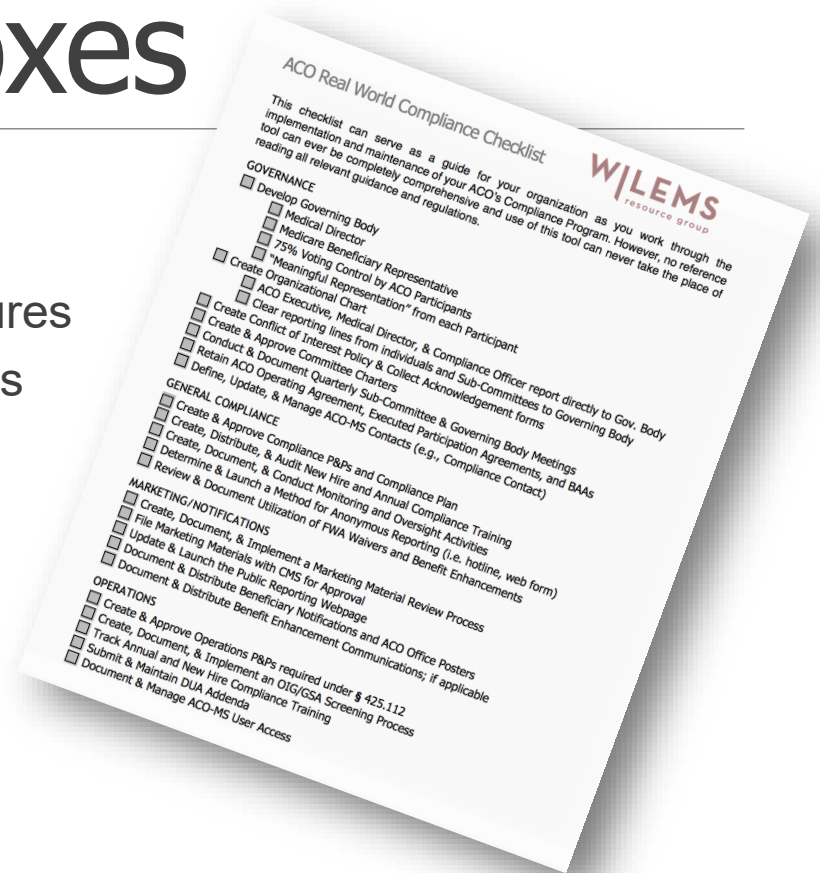
* CMS has shared a requirement that the Compliance Official have 2 years of Compliance Experience. This was not included in the GPDC Model Participation Agreement.

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



Compliance

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

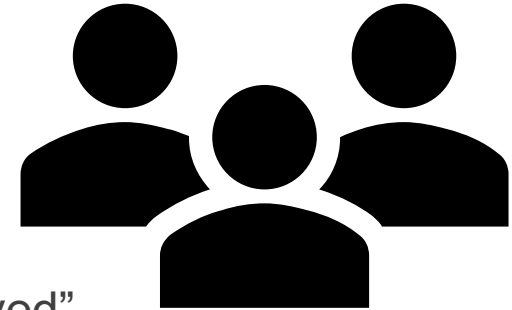
Major Program Differences: Governance

❑ 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: Contracting

- ❑ Shared Savings Program signs downstream Participation Agreements at the TIN Level.

- ❑ NextGen Model requires provider level agreements, but CMS was open to TIN level agreements where the NGACO could point to appropriate language in contracts with providers.

- ❑ GPDC Model requires provider level agreements unless all of the following are met:
 - ✓ The TIN is Medicare enrolled and approved to be a DC Participant or Preferred Provider
 - ✓ The Agreement identifies each provider
 - ✓ The Agreement requires TIN and each provider to participate in the Model
 - ✓ Each provider is employed by or under contract with the TIN
 - ✓ The TIN is legally authorized to bind each provider
 - ✓ The TIN is the same participant type as the individual providers

Contracting: What You Need to Know

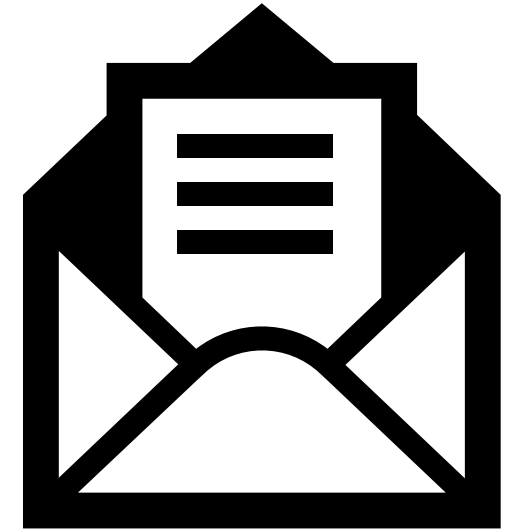
- ❑ To avoid provider level agreements in the GPDC Model:
 - Specifically add each of the six (6) elements to your downstream agreements.
 - Don't forget about mid-year additions!
 - ❖ **CYA:** Add an Exhibit listing each NPI and a clause allowing the Exhibit to be updated upon notice to the TIN Executive.

- ❑ **CYA:** Compare Legal Business Name, TIN and NPI across all of the following documents to ensure compliance before submission:
 - ACO-MS, ACO-UI or 4i: These systems check PECOS and will ensure you are using the correct LBN
 - The Provider and TIN Executive Notices
 - The Downstream Agreement: signature blocks and NPI Exhibit, if applicable
 - The Fee Reduction Agreement, if applicable

Major Program Differences: Beneficiary Notifications

❑ Beneficiary Notification Requirements

- Shared Savings Program: Office poster on display and written notice prior to or at the first office visit
- NextGen & GPDC Models: written notice by a CMS-specified date during each Performance Year
- GPDC Model:
 - Language translation requirements - “primary language of at least 5% of aligned Beneficiaries”
 - *Notifications are **not** required in IP2!!!*



Major Program Differences: Provider & TIN Notifications

- ❑ Participant, TIN Executive & Preferred Provider Notification Requirements
 - Only required in NextGen and GPDC Model
 - Deadlines are extremely rigid.
 - **NextGen**: at least 7 days prior to submission of list
 - **GPDC Model**: 7 days prior to initial list and "prior to" submission of ad hoc additions
 - Preferred Provider and TIN Executive Notifications may go to the same person. Send them both anyway.



Notifications: What You Need to Know

❖ CMS **WILL** AUDIT THESE PROCESSES

❑ Beneficiary Notification Requirements

- **CYA:** Send it any way 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 & NPI Exhibit to check three 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 must approve your plan – just watch out for Cherry Picking
 - **CYA**: Exclude Beneficiaries outside the DC Service Area for mailings
 - **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
 - GPDC Model: 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
 - GPDC Model 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”
 - No texting or phone calls – even if they've opted in.
 - No activities outside of the DC Service Area
- ❑ CMS Approval Timeframes
 - Shared Savings Program is 5-day file and use
 - NextGen and GPDC Model have 10-day file and use
 - CMS can disapprove at any time
- ❑ GPDC Model 5% Translation Requirements

Marketing Compliance: What You Need to Know

❑ Operations

- Translation requirements can be met by printing front and back to reduce costs
- 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:
 - NextGen ACO Model: Population-Based Payments Fee Reduction Agreement
 - NextGen 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: Every TIN/NPI on Participant List must participate starting in 2022
- Preferred Providers can pick either way
- Must collect Direct Contracting Fee Reduction Agreement
 - Must include specified percentage of reduction
 - ❖ **CYA:** the Fee Reduction Form does not include a place for this. List it anyway.

❑ Advanced Payments

- Does not require participation of entire TIN
- Must collect Direct Contracting Fee Reduction Agreement

Capitation & Advanced Payments: What You Need to Know

❑ Practical Tips:

- Fee Reduction Forms can be signed by the TIN Executive but must include a list of NPIs who have affirmatively agreed
- Notice and Education requirements are not met solely by completion of the Fee Reduction Form
- Participation in the DCE 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: GPDC Safe Harbors – Financial Arrangements

- ❑ Must meet all requirements of:
 - GPDC Model PA for Financial Arrangements
 - 42 CFR § 1001.952(ii)(1); **and**
 - Applicable appendices of GPDC Model PA as they relate to Payment Arrangements.

- ❑ Does **not** require Governing Body Approval
 - **CYA:** Have Governing Body “reasonably determine” that the incentive will advance one or more goals of the GPDC Model.

- ❑ Does **not** require Public Disclosure

Major Program Differences: GPDC Safe Harbors – Beneficiary Incentives

- ❑ Must meet all requirements of 42 CFR §1001.952(ii)(2)
 - ❑ “Reasonably determine” that the incentive will advance one or more goals of the GPDC Model
 - ❑ Incentive must have a direct connection to the patient’s health care
 - ❑ Incentive must be furnished by the DCE, DC Participant or DC Preferred Provider
 - ❑ Must meet “additional program requirements”.

- ❑ “Additional program requirements” mirror SSP and NextGen: In-kind item or service must:
 - ❑ be preventive in nature or advance one of the clinical goals;
 - ❑ have a “reasonable connection” to Beneficiary’s health care;
 - ❑ not be furnished in relation to Voluntary Alignment;
 - ❑ be furnished directly by the DCE, DC Participant or Preferred Provider

Waivers & Safe Harbors: What You Need to Know

- ❑ Use of a waiver or safe harbor 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/Safe Harbor Checklist – capture compliance and approval in one document
 - Records should prove compliance with all elements not just documentation requirements
 - 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

Shared Savings Program

- 3-Day SNF Rule Waiver
- Telehealth Services

NextGen added

- Post-Discharge Home Visits
- Chronic Disease Management Reward
- Cost Sharing Support for Part B Services
- Care Management Home Visits

GPDC added

- Home Health Homebound Waiver
- Note: CMS calls these two Beneficiary Engagement Incentives instead of Benefit Enhancements in GPDC:
 - Part B Cost-Sharing Support
 - Chronic Disease Management Reward

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 – HIPAA Authorized Use Disclosure Form as part of Participation Agreement
 - GPDC Model – separate HIPAA Authorized Disclosure signed in 4i
- ❑ Requirements are largely the same
 - NextGen and GPDC Model 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

[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: [Click here to purchase!](#)

❑ NAACOS Online Library

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



❑ Listserv

- **NAACOS** members ask questions on the fly and receive timely answers from the ACO community
- Go to the member resources tab and click listserv to get the conversation started!

❑ 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!](#)

Final Comments

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

THANK YOU!

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".

Questions? Fears? Concerns? Awake?

NAACOS

Brian Hammer

bhammer@naacos.com

609.532.6125

Elizabeth Holder

support@naacos.com

202.640.1850

Wilems Resource Group, LLC

Kimberly Busenbark

kwilems@wilemsrg.com

713.893.7902

Maddie Short

mshort@wilemsrg.com

210.872.0134