COMPLIANCE HANDBOOK

ACO REACH Model

WILEMS resource group

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INTRODUCTION

The regulatory requirements placed on Accountable Care Organizations (ACOs) within the REACH Model are extensive and can be overwhelming as ACOs shift from the Fee-For-Service world or the Medicare Shared Savings Program (Shared Savings Program). This Compliance Handbook is designed to be a quick reference tool to help organizations more readily understand the operational and compliance requirements placed on them by the Centers for Medicare & Medicaid Services (CMS) and the Center for Medicare and Medicaid Innovation (CMMI).

DISCLAIMER

Although prepared by industry experts, this Handbook should not be used as a substitute for seeking legal or other professional services in specific situations. While we believe that this Handbook can serve as a guide for your organization as you work through the implementation and maintenance of your ACO's operational activities and attempt to create processes which will allow your Compliance team to meet their obligations, Wilems Resource Group is not responsible for the manner in which it is used.

The information contained in this Handbook covers only minimum requirements and does not address specific state rules and regulations for health or medical practice. This Handbook does not constitute legal advice, nor is it intended to be a comprehensive solution to every ACO's compliance needs. The ACO is encouraged to make appropriate inquiries regarding additional considerations, including state specific regulations, beyond the scope of this Handbook. 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 from CMS and other state and federal regulatory entities which may have oversight of your organization.

This handbook is provided with the understanding that Wilems Resource Group, LLC, including the authors of this handbook, are not engaged in rendering legal, medical, or other professional services. If legal, medical, or other expert advice is required, engage the appropriate professional or contact your own Compliance or Legal department for help.

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UNDERSTANDING ACO REQUIREMENTS

As with any government program, there are a number of requirements outlined for organizations participating in the ACO REACH Model. These requirements can be found in state and federal regulations, agreements between the ACO and CMS/CMMI, regulatory guidance, and informal CMS communications (such as the Weekly Newsletter).

It is important to note that regulatory requirements change often for the ACO REACH Model and CMS guidance and informal communications create new standards and requirements much more frequently. In any regulated industry, it is vital for someone within the organization to continuously monitor all applicable entities for updated information, guidance and requirements. This is particularly true for ACOs. The ACO should ensure there is a plan in place for disseminating information and reacting to it in a timely manner.

ACO Governance

ACOs are required to maintain certain governance requirements in order to remain in good standing within the ACO REACH Model.

Governance Requirements

ACO Governance

ACO REACH Model Participation Agreement Section 3.02

Under the ACO REACH Model, the ACO is required to maintain an identifiable Governing Body with sole and exclusive authority to execute the functions of the ACO and make final decisions on behalf of the ACO. The ACO can call the Governing Body by any number of names, as long as the following requirements are met:

1. The Governing Body must have responsibility for oversight and strategic direction of the ACO and be responsible for holding ACO management accountable for the ACO's activities.
    - *Note: In recent governance audits, CMS required proof that the Governing Body had authority for appointment and removal of the ACO Executive. We recommend including this in formal ACO documents such as the Operating Agreement and/or Policy and Procedure.*
2. The Governing Body must be separate and unique to the ACO and cannot be the same as the Governing Body of the legal entity of any Participant or Preferred Provider (unless the ACO is formed by a single Participant).
    - *Note: In cases where one entity serves multiple ACOs, you cannot use the same Governing Body without change across multiple ACOs as you must include Participant Representatives. You will likely have some overlap across the Governing Bodies; this is acceptable.*

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3. The Governing Body must have a transparent governing process.

4. When acting as a member of the Governing Body, each member has a fiduciary duty to the ACO, including the duty of loyalty, and shall act consistent with that duty. It is important to note that CMS has interpreted this duty to mean that the Governing Body cannot represent any individual or entity which is not participating in the ACO.

5. The Governing Body must receive regular reports from the designated compliance official of the ACO.

6. At least 75% control of the ACO Governing Body must be held by Participants or their designated representatives. Under the ACO REACH Model, designated representatives must be employed by or under contract with the Participant they are representing, and the Participant must remain on the ACO's roster for the entire tenure of the representative's membership on the Governing Body.

7. The Governing Body must include at least one Beneficiary served by the ACO who:

    a. Has voting authority as a member of the Governing Body;

    b. Is **not** the same person as the Consumer Advocate identified under paragraph 8 below;

        - *Note: if a High Needs ACO experiences an extreme hardship in finding a Beneficiary Representative to serve on the Governing Body, the ACO may notify CMS and request CMS approval of an alternative mechanism to ensure that its* policies and procedures reflect consumer and patient perspectives. This request for exception can be submitted to the Help Desk.

    c. Does not have a conflict of interest with the ACO;

    d. Has no immediate family member with a conflict of interest with the ACO;

    e. Is not a Participant or Preferred Provider; and

    f. Does not have a direct or indirect financial relationship with the ACO, a Participant, or a Preferred Provider.

        - *Note: This requirement does not prevent the Beneficiary from being compensated by the ACO for his or her duties as a member of the Governing Body.*

8. The Governing Body must include at least one person with training or professional experience in advocating for the rights of consumers who:

    a. Has voting authority as a member of the Governing Body;

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b. Is **not** the same person as the Beneficiary Representative identified under paragraph 7 above;

c. Does not have a conflict of interest with the ACO;

d. Does not have an immediate family member with a conflict of interest with the ACO;

e. Is not a Participant or Preferred Provider; and

f. Does not have a direct or indirect financial relationship with the ACO, a Participant, or a Preferred Provider.

- *Note: This requirement does not prevent the Consumer Advocate from being compensated by the ACO for his or her duties as a member of the Governing Body.*

◊ Resource: Wilems Resource Group offers an online Consumer Advocate Training to help ACOs satisfy this requirement. This training provides background information on the ACO REACH Model and the expectations for the Consumer Advocate within that Model. Contact Rebecca Cooper at rcooper@wilemsrg.com for more information.

Beginning in PY 2026, while the Medicare Beneficiary and Consumer Advocate Representatives are required to have voting authority on the Governing Body, their voting percentage is not considered in the numerator or denominator for purposes of the 75% threshold calculation for Participant representation.

9. Each member of the Governing Body must receive a copy of the ACO REACH Model Participation Agreement signed by the ACO. We recommend emailing the document so that you can prove compliance with this requirement in an audit.

CMS does allow for an ACO to deviate from these specific requirements under certain circumstances. However, the ACO must provide notice to CMS explaining why it seeks to differ from the requirements and how the ACO's policies involve Participants and reflect consumer and patient perspectives. In the recent Governance Audits conducted by CMS, the ACO was required to show documentation supporting the fact that each of these requirements were met. Merely meeting the requirement was not sufficient. We recommend each ACO review its Governance and/or Operating Agreement and applicable policies and procedures to ensure each requirement is appropriately documented.

Conflict of Interest

The ACO REACH Model requires the ACO to have a Conflict of Interest policy that applies to members of the Governing Body, though it may also include any other

Conflict of Interest

ACO REACH Model Participation Agreement Section 3.02(C)

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individuals or entities providing functions or services related to ACO Activities. This Conflict of Interest Policy must:

1. Require each member of the Governing Body to disclose relevant financial interests;
2. Provide a procedure to determine whether a conflict of interest exists and set forth a process to address any conflicts that arise; and
3. Address remedial actions for members that fail to comply with the policy.

Wilems Resource Group recommends obtaining updated Conflict of Interest forms from all members of the Governing Body and any subcommittees at least annually.

- *Note: While there is no specific deadline listed by CMS for obtaining the signed forms, during the Governance Audits conducted in January 2024, CMS asked each ACO to attest that Governing Body members had been screened for conflicts* ***prior to*** *the start of the Performance Year. CMS did not ask the ACO to provide the documentation used to complete that screening; this would be expected should CMS seek to prove the validity of the ACO's attestation.*

Management and Leadership Requirements

The ACO is required to hire an ACO Executive and a Medical Director, whose appointment and removal are under the control of the Governing Body. The ACO Executive (and his or her team) must have demonstrated the ability to influence or direct clinical practice to improve the efficiency of processes and outcomes, though there are no other specific requirements listed. As noted above, CMS required proof of the Governing Body's authority over the ACO Executive during the January 2024 Governance Audits.

Management and Leadership Requirements

ACO REACH Model Participation Agreement Section 3.03

The Medical Director, on the other hand, is responsible for managing the ACO's clinical management and oversight and must:

1. Be a board-certified physician, licensed in a State in which the ACO operates.
2. Be physically present on a regular basis at any clinic, office or other location participating in the ACO.
3. Be a Participant.

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Participant and Preferred Provider Additions

The ACO is required to meet certain requirements before submitting any new Participant or Preferred Provider to CMS. This is true for the Initial Participant or Preferred Provider List and for additions during the Performance Year. In our experience, many ACOs fail to meet the deadlines for these requirements, as they are specified in Article IV of the ACO REACH Model Participation Agreement. This is particularly problematic as this is audited by CMS. As such, while these are not strictly part of the implementation of the ACO's Compliance Program, we wanted to take a moment to highlight them.

Participants and Preferred Providers

ACO REACH Model Participation Agreement Sections 3.04 & 4.05

ACO REACH PY2023 Ad Hoc Provider Guidance

1. The ACO must have a written agreement in place with each Participant or Preferred Provider prior to submission of the individual or entity. This agreement must meet the requirements detailed in Section 3.04.G of the ACO REACH Model Participation Agreement. This includes a requirement to have a completed ACO REACH Model Fee Reduction Agreement for each individual or entity. While you can obtain these agreements at the TIN level, they must specify each individual and their NPI. Section 12.02.E.3.b also requires that the fee reduction percentage be listed on the Fee Reduction Agreement, despite CMS not providing a location for that percentage to be included.

2. Participants and Preferred Providers may be added using the ad hoc additions process. The details of this process are not well documented in the ACO REACH Model Participation Agreement. ACOs should review the ACO REACH Ad Hoc Provider Updates: Policy and Operating Procedures. In practice, the ACO should follow the CMS provided calendar for ad-hoc additions and deletions which is much easier to use for ACO planning.

    - *Note: The latest effective date of an addition to an ACO during a Performance Year is December 1st. The December window for Participant or Preferred Provider submissions will not be effective until January 2nd of the subsequent Performance Year.*

3. The ACO must submit written notice of the ACO's intent to include the Participant or Preferred Provider on the ACO's Participant or Preferred Provider List. This notice must be submitted to the Participant or Preferred Provider, as well as the executive of the TIN through which the individual or entity bills Medicare. This notice must meet all requirements specified in Section 4.05.C-E, as applicable.

    - *Note: This notice must be sent directly to the individual Participant even if the Written Arrangement is executed at the TIN level.* ***CMS has specifically stated that sending the Participant notice to the practice and having them forward on to the Participants is not sufficient to meet this requirement.*** *As such, we*

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recommend including provider emails in the initial request to the practice for provider roster information.

4. If a Legacy TIN has been added to a Participant in 4i, the ACO must also submit notice to the Legacy TIN. There are no specific requirements for the content of this notification.

5. The ACO must submit a certification attesting to compliance with all requirements outlined in Section 4.05 of the ACO REACH PA. This certification is built into the 4i submission process and does not require additional action.

These notices must be sent annually for those added during the summer submission process prior to the start of the next Performance Year, as well as those added through the ad-hoc process. Participants and Preferred Providers added during the Performance Year can be included in Voluntary Alignment activities and active Benefit Enhancements and Beneficiary Engagement Incentives **but cannot participate in the ACO's alternative payment mechanisms** until the subsequent Performance Year.

Five Elements of an ACO Compliance Program

Five Elements of an ACO Compliance Program

ACO REACH Model Participation Agreement Article XV

If you are moving to the ACO REACH Model from a Medicare Shared Savings Program ACO, your organization will be familiar with the five (5) element Compliance Program favored by CMS in this area. For those who are jumping straight into the ACO REACH Model, CMS has deviated from the standard seven (7) Element Compliance Program. Many administrative burdens have been reduced for the ACO based on this intentional departure from the standard requirements; however, additional requirements have been included in the five (5) element program.

Element 1: Designated Compliance Official

The ACO is required to have a designated Compliance Official who is not legal counsel to the ACO and who reports directly to the ACO's Governing Body. This does not prevent this individual from being an attorney. In fact, many Compliance Officials are licensed attorneys. However, the responsibilities of a Compliance Official are often at odds with those of an entity's legal counsel. An effective Compliance Official cannot wear both hats.

Element 2: Mechanisms for Identifying and Addressing Compliance Concerns

The ACO must implement mechanisms for identifying and addressing compliance concerns related to the ACO's operations and performance. CMS does not provide any further insight into what types of mechanisms would meet this requirement. However, there are several best practice standards used throughout the industry.

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Identifying Compliance Concerns

First, the ACO must create mechanisms and processes which will allow for the timely identification of compliance concerns. These include, but are not limited to:

1. Policies and Procedures (P&Ps): P&Ps set expectations for ownership and completion of ACO Activities across operational areas and are an excellent source of documentation for audit purposes.

2. Monitoring Activities: These are informal processes by which Compliance ensures that operational areas are meeting their requirements.

3. Oversight Activities: These are the formal audit processes completed by Compliance, another operational area (such as Internal Audit), or by an outside entity.

Regardless of how carefully the ACO's Compliance Official creates and implements these mechanisms, the ACO's Compliance Program can only be successful if the Governing Body understands, supports, and fully buys-in to the importance of recognizing and enforcing compliance requirements.

Addressing Compliance Concerns

Once identified, compliance concerns must be addressed and the ACO should implement processes to ensure that the issue does not recur. As such, the consequences of non-compliance need to be clearly communicated and consistently utilized. No matter how the ACO chooses to communicate these consequences, there are a few tools that an ACO should be ready and willing to utilize to enforce compliance across the ACO.

1. Corrective Action Plans: documentation of how the ACO plans to correct the issue.

2. Remedial Training: should not be used as a disciplinary tool.

3. Disciplinary Actions: should include options other than termination and must be used consistently.

4. Termination: while the ACO should have other disciplinary actions available to enforce smaller compliance requirements, ACO related individuals must understand that termination of their participation or contract may occur for severe or repeat offenses.

It is vital that all consequences be used consistently and that the Compliance Official has the support of ACO leadership to utilize them as necessary. Without support, the Compliance Official cannot enforce even the most basic compliance requirements, and the ACO cannot be successful.

Element 3: Method for Anonymous Reporting

The ACO is required to implement a method by which ACO related individuals and Medicare Beneficiaries can anonymously report suspected problems related to the ACO. The anonymous

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portion of this requirement essentially means the ACO must set up a hotline number, a web form, or any method through which individuals can make a formal report without being identified or feeling pressure to reveal their identity. There are no specific requirements for the method. As such, the ACO should consider the following questions:

1. If using a Hotline:
    - How often should the hotline be available?
    - Should the hotline be staffed?
    - Where/How should reports be routed?
2. If using a Web Form:
    - What options should be available to the reporter?
    - Where should reports be routed?

The ACO should implement a mechanism to ensure that there is oversight in the unlikely event that a report implicates the individual who would ordinarily receive reports. As an example, hotline calls generally routed to the Compliance Official could be routed to the ACO Executive if the Compliance Official is implicated. Alternatively, web form reports are routinely routed to the Compliance Official and the ACO Executive. The Compliance Official would be responsible for follow-up unless he or she is implicated.

No matter how the ACO answers the above questions, how to access the anonymous reporting tool should be included in the ACO's compliance training and communicated through other materials as appropriate. Any time the method is listed, it should include a reminder of the ACO's non-retaliation policy to reassure individuals contemplating a report.

◊ Resource: Wilems Resource Group offers an online Compliance Reporting Tool to help ACOs satisfy this requirement. The tool ensures that ACO related individuals can submit a report anytime from anywhere and choose to remain anonymous. If you'd like to learn more about this product, contact Rebecca Cooper at rcooper@wilemsrg.com.

Element 4: Compliance Training

The ACO is also required to provide compliance training for the ACO, its Participants and Preferred Providers. The determination of who needs to complete the training for "the ACO" can be complicated. This is particularly true when you consider the fact that most ACOs do not have many, if any, actual employees. The operational work is usually completed by employees of a Participant, parent company, or an outside entity. The ACO's Compliance Official should determine what level of training is appropriate for their organization.

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Similarly, there is no requirement as to what this training should include. Most ACOs ensure that the appropriate individuals complete Privacy Training, Fraud, Waste and Abuse (FWA) Training, and some ACO specific compliance training.

The ACO may find that most identified individuals already receive HIPAA and FWA training as part of their employment. It is not necessary for the ACO to require duplicative training, though the ACO specific materials should still be required. Documentation of training completion for all elements should be maintained by compliance for audit purposes.

- ◊ Resource: Wilems Resource Group offers online Compliance Training to help ACOs satisfy this requirement. The online training covers an overview of the REACH ACO, voluntary alignment do's and don'ts, HIPAA/Privacy and beyond, and Fraud, Waste, & Abuse. If you'd like to learn more about this product, contact Rebecca Cooper at rcooper@wilemsrg.com.

Element 5: Requirement to Report Probable Violations of Law

The ACO's Compliance Plan must include a requirement for the ACO to report probable violations of law to an appropriate law enforcement agency. This does **not** require that the average employee, or ACO related individual, report directly to law enforcement. Many ACOs meet this requirement by implementing processes through which concerns are reported to Compliance and/or Legal. Those departments then work together to determine whether, and to whom, to report.

Privacy and Data Considerations for ACOs

ACOs must comply with all state and federal privacy laws and regulations. This includes HIPAA and HITECH, and the ACO should ensure that there are processes and protocols in place to meet those requirements. For purposes of this Handbook, however, the focus is on those issues that are unique to ACOs.

The first thing to consider is whether the ACO is structured as a Covered Entity, in which case the ACO will be required by HIPAA to send out an annual Notice of Privacy Practices; or as a Business Associate of each Participant. Most ACOs are set up as Business Associates as it limits the administrative burden for the ACO and confusion for Beneficiaries. Under this arrangement, the ACO will sign a Business Associate Agreement (BAA) with each Participant.

In addition, Article VI of the ACO REACH Model Participation Agreement references the HIPAA-Covered Data Disclosure Request Form which places additional obligations above those required by HIPAA in order for the ACO to share data. These requirements need to be addressed by the ACO and properly communicated across all ACO-related individuals to ensure compliance. The ACO can document a vendor or subcontractor's obligation to meet these additional requirements by adding these requirements to an existing BAA template, or by having the entity sign a separate document referencing the HIPAA-Covered Data Disclosure Request Form and the additional requirements found therein. Regardless of how you document

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downstream compliance with these requirements, the ACO should be prepared to provide CMS with the following information in the event of an audit:

- Full legal name of the entity with whom the ACO is sharing data provided by CMS as part of the ACO REACH Model;
- Physical address of the entity;
- The date the ACO began sharing data with the entity;
- The date the ACO stopped sharing data with the entity; and
- Certification by the entity that all data received has been destroyed in accordance with the HIPAA-Covered Disclosure Request Attestation and Data Specification Worksheet.

Marketing Activities and Materials Compliance

ACO Marketing Compliance is an operational area that causes concerns for many ACO's early in their participation. **The ACO is required to submit a Marketing Plan that details the strategy for outreach, including Voluntary Alignment activities. This plan must be approved by CMS.**

Marketing Material Compliance

ACO REACH Model Participation Agreement Section 5.04

In addition, any materials that are deemed to meet the definition of a Marketing Material, Activity or Event within the ACO REACH Model Participation Agreement must be submitted to CMS for review and approval. There is a ten business (10) day file and use period, meaning that as long as the material is not disapproved the ACO can distribute 10 business days after filing.

CMS can disapprove a material at any time, even after the expiration of the file and use period. If a material is disapproved for any reason, the ACO must immediately discontinue use of the material until any issues are corrected and the material is approved by CMS.

The ACO should maintain records for all marketing materials, events and activities.

Under the ACO REACH Model, Marketing Materials include, but are not limited to, general audience materials or activities conducted by or on behalf of the ACO or its Participants or Preferred Providers, when used to educate, notify, or contact Beneficiaries regarding the ACO's participation in the Model. *Note: Provider facing materials are **not** included in this definition.*

1. Materials may not include any misleading information. This includes, but is not limited to, language suggesting Beneficiaries must see providers only within the ACO or are prohibited in any way from seeing providers outside of the ACO or that CMS endorses one ACO over another.

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2. Materials and Activities may not discriminate or selectively target Beneficiaries on the basis of race, ethnicity, national origin, religion, 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.

3. Similar to the above requirement, ACOs are required to translate Marketing Materials into any non-English language that is the primary language of at least 5 percent of aligned Beneficiaries.

4. ACOs are strictly prohibited from conducting any Marketing Activities or Events outside of the ACO Service Area.

5. ACOs may not conduct communication or activities related to Medicare Advantage (MA) or any other Medicare managed care plan targeted to REACH Beneficiaries nor may the ACO conduct activities targeted to Beneficiaries enrolled in MA or any other Medicare managed care plan.

In addition to the above requirements, CMS has added a specific prohibition on targeting REACH Beneficiaries for communications related to Medicare Advantage or any other Medicare managed care plan.

- *Note: Prior to distributing any press releases, journal articles, or other content to the general public that includes ACO reports or statistical/analytical material, your ACO should file the content for CMS approval AND 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 views or policies of CMS. The authors assume responsibility for the accuracy and completeness of the information contained in this document."*

Beneficiary Notification Requirements

Beneficiary Notifications Compliance

ACO REACH Model Participation Agreement Section 5.05

CMS provides ACOs with a template Beneficiary Notification letter which must be utilized to meet the Beneficiary Notification requirements. CMS indicates variable fields in the letter where the ACO is allowed to insert its own original content such as ACO phone number, website, and overview of care coordination services. Final content must be approved by CMS prior to use by the ACO. CMS sets quarterly deadlines for release of this notice each year. Notices can be sent via any method, as long as the ACO can provide evidence of distribution at the Beneficiary level. If using a portal or e-Mail service, the ACO should consider using a paper mailing to close any gaps for undeliverable messages.

- *Note: Your ACO can only use a portal system to send this message if the Beneficiary receives a notification (via email or otherwise) that there is a new message in the portal.*

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- *Note: Your ACO should consider how to identify and track those Beneficiaries who have "unsubscribed" from any e-mail notifications, either from the practice or the portal itself. The Notifications will need to be sent through an alternative method in these instances.*

Your ACO should also determine how to process returned mail. CMS requires the ACO to make two (2) documented attempts to complete the Beneficiary Notification. You should consider how you will conduct, and document, the second attempt if the first Notification fails for any reason.

Public Reporting Requirements

CMS views transparency as vital to a Beneficiary-centered approach and Beneficiary engagement. As a result, ACOs are required to maintain a publicly facing website to report ACO specific information as determined by CMS.

Public Reporting Compliance

ACO REACH Model Participation Agreement Section 14.01

The ACO REACH Model Participant Agreement Article XIV requires the ACO report the following on a publicly facing website maintained by the ACO:

1. Organizational information including all of the following:
    a. Name and location of the ACO;
    b. Primary contact information for the ACO;
    c. Identification of all Participants and Preferred Providers;
    d. Identification of all joint ventures between or among the ACO and any of its Participants and Preferred Providers;
    e. Identification of the ACO's key clinical and administrative leaders and the name of any company by which they are employed;
    f. Identification of members of the ACO's Governing Body and the name of any entity by which they are employed;
        - Note: while not strictly required, CMS has shown a preference for the ACO to include voting authority for each member of the Governing Body.
    g. Shared Savings and Shared Losses information, including all previous participation years; and
    h. The ACO's performance on the quality measures, including performance in all previous participation years.

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FRAUD, WASTE AND ABUSE SAFE HARBORS

In November 2020, the Department of Health and Humans Services (HHS) Office of Inspector General (OIG) issued the final rule "Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements," and the CMS issued the final rule "Modernizing and Clarifying the Physician Self-Referral Regulations." These waivers do not replace the waivers available to Shared Savings Program ACOs. As such, many ACOs have not given them the attention they may deserve. In the ACO REACH Model Participation Agreement, CMS has chosen to rely on these Safe Harbors rather than work with OIG to develop waivers specific to the ACO REACH Model. One thing has not changed - **none of these waivers apply to similar State laws!** It is important to ensure that Compliance and/or Legal for the ACO evaluate any new programs for compliance with state laws.

ACO Financial Arrangements Safe Harbor

ACO Financial Arrangements

ACO REACH Model Participation Agreement Section 3.04.M

CMS has determined that the Federal anti-kickback statute Safe Harbor for CMS-sponsored model arrangements is available to protect ACO financial arrangements reasonably related to the provision of ACO Activities. As such, while ACOs may be accustomed to developing initiatives under the requirements of the Participation Waiver, that language will not be seen in the ACO REACH Model. The ACO will still need to document the details of the arrangement, in advance of or contemporaneous with the commencement of activity. While the regulations only require documentation of the financial aspects of the arrangement, we recommend the ACO ensure all of the following elements are documented:

- How the arrangement is reasonably related to the provision of ACO Activities as defined by the ACO REACH Model PA;
- How the ACO has reasonably determined that the arrangement advances one or more goals of the ACO REACH Model;
- Confirmation that the arrangement does not induce providers or suppliers to furnish medically unnecessary items or services, or reduce or limit medically necessary items or services furnished to any patient;
- Confirmation that the ACO has not, and the arrangement does not, offer, pay, solicit, or receive remuneration in return for, or to induce or reward, any Federal health care program referrals or other Federal health care program business generated outside of the ACO REACH Model; and

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- Confirmation that the arrangement complies with Section 3.04(A)-(E) and (I) of the ACO REACH PA, all Safe Harbor requirements set forth in 42 CFR §1001.952(ii)(1), and any applicable requirements for PCC, APO and TCC Payment Arrangements.

Beneficiary Incentives Safe Harbor

As with the Shared Savings Program, ACOs are generally prohibited from providing gifts or other remuneration to Beneficiaries unless certain requirements are met.

If the remuneration is not being provided under the Part B Cost-Sharing Support or the Chronic Disease Management Reward Beneficiary Engagement Incentives (BEI), then it must meet all of the following requirements from 42 CFR §1001.952(ii)(2):

- The ACO must reasonably determine that the incentive will advance one or more goals of the ACO REACH Model.
- The incentive must have a direct connection to the patient's health care.
- The incentive must be furnished by the ACO, a Participant or Preferred Provider.
- The incentive must meet any additional program requirements imposed by CMS.
- The ACO must maintain, and make available, records sufficient to establish compliance with these conditions.

If the ACO is utilizing the Part B Cost-Sharing Support or the Chronic Disease Management Reward BEI, all requirements of the applicable ACO REACH Model PA Appendix must be met. These elements will be reviewed when the ACO submits an Implementation Plan to CMS.

Beneficiary Incentives - Additional Program Requirements

While these requirements are not referred to as a Beneficiary Inducement Waiver, the additional program requirements for Beneficiary Incentives will be very familiar to any organization with experience under the Shared Savings Program or Next Generation ACO Model. The ACO REACH Model PA allows ACOs to provide certain in-kind items or services to Beneficiaries in conjunction with any ACO Activities if the following conditions are satisfied:

- The in-kind items or services are preventive care items or will advance one or more of the following clinical goals for the Beneficiary:
    - 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.

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- The in-kind item or service has a reasonable connection to the Beneficiary's health care;
- The in-kind item or service is not a Medicare-covered item or service for the Beneficiary on the date it is furnished;
    - *Note: "Medicare-covered" includes items or services covered by a Benefit Enhancement or Beneficiary Engagement Incentive, even if the ACO is not participating in that BE or BEI for the Performance Year.*
- The in-kind item or service is not furnished in whole or in part to reward the Beneficiary for completing or agreeing to complete Voluntary Alignment; and
- The in-kind item or services is furnished directly by the ACO, a Participant or a Preferred Provider.

It is important to remember, the ACO must meet all of the requirements of the Safe Harbor from 42 CFR §1001.952(ii)(2) as well as the additional requirements from the ACO REACH Model PA.

Beneficiary Incentives – Documentation

The ACO is required to maintain, and make available, documentation sufficient to prove compliance with all of the above listed requirements. This includes, at a minimum, records documenting the following information related to any incentives provided:

- The nature of the in-kind item or service;
- The identity of each Beneficiary that received the in-kind item or service;
- The identity of the individual or entity that furnished the in-kind item or service; and
- The date the in-kind item or service was furnished to the Beneficiary.

Benefit Enhancements and Beneficiary Engagement Incentives

In addition to the Safe Harbors, ACOs can also utilize any of these Benefit Enhancements (BEs) and Beneficiary Engagement Incentives (BEIs) as long as the ACO timely elects to participate in the program for the next Performance Year and submits an Implementation Plan to CMS detailing how the ACO will compliantly implement the requirements of the applicable ACO REACH Model PA Appendix. Don't forget to have your Governing Body sign off on the use of any BEs or BEIs each Performance Year. A quick report and documentation of their approval in the meeting minutes is all you need.

Benefit Enhancements/ Beneficiary Engagement Incentives

ACO REACH Model Participation Agreement Article X

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Available Benefit Enhancements

- 3-Day SNF Rule Waiver
- Telehealth
- Post-Discharge Home Visits,
- Care Management Home Visits
- Home Health Homebound Waiver
- Concurrent Care for Beneficiaries that Elect Medicare Hospice
- Nurse Practitioner and Physician Assistant Services

Available Beneficiary Engagement Incentives

- Part B Cost-Sharing Support
- Chronic Disease Management Reward
- Substance Access

Beneficiary Eligibility

In order to be eligible to receive services under these BEs and BEIs, the Beneficiary must be aligned to the ACO at the time or be an Originally Aligned Beneficiary excluded from alignment to the ACO within the 90 days prior.

The ACO should be aware the 90 day grace period does not apply to the BEIs. For Benefit Enhancements, the grace period does not apply when exclusion occurs for any of the following reasons:

- Transition to Medicare Advantage or other Medicare managed care plan;
- Medicare is no longer the primary payer;
- Loss of Medicare coverage for Part A, if the furnished service would have been reimbursed by Medicare Part A; or
- Loss of Medicare coverage for Part B, if the furnished service would have been reimbursed by Medicare Part B.

Participants and Preferred Providers must be able to access the most current information regarding beneficiary alignment in order to ensure a BE or BEI is not furnished inappropriately. The ACO must consider how to disseminate roster updates to providers in a timely manner.

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ACO Requirements

Use of a BE or BEI requires sophisticated operational processes and a robust compliance monitoring program to ensure that all elements of the selected program are met. The ACO must be prepared, not only to meet those requirements, but also to maintain documentation sufficient to prove compliance. In many cases, the implementation of processes and internal control measures prohibits organizations from implementing otherwise useful programs. Talk to your compliance officer and build internal protocols that make sense, avoid bottlenecks and create documentation throughout the process to ensure the ability to implement these programs efficiently and compliantly.

Terminating a Benefit Enhancement or Beneficiary Engagement Incentive

The ACO may discontinue any BE or BEI **at the end of the Performance Year** but must notify all Participants, Preferred Providers and affected Beneficiaries within 30 days prior to the start of the subsequent Performance Year.

The ACO must obtain consent before voluntarily discontinuing any Benefit Enhancement or BEI **during a Performance Year**. The ACO must provide written notice of termination to CMS at least 30 days in advance. If CMS consents to termination, the effective date of the termination will be provided by CMS. In this case, the ACO must notify all Participants, Preferred Providers and affected Beneficiaries within 30 days after the effective date of the termination.

BENEFICIARY VOLUNTARY ALIGNMENT

Generally, alignment is determined by the CMS claims-based process. However, Beneficiaries may choose to be aligned to the ACO through either Medicare.gov Voluntary Alignment (MVA) or Signed Attestation-Based Voluntary Alignment (SVA). ACO REACH Model Beneficiaries are aligned prospectively, prior to the start of the relevant Performance Year. An ACO may elect Prospective Plus alignment, wherein CMS will update the ACO's Alignment Roster each quarter to account for additions through Voluntary Alignment.

Voluntary Alignment

ACO REACH Model Participation Agreement Section 5.02

ACOs may communicate orally with Beneficiaries regarding their ability to complete voluntary alignment online at Medicare.gov or through the use of a Voluntary Alignment Form but should be careful not to say anything which might be construed to limit freedom of choice. The ACO cannot offer any inducements for completing voluntary alignment and may not complete the process on behalf of the Beneficiary. Your ACO should ensure Beneficiaries are instructed to contact the ACO with questions about how to make changes to the Voluntary Alignment Form.

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Signed Attestation-Based Voluntary Alignment

If the ACO elects to participate in SVA, the ACO may conduct targeted outreach by providing the Voluntary Alignment Form and cover letter to eligible Beneficiaries. CMS provides a template Voluntary Alignment Form and cover letter and the ACO is not allowed to make changes to these materials. The ACO may also provide the Voluntary Alignment Form at the point of care in the offices of Participants but must notify CMS of the intention to do so. If a Beneficiary receives all of their care in home or in an institutional setting, the ACO may conduct SVA Activities in those locations only after a relationship has been established with the patient. CMS defines this establishment as at least one previous visit. The SVA Form should only be provided at the beginning or end of, never during, the visit.

The Form cannot be provided in Preferred Provider offices. The ACO should also ensure that all Beneficiaries who receive care from a Participant are provided a Voluntary Alignment Form upon request. This is true even if the Beneficiary has already completed a form and wishes to make a change.

If conducting SVA activities, the ACO must:

1. Submit a Marketing Plan to CMS for approval and maintain a list of Beneficiaries included in the outreach, as well as the forms and letters sent to Beneficiaries;

2. Maintain records related to Voluntary Alignment, including all materials returned to the ACO from Beneficiaries; and

3. Submit the SVA Data Template list to CMS, as required.

CMS provides specific deadlines for when the ACO is required to submit the SVA Data Template. As such, the ACO should consider their internal processes and capabilities in order to set a reasonable internal timeline for submission to CMS. In an audit, CMS requests executed Voluntary Alignment Forms received from Beneficiaries to verify that the SVA list is complete and accurate. If the SVA Form does not specifically list the Participant identified by the ACO in the SVA Data Template, the ACO will be required to provide documentation linking the Beneficiary to the provider listed. This can be done using claims data or medical records showing a visit on or about the date that the Beneficiary signed the SVA Form.

- ◊ *Resource: WRG now offers an SVA Training Module through our wrgtraining.com website. This training covers the specific requirements around SVA, how to identify a valid form, and other key tips for ensuring your SVA resources lead to alignment through compliant processes. For more information reach out to Rebecca Cooper at rcooper@wilemsrg.com*

Medicare Voluntary Alignment

Under MVA, a Beneficiary may elect to align with the ACO by designating a Participant as their primary clinician on Medicare.gov. CMS provides information on how to complete MVA online.

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The ACO may share this information with eligible Beneficiaries but must first submit a document to CMS describing the process the ACO will use for distribution and identification of Beneficiaries. This is intended to help prevent cherry picking. As such, the ACO should be careful to avoid plans which may unintentionally lead to cherry picking.

RED FLAG AREAS FOR ACOS

There are a few red flag areas for CMS, and the ACO should actively avoid activities which might suggest inappropriate tactics in operational activities, marketing materials, or creation of new incentive programs in the ACO.

Limiting Beneficiary Freedom of Choice

A major criticism in the early days of ACOs was that the program would end up being another version of managed care; an extension of the Health Maintenance Organization (HMO) model or the Medicare Advantage (MA) model that most Beneficiaries were actively trying to avoid. As a result, a major component of the ACO REACH Model is the ability of assigned and aligned Beneficiaries to maintain freedom of choice in their provider. ACOs are not allowed to limit a Beneficiary's ability to receive services from providers who are not participating in the ACO. More than that, however, the ACO must be sure not to provide any information which might be construed as suggesting that this might be the case.

- ◊ *Note: Beneficiaries should never be referred to as "members" or "patients" of the ACO. They are not a part of the ACO, only the Participants and Preferred Providers are participating in the ACO.*

Cherry Picking - Keeping the Healthy, Avoiding the Sick

Another early concern revolved around the idea that ACOs were "death-panels" designed to determine which individuals were young and/or healthy enough to receive services. Critics felt that ACOs would take steps to avoid at-risk and/or high-cost patients in an effort to lower costs and thus achieve shared savings - also known as "cherry picking".

In simpler terms, cherry picking refers to programs or activities that target healthy, presumably low cost, Beneficiaries to remain assigned or receive services from the ACO or that discourage high risk/cost Beneficiaries. In response to these concerns, CMS agreed to monitor ACOs to identify trends and patterns suggesting that an ACO has avoided at-risk Beneficiaries.

The ACO should also consider the risks involved when participating in Voluntary Alignment outreach. When sending Voluntary Alignment outreach, the ACO should target all eligible Beneficiaries, rather than focusing on a certain demographic. For example, the ACO should not restrict targeted outreach to eligible Beneficiaries living in low-income areas.

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- ◊ *Note: It is important to remember that cherry-picking may be intentional but could also be an unintended outcome of a program designed to help the ACO. The ACO must explore potential side effects prior to the launch of any new program or activity to determine whether it could create an appearance of impropriety. Documenting the intent and details of any new program prior to implementation can help the ACO answer any questions which might be raised as a result of unintended consequences.*

ABOUT US

Wilems Resource Group, LLC is a boutique consulting firm specializing in Compliance and Engagement solutions for CMS Value Based Models and Programs. We measure success on our ability to help our clients understand program requirements, determine the appropriate level of acceptable compliance risk, and create programming that meets all regulatory requirements. We first take the time to understand the client's company culture and business goals. Working alongside the client's team, we build customized compliance and engagement programs for the ACO, physicians, practice managers, and Beneficiaries.

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